



*Annual Financial Report at  
December 31<sup>st</sup>, 2019*



*From genes...*

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

*...to therapy*



## Table of contents

General company information.....	3
Corporate bodies .....	4
1. A history of excellence in R&D and cell & gene manufacturing.....	5
2. MolMed's operations: research and development, and manufacturing of cell and gene therapies.	5
3. Intellectual Property .....	10
4. Human resources.....	11
5. Dealing with the environment and health and safety issues in the workplace.....	11
6. Corporate Governance.....	11
7. Report on operations.....	14
8. Main risks and uncertainties .....	24
9. Significant events after the reporting period .....	32
10. Business outlook .....	33
11. Proposal for allocation of losses for the year .....	34
Financial Statements at December 31 <sup>st</sup> , 2019 .....	35
12. Statement of financial position .....	35
13. Income statement.....	36
14. Statement of comprehensive income.....	37
15. Statement of cash flows .....	37
16. Statement of changes in equity.....	38
Notes .....	39
1. General information.....	39
2. Accounting standards and basis of measurement.....	39
3. Segment reporting.....	54
4. Notes to the statement of financial position .....	55
5. Notes to the income statement .....	65
3. Other notes .....	71



Right to depart from disclosure requirements in the event of significant transactions .....	78
Certification of the Financial Statements pursuant to Article 81-ter of Consob Regulation no. 11971 of May 14th, 1999 and subsequent amendments and additions.....	79
Statutory Auditors' Report .....	80
Independent Auditors' Report.....	87



## General company information

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

### **DISCLAIMER**

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

*Although the Company believes that its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties that are beyond Managers' control, including scientific, business, economic and financial factors, which could cause actual results to differ materially from those projected in the forward-looking statements.*

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

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



## Corporate bodies

### Board of Directors

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

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

### Board of Statutory Auditors

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

The Board of Statutory Auditors, appointed by the Shareholders' Meeting held on April 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.

### Control and Risk Management Committee \*

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

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

### Remuneration and Nomination Committee

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

### Scientific Advisory Board

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

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

### External Auditors

EY S.p.A.



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

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

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

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

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

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

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

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

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



## *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 addition, during 2019 the Company conducted 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.

## *GMP production*

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

The Pharmaceutical Manufacturing Facility in Milan, located within San Raffaele's science park, obtained authorization from AIFA in December 2015 to manufacture Strimvelis™, one of the first gene therapies with marketing authorization. The product is distributed by Orchard Therapeutics. The Pharmaceutical Manufacturing Facility includes Grade A, B, C, and D areas for the manufacturing of sterile products in accordance with cGMPs, quality control areas for product testing purposes, and storage areas for raw materials and products, resulting in a total surface area of nearly 1,500 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 has 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. In 2018, AIFA granted the authorization for the manufacturing of genetically modified cell therapy products to be used in clinical trials and for commercial use.

During 2017 and 2018, AIFA authorized the production area of the Pharmaceutical Manufacturing Facility in Bresso named Stream 1, which includes Grade A, B, C, and D areas for the manufacturing of sterile products (medicinal products and vectors) (approx. 600 square meters). In February 2020, AIFA authorized the production area of the Pharmaceutical Manufacturing Facility in Bresso named Stream 2, which includes Grade A, B, and C areas for the manufacturing of sterile products (vectors). The availability and authorization of the new areas at the Pharmaceutical Manufacturing Facility in Bresso further 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*

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

The Company is thus focusing on cancers for which there are no or very few therapeutic options available (so-called unmet clinical needs). The clinical trials of MolMed's therapies are currently focused on the onco-hematological area but could potentially be expanded to include also solid tumors—always relying on the expertise and experience acquired in cell & gene therapies over the years. MolMed's pipeline, diversified in terms of stage of advancement and product type, includes the following products:

### *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, MolMed's CD44v6 CAR targets an original receptor that stands out for the following reasons:

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

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

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

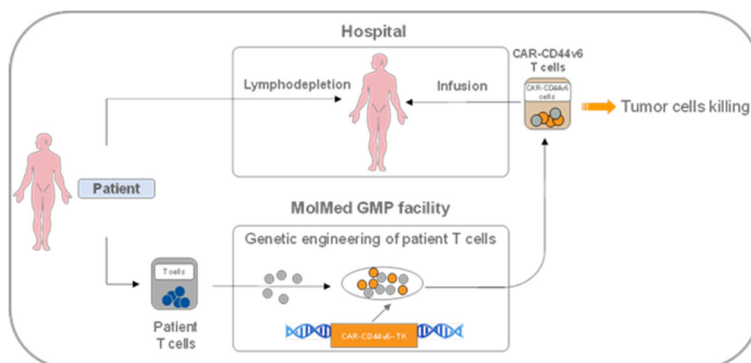


Figure 1. Summary of CAR CD44v6 therapeutic procedure

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

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

The 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 five 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 aims to identify the Maximum Tolerated Dose (MTD) among the levels specified in the protocol; the second phase will involve also child patients and pursue the primary goal of assessing the therapeutic activity and safety of CAR-T cells for each pathology in a larger number of patients.



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

#### *Autologous CAR T and allogeneic CAR NK*

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

One of the main advantages expected from these therapies is that they can be manufactured and administered off-the-shelf, without needing to match the individual patient: starting from a single batch derived from the cells of a healthy donor's immune system, they can potentially treat a large number of cancer patients.

To accomplish this, the Company has entered into partnership agreements with AbCheck and Glycostem.

The agreement signed with Glycostem, the Dutch biotech company clinically developing off-the-shelf allogeneic cell immunotherapies based on natural killer (NK) cells, focuses on the co-development of off-the-shelf allogeneic cell immunotherapies based on natural killer (NK) cells. Based on the agreement, MolMed and Glycostem cooperate in the development and manufacturing of specific CAR-NK cells for selected tumor antigens. Glycostem is responsible for GMP manufacturing and the release of the finished product, while MolMed has exclusive rights to use any final product in return for relevant upfront, milestone and royalty payments following achievement of relevant objectives.

The Company has also continued to cooperate with AbCheck s.r.o., the Czech company focusing on the research and optimization of high quality antibodies to develop innovative autologous CARs for new tumor antigens. According to the agreement, AbCheck will use its proprietary platform for the research, selection, optimization and manufacturing of various human single-chain variable fragments (scFvs) which are capable of specifically recognizing every potential target chosen by MolMed. The scFvs are CAR fragments that confer specificity to the CAR itself by recognizing and binding to tumor antigens.

#### *Zalmoxis® (TK)*

Zalmoxis® is a patient-specific cell therapy based on immune system engineering that, combined with haploidentical hematopoietic stem cell transplantation, allows treating adult patients with leukemias and other high-risk hematological tumors.

Chemotherapy is currently the main therapeutic strategy for leukemia patients. After undergoing several chemotherapy cycles, the patient's hematopoietic and immune systems are severely weakened. One way of promoting their regeneration is through hematopoietic stem cell transplantation from a partially compatible donor. However, it takes time for the stem cells reinfused through transplantation to differentiate into the mature cells of a fully functional immune system. In the meantime, the patient lacks any defense against both infections and potential leukemia relapses.



### 3. Intellectual Property

The cell & gene therapy industry develops innovative biotechnology-based therapeutic options. In this regard, patents and know-how are essential to protect and promote knowledge and innovation. Given the peculiar nature of this industry, potentially patentable inventions concern technical applications of biology such as therapeutic genes or variants of existing genes with therapeutic or diagnostic applications, manufacturing processes for genetically modified cells, gene transfer technology such as viral vectors, proteins, and the relevant manufacturing processes. Patents give exclusive rights to market therapies developed on the basis of such inventions for the term of the patent (20 years from the filing date). In addition, protecting know-how allows to build a body of knowledge concerning operational processes and methods that are especially relevant to manufacturing—thus offering indirectly an additional exclusivity tool. MolMed has rights to a portfolio of patents protecting its products and technologies that include patents and patent applications owned or licensed from third parties, and constantly strives to expand and consolidate its patent portfolio.

During 2019, MolMed revised its patent portfolio in line with strategic corporate changes. Specifically, it decided not to invest any further to maintain patents on NGR-TNF and the relevant vascular targeting area. Meanwhile, it decided to maintain the patents protecting technology originally used in Zalmoxis or the relevant manufacturing process, such as the suicide gene HSV-TK Mut2, as these are applicable also to the CD44v6 CAR—and may also be of interest to third parties. Concerning the Supplementary Protection Certificate for the patent on the HSV-TK gene's non-splicing variant, this was indirectly affected by the withdrawal of the CMA for Zalmoxis. Under the applicable laws in force in the various countries, following the withdrawal of the CMA underlying the application for the Supplementary Protection Certificate, the applications still pending will not be granted and previously issued certificates will lapse.

At December 31<sup>st</sup>, 2019, MolMed had rights as owner or licensee to 13 patent families and two international patent applications, for a total of 303 patents granted and patent applications filed—i.e. 269 patents granted and 34 patent applications filed. MolMed's patent portfolio includes:

- 1 patent family (42 patents granted) registered in the name of MolMed protecting efficacious and safe variants of the TK gene for use as suicide gene in gene therapies. The technology, originally used in Zalmoxis®, is currently applied in the product CAR-CD44v6 and could potentially be used in conjunction with other CAR molecules as well as in other gene therapy approaches requiring to control severe toxic events.
- 1 patent family (32 patents granted) protecting a process to manufacture a population of genetically modified cells in a closed system. Originally developed to manufacture Zalmoxis, this technology is applicable to other areas of production;
- 2 patent families and a PCT international patent application (63 patents granted 18 patent applications filed) on Chimeric Antigen Receptors (CARs) technology—specifically, the CARs featuring new spacer molecules between the portion targeting the antigen and the one responsible for activating the intracellular signal, CARs featuring optimized spacers, and a manufacturing process for genetically modified cells;
- 6 in-licensed patent families and a new PCT international patent application co-owned by MolMed with third parties (53 patents granted and 11 national patent applications filed) on manufacturing processes and products based on allogeneic therapies with NK cells;
- 3 patent families registered in the name of MolMed (79 patents granted and 3 national patent applications filed) on semi-stable and stable packaging cell lines for the production of lentiviral vectors and manufacturing methods based on their use.



#### *4. Human resources*

Highly skilled and specialized employees represent a key competitive advantage in a high-tech global industry that is constantly and rapidly innovating such as advanced therapies, where know-how and intellectual property are especially important. At December 31<sup>st</sup>, 2019, MolMed had 213 employees, of which 79% were graduates, 21% were postgraduates, and 65.3% were women.

#### *5. Dealing with the environment and health and safety issues in the workplace*

Both the Company's facilities and operations shall comply with stringent environmental and work safety regulations.

The Company has adopted safety procedures for the manipulation and disposal of waste in accordance with Italian Legislative Decree 81/2008 and Italian Legislative Decree 206/2001 on the manipulation of genetically modified microorganisms (GMMs). The Company's personnel is provided with specific training on the issue and comply with procedures aimed at minimizing the risk of biological contamination. Special waste is disposed of in compliance with current regulations (Italian Legislative Decree 152/06), based on a specific procedure, with the support of a specialized firm. The Company appointed a certified consultant for the transport of dangerous goods pursuant to Italian Legislative Decree 35/2010.

In compliance with the provisions of Article 37 of Italian Legislative Decree 81/2008 and pursuant to the procedures indicated by the State-Region Agreement of December 21<sup>st</sup>, 2011, the Company held training and refresher courses on safety issues for employees, distinguishing general training from specific training.

As part of its operations, the Company uses chemical and biological agents for which it carries out specific risk assessments in accordance with Italian Legislative Decree 81/2008. Furthermore, staff uses personal protective equipment in line with regulations.

The Company carries out its activities in compliance with regulations on environmental issues, and has obtained all the authorizations required by law. It is committed to operate responsibly as regards the environment also through the implementation of measures aimed at improving the impact of its operations by reducing the use of natural resources in line with its business, financial and investment plans.

#### *6. Corporate governance*

MolMed complies with the Corporate Governance Code of listed companies issued by the Corporate Governance Committee promoted by Borsa Italiana (the "Code"). In compliance with regulations and Code provisions, MolMed prepares an annual Report on Corporate Governance, providing information on ownership, compliance with Codes of Conduct and relevant commitments, and focusing on the Company's actual application of corporate governance principles. The Corporate Governance Report, to which reference should be made, is available at the Company's website ([www.molmed.com](http://www.molmed.com)) and was filed with the centralized storage mechanism IINFO-STORAGE pursuant to applicable regulations.

## 6.1 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 l) of the Consolidated Law on Finance (“rules governing appointment and replacement of directors [...] and amendments to company by-laws, if different from supplementary applicable law and regulations”) is provided in Chapter 4 of the corporate governance report devoted to the board of directors.

## 6.2 Organization, Management and Control Model (as per Italian Legislative Decree 231/2001).

To clearly and transparently define the set of values that guide the Company in pursuing its institutional goals, MolMed has adopted an organization, management and control model as per Italian Legislative Decree 231/2001 that is updated from time to time to reflect changes in applicable laws (the “**Model**”).

MolMed decided to adopt the Model believing that, leaving aside the provisions of Italian Legislative Decree 231/2001—according to which the Model and, therefore, the code of ethics are optional, and not mandatory—it can be an effective way to raise awareness among all the Company's employees, as well as anyone that operates in the name or on behalf of the Company or deals with the latter (i.e.: customers, suppliers, and partners in any capacity), about the need to act fairly and honestly in the discharge of their duties, so as to prevent the risk of committing the crimes as per Italian Legislative Decree 231/2001.

At the same time, it adopted the Model, the Company set up a Supervisory Body, currently consisting of a board, that meets the applicable requirements in terms of autonomy, independence, and professionalism and is vested with inspection and monitoring powers as well as the responsibilities set out in the Model. Since adopting the Model, the Company has regularly provided training on its contents that is considered key to ensure the Model is effective and properly implemented by all employees and partners.

After corruption between private individuals was added to the list of crimes under Italian Legislative Decree 231/2001, the Company issued also anti-corruption guidelines. The Model is constantly updated, including with the aid of external advisors, to reflect regulatory changes as well as account for changes in the organizational structure that affect the Model itself.

Both the public version of the Model (to which reference should be made for more information) and the anti-corruption guidelines are publicly available at the Company's website ([www.molmed.com](http://www.molmed.com)).



### *6.3 Transactions with related parties*

MolMed has adopted the “Procedures for transactions with related parties” that govern the approval and handling of transactions with related parties pursuant to Article 4 of Consob Regulation no. 17221/2010 on related-party transactions. Therefore, the Control and Risk Management Committee, consisting of three non-executive Directors (mainly independent), was assigned by the Board of Directors the function of Committee responsible for transactions with related parties: it was deemed suitable to carry out such duties by virtue of its composition, competencies and nature.

The procedures are published on the Company's website ([www.molmed.com](http://www.molmed.com)). Any information on Transactions with Related Parties is reported in **Note 36** of the Notes, to which reference should be made.



## 7. Report on operations

### 7.1 Summary of activities performed in 2019

#### *GMP development and manufacturing activities*

In 2019, development and manufacturing activities on behalf of third parties continued regarding both cancer and rare diseases.

On March 7<sup>th</sup>, 2019, the Company renewed and extended its partnership agreement in the field of oncology, signed in March 2016 with Genenta Science, a biotechnology company operating in the development of new generation gene therapies based on transcriptional and microRNA controls. In this regard, MolMed has successfully validated the analytical and manufacturing methods of Genenta's proprietary product TEMferon™, an innovative gene therapy for cancer treatment.

Following AIFA's approval of the Investigational Medicinal Product Dossier (IMPD) for the initiation of clinical trials with TEMferon™, Genenta has selected MolMed as the exclusive supplier of the modified cells for use in human trials. These clinical trials aim to demonstrate the safety of TEMferon™ and its clinical efficacy in these two indications, thus supporting the potential development of this product in relation to a wide range of tumors.

On March 13<sup>th</sup>, 2019, the Company renewed and, above all, extended to three new therapeutic indications the partnership started in February 2017 with Rocket Pharmaceuticals Ltd (Nasdaq: RCKT), a US company specialized in the development of innovative therapies for the treatment of rare genetic diseases.

With the renewal and extension of the agreement—initially relating to the development and manufacturing of a gene therapy to treat Fanconi anemia—Rocket Pharma will entrust MolMed with the activities related to the manufacturing of lentiviral vectors for three new indications.

In this specific business field, the Company continues to search for new partners and customers with the aim of further increasing the number of partnerships in relation to both the manufacturing of both viral vectors and genetically modified cells.

In 2019, the development and manufacturing of viral vectors supporting GSK's cancer research, launched in the second half of 2018, were stepped up significantly—to the point that GSK became the Company's second largest customer in the span of 12 months.

Also the manufacturing of viral vectors and cell therapies for clinical trials and marketing purposes that began with Orchard Therapeutics in mid-2018 was significantly stepped up during the year—also thanks to the submission of the MLD file to European Regulatory Authorities in the fourth quarter of 2019, to which the Company collaborated with respect to its technological contents.

#### *CAR CD44v6*

CAR-T CD44v6 has recently entered the clinical trial stage in patients with acute myeloid leukemia (AML) and multiple myeloma (MM) with the multicentric phase I/II "A Phase I-IIa trial to assess the safety and antitumor activity of autologous CD44v6 CAR T-cells in acute myeloid leukemia and multiple myeloma expressing CD44v6".

The lack of harmonized European authorization procedures for clinical trials in cell & gene therapies, the time required to finalize clinical trial agreements, and the need to certify and validate the laboratories responsible for screening patients have led to a series of delays in the enrollment in the clinical trial. To date, the competent authorities in Italy and the Czech Republic have authorized the clinical trial, whereas Germany and Spain have





declined to do so.

Two top-level clinical centers are participating in the trial (IRCCS San Raffaele Hospital of Milan, which coordinates the clinical study, and Rome's Bambino Gesù Pediatric Hospital) as well as the Fakultni Nemocnice S Poliklinikou in Ostrava (Czech Republic) where patients have started to be enrolled. Since the last quarter of 2019, six patients have enrolled in the trial—including five at Milan's IRCCS Ospedale San Raffaele and one in Ostrava. One of them was found eligible for the treatment and underwent infusion at Milan's IRCCS Ospedale San Raffaele with the minimum dose required by the dose escalation protocol (entry level) of the Phase I/II trial. Meanwhile, the centers participating in the trial continue identifying and recruiting patients in order to expand the number of individuals treated, assess the safety and therapeutic activity of the CD44v6 CAR-T, and identify the optimal dose.

On May 24<sup>th</sup>, 2019, the European Patent Office (EPO) announced its decision to grant patent EP3194434 titled "Chimeric Antigen Receptors" for protecting an innovative structural component applicable to CAR technology and used in the proprietary product CAR-T CD44v6. The patent will be valid through 2035, granting market exclusivity in all countries where it will be validated, within the 29 countries that are signatories to the European Patent Convention. The Company has filed equivalent patent applications in the United States, Japan, and other major emerging markets.

### *Autologous CAR T and allogeneic CAR NK*

In 2019, the Company continued working together with AbCheck and Glycostem under the agreements entered into during 2018.

Specifically, the Company has conducted several experiments in partnerships with Glycosystem to optimize the manufacturing process of the end product.

MolMed has continued working together with AbCheck s.r.o, which has used its proprietary platform to research and select various scFvs capable of recognizing the target antigen selected by MolMed that meets the following characteristics: i) originality, ii) freedom to operate in terms of intellectual property, iii) clinical application potential in treating both liquid and solid tumors. Using the scFvs isolated by AbCheck, in 2019 the Company produced 7 CARs that have been characterized in vitro as well as in vivo in the animal model.

Considering the progress on early-stage research projects, management—aided by members of the Scientific Advisory Board—has defined the scientific milestones and outcomes required to make future investment decisions concerning the so-called early stage projects (preliminary preclinical studies) on both autologous and allogeneic CARs, whose results are expected by the first quarter of 2020. These will serve as the basis for making appropriate strategic decisions.

### *Zalmoxis® (TK)*

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

Indeed, the adoption of the so-called Baltimore Protocol by Bone Marrow Transplantation Centers as a standard of care has improved the survival of high-risk blood cancer patients that must undergo haploidentical



transplantation—that is from a donor that is only partially compatible, which reduces the benefit of using Zalmoxis® in an increasingly less used transplantation procedure such as T-depletion. Based on this data, the Company has decided for commercial reasons to withdraw the Conditional Marketing Authorization (CMA) issued by the European Commission for Zalmoxis® in 2016 and to stop investing in a product that the evolution of clinical practices has made obsolete in terms of therapeutic impact.

### *Intellectual property and protection*

During 2019, MolMed revised its patent portfolio in line with strategic corporate changes.

Specifically, it decided not to invest any further to maintain patents on NGR-TNF and the relevant vascular targeting area. Meanwhile, the Company continued maintaining the patents that protect technology originally used in, or developed for, Zalmoxis, but that are applicable also to other products within MolMed's portfolio or may be of interest to third parties.

Therefore, the Company has taken all steps necessary to maintain the patents that give exclusive rights to the process for manufacturing a pure population of genetically modified cells in a closed system and the non-splicing variants of the TK suicide gene—a technology originally used in Zalmoxis and currently used in conjunction with the CD44v6 CAR to control any potential toxic effects associated with the therapy.

The withdrawal of the CMA has affected and/or will affect the application for the Supplementary Protection Certificate for the patent on the non-splicing variant of the HSV-TK gene as well as the validity of the Supplementary Certificates already issued. Specifically, without a current CMA or MA in place, the applications still pending will not be granted and previously issued certificates will lapse.

Throughout 2019, MolMed continued expanding the patent portfolio protecting the CAR technology: specifically, it obtained the European patent EP3194434 entitled “Chimeric Antigen Receptors”, which protects the CARs featuring new spacer molecules between the portion targeting the antigen and the one responsible for activating the intracellular signal—a technology used specifically in the proprietary product CAR-CD44v6. It then took the steps necessary to obtain and subsequently validate the patent in 29 countries that are signatories to the European Patent Convention. With respect to research into the allogeneic technological platform, a PCT international patent application co-owned by MolMed with third parties has been filed.

Finally, as for the protection of viral vector manufacturing technologies, in 2019 MolMed took steps to extend and maintain patents and patent applications concerning the stable packaging cell line for the production of lentiviral vectors for gene therapy purposes, as well as the relevant semi-stable intermediate and manufacturing processes, and requested the European Patent Office to examine a PCT international patent application concerning technology that enables the stable integration of transfer vectors to obtain stable manufacturing cell lines.

### *Organizational chart and human resources*

In 2019, MolMed once again invested in its people to ensure they maintain world-class skills by participating in courses, workshops, conferences, and other events according to their specific professional category or organizational area. Besides technical-scientific and quality skills, said events explored topics concerning project management, budgeting and management control, supply chain management, negotiations, and public speaking in English. Employees have received training and updates on workplace safety in accordance with Italian Legislative Decree 81/08.

### *Environment and workplace safety*



During 2019, the Company continued regularly reviewing and implementing safety procedures at the Milan site as well as implementing and updating safety procedures at the new Bresso site pursuant to Italian Legislative Decree 81/2008 and Italian Legislative Decree 206/2001 on the manipulation of genetically modified microorganisms (GMMs). For each new GMM introduced in both the Milan and Bresso laboratories, the Company has applied for a specific authorization from the Italian Ministry of Health to use them.

In addition, pursuant to Italian Legislative Decree 81/2008, MolMed updated and prepared the general risk assessment document (RAD) and the risk assessment document concerning exposure to chemical, biological, carcinogenic and mutagenic agents as well as ionizing radiation.

In compliance with the provisions of Article 37 of Italian Legislative Decree 81/2008 and pursuant to the procedures indicated by the State-Region Agreement of December 21<sup>st</sup>, 2011, the Company held training and refresher courses on safety issues for employees at the Bresso and Milan sites, distinguishing general training from specific training.

Special waste—which is potentially infected or chemical—is disposed of in compliance with current regulations (Italian Legislative Decree 152/2006), based on a specific procedure, with the support of a specialized and authorized firm. During the year, the Company aligned said procedure and its waste management operations to new European regulations on the transport of dangerous goods by road.

At December 31<sup>st</sup>, 2019, there are no environmental issues that might affect the Company's use of its tangible assets.

### *Investor Relations and Communication*

MolMed had several meetings with the financial community throughout the year, held either on an ad hoc basis or as part of banking conferences—from the participation in the industry's largest investor conference, the JP Morgan Conference in San Francisco, to the Mid & Small conference held at the Italian Stock Exchange in November.

In addition, during 2019 MolMed attended the world's largest scientific conferences, holding presentations and symposiums on GMP development and manufacturing on behalf of third parties as well as the CD44v6 CAR T project.

### *Supervisory Body*

As in previous years, the Supervisory Body duly monitored the Company's operations, including through targeted audits of business functions. Based on audit findings and the information received during the period, to date no violations of the Model or Italian Legislative Decree 231/2001 have been found. In addition, the Supervisory Body monitored the update of the model completed in December 2019 and the operational procedures as per Italian Legislative Decree 231/2001.

Finally, the Supervisory Body confirmed that during 2019 the Company (i) continued providing in-house and external training on the prevention and repression of market abuses, and (ii) provided training and information to new hires.



## 7.2 Other information

### *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 Euro 5,903 thousand grant was awarded in December 2016. MolMed received Euro 1,995 thousand: this amount will cover a portion of R&D costs over a period of 48 months.

### *Financing*

In December, the Company entered into a financing arrangement with the European Investment Bank (“EIB”) up to Euro 15,000 thousand over a term of 60 months. The funds can be drawn down in two tranches of Euro 7,500 thousand. 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 December 31<sup>st</sup>, 2019, the Company had not drawn down any tranche.

### *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.

### *Protection of personal data and information*

The protection of personal data and information collected and stored – both electronically and using traditional methods – is of great importance to the Company. To this end, MolMed has implemented a personal data protection system in accordance with applicable laws (Reg. (EU) no. 2016/679 and Italian Legislative Decree 196/2003 as amended by Italian Legislative Decree 101/2018), complying with the guidelines of the European Data Board Protection as well as the requirements of the Italian Data Protection Authority as far as applicable.

In particular, during the year MolMed (i) updated part of the documentation that affects also the protection of personal data, and (ii) prepared specific procedures for the operation of the entire personal data management system (concerning specifically the operation of the personal data management system, responses to data subjects, the management of data breaches, and the performance of data protection impact assessments), publishing this information on the Company's intranet to ensure employees have access to information that is always up-to-date.

In addition, MolMed updated the information as per Articles 13 and 14 of Reg. (EU) no. 2016/679, the appointments of the persons authorized to process personal data, and the legal acts designating data processors as required.

Finally, the Company appointed a Data Protection Officer and a designated privacy officer to better coordinate and supervise the protection of personal data. In any case, it should be noted that in 2019 there were no



omissions, deletion or any other situation that might have threatened the safety of anyone's personal data within the Company.

*Shares held by Directors, General Managers, Statutory Auditors and Executives with strategic responsibilities (Article 79 of Consob Regulations, Resolution 11971 of May 14, 1999)*

Pursuant to Article 79 of the Consob Issuers' Regulations, MolMed specifies that, based on information received at December 31<sup>st</sup>, 2019, the following shares were held by Directors and Statutory Auditors as well as by their spouses who are not legally separated, and their underage children, either directly or through a subsidiary, fiduciary business or any other intermediary.

In 2019 the Company's staff did not include any General Managers or Executives with strategic responsibilities.

Name	Role	Company in which stake is held	Shares held at December 31, 2018	Shares purchased	Shares sold	Shares held at December 31, 2019
Alfredo Messina	Director	MolMed S.p.A.	1,343,495	-	-	1,343,495



### 7.3 Performance and financial highlights

#### Income statement

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

(amounts Euro thousand)	2019	2018	Change	Change %
Revenues from development and manufacturing activities	34,338	24,224	10,114	41.8%
Revenues from Zalmoxis®	-	4,223	(4,223)	(100.0%)
Other income	1,934	1,433	501	35.0%
<b>Total operating revenues</b>	<b>36,272</b>	<b>29,880</b>	<b>6,392</b>	<b>21.4%</b>
Total operating costs (amortization and depreciation excluded)	(32,975)	(32,098)	(877)	2.7%
<b>EBITDA</b>	<b>3,297</b>	<b>(2,218)</b>	<b>5,515</b>	<b>(248.7%)</b>
Amortization	(2,991)	(1,570)	(1,421)	90.5%
Devaluation	(542)	(77)	(465)	603.9%
<b>Total amortization and deprecitaion</b>	<b>(3,533)</b>	<b>(1,647)</b>	<b>(1,886)</b>	<b>114.5%</b>
<b>EBIT</b>	<b>(236)</b>	<b>(3,865)</b>	<b>3,629</b>	<b>(93.9%)</b>
<b>Net financial income (charges)</b>	<b>(105)</b>	<b>(258)</b>	<b>153</b>	<b>(59.4%)</b>
<b>Pre-tax result</b>	<b>(341)</b>	<b>(4,123)</b>	<b>3,782</b>	<b>(91.7%)</b>
Income taxes	(87)	-	(87)	100.0%
<b>Profit (loss) for the period</b>	<b>(427)</b>	<b>(4,123)</b>	<b>3,695</b>	<b>(89.6%)</b>

In 2019, operating revenues continued their positive trend, growing by Euro 6,392 thousand or 21.4% year-on-year despite the termination of the licensing and distribution agreement for Zalmoxis® with Dompé Farmaceutici S.p.A., which had contributed Euro 4 million to the total Euro 4,223 thousand in the prior year. The growth in operating revenues is even more significant when looking at just revenues from development and manufacturing on behalf of third parties, which, thanks to the expansion in the customer base and the increase in work performed on behalf of existing customers, increased by Euro 10,114 thousand from Euro 24,224 thousand at December 31<sup>st</sup>, 2018 to Euro 34,338 thousand at December 31<sup>st</sup>, 2019—a 41.8% rise.

Other income increased by 501 thousand Euro or 35.0% from Euro 1,433 thousand at December 31<sup>st</sup>, 2018 to Euro 1,934 thousand at December 31<sup>st</sup>, 2019, and is mainly linked to the recognition of an higher tax credit for R&D pursuant to the Ministerial Decree of 27 May 2015 in 2019.

Operating costs less impairment, depreciation, and amortization increased by Euro 877 thousand (or 2.7%) from Euro 32,098 thousand at December 31<sup>st</sup>, 2018 to Euro 32,975 thousand at December 31<sup>st</sup>, 2019. The change in costs was largely attributable to (i) the increased cost of raw materials, consumables, and reagents used in manufacturing and development, up Euro 1,278 thousand (+22.5%) as a result of rising revenues from services and manufacturing on behalf of third parties, and (ii) the Euro 1,110 thousand (+8.6%) increase resulting from new hiring—the average number of employees for 2019 was 215, compared to 199 in 2018—the provision for MBO bonuses, and the provision for the costs associated with a corporate restructuring launched in December.



EBITDA increased from a negative amount of Euro 2,218 thousand in 2018 to Euro 3,297 thousand in 2019, increasing by Euro 5,515 thousand or 248.7%. 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 has undertaken. Meanwhile, the review of proprietary research projects, which led to abandoning the Zalmoxis project, and the ongoing revision of the proprietary pipeline, allowed to curb research and development costs as well as generate Euro 3,297 thousand in EBITDA, even though in 2019 MolMed recorded Euro 5,971 thousand in direct research costs for proprietary projects compared to Euro 7,593 thousand in 2018. As a consequence of the first-time adoption of IFRS 16 “Leases”, effective for annual periods beginning on or after January 1<sup>st</sup>, 2019 the Company reclassified Euro 1,355 thousand related to rental costs and recognized Euro 1,262 thousand of depreciation and amortization and Euro 132 thousand of financial charges: as a result, EBITDA improved compared to the previous year, while depreciation and amortization expenses increased.

Amortization, depreciation and impairment costs amounted to Euro 3,533 thousand at December 31<sup>st</sup>, 2019, increasing by Euro 1,886 thousand compared to the previous year (Euro 1,647 thousand). This change is mainly due to the effects arising from the adoption of the new IFRS 16 “Leases”, effective for annual periods beginning on or after January 1<sup>st</sup>, 2019.

The Company’s financial activities also improved despite the recognition of Euro 132 thousand in interest expenses associated with the adoption of the accounting standard IFRS 16 “Leases”. In 2018 the Company had incurred Euro 155 thousand in financial expenses resulting from the underwriting of the last installment within the SEF “Standby Equity Facility” agreement with Société Générale.

Income taxes include regional tax on productive activities (IRAP) of Euro 87 thousand. At December 31<sup>st</sup>, 2019, the Company recognized tax losses for Euro 211,022 thousand.

The Company reported a Euro 427 thousand loss for the period—increasing is results of Euro 3,696 thousand (or 89.6%) compared to the loss of Euro 4,123 thousand for the previous year.



## Statement of financial position

Below we present condensed versions of the reclassified statement of financial position and the statement of cash flows to highlight the Net invested capital and the 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)	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	Change %
<b>Non-current assets</b>				
Fixed assets and other non-current assets	22,201	14,676	7,525	51.3%
<b>Total non-current assets</b>	<b>22,201</b>	<b>14,676</b>	<b>7,525</b>	<b>51.3%</b>
<b>Net working capital</b>				
Inventories	1,830	1,718	112	6.5%
Trade receivables and other commercial assets	9,911	5,470	4,441	81.2%
Tax receivables	2,528	1,742	786	45.1%
Other receivables and current assets	992	622	370	59.5%
Trade payables	(8,230)	(9,620)	1,390	(14.4%)
Tax payables	(87)	-	(87)	100.0%
Other liabilities	(3,642)	(3,525)	(117)	3.3%
Provision risk	(611)	-	(611)	100.0%
<b>Total net working capital</b>	<b>2,691</b>	<b>(3,593)</b>	<b>6,284</b>	<b>(174.9%)</b>
<b>Non-current liabilities</b>				
Other non-current liabilities	(3,094)	(3,954)	860	(21.8%)
<b>Total non-current liabilities</b>	<b>(3,094)</b>	<b>(3,954)</b>	<b>860</b>	<b>(21.8%)</b>
<b>TOTAL USES</b>	<b>21,798</b>	<b>7,129</b>	<b>14,669</b>	<b>205.8%</b>
<b>Shareholders' equity</b>	<b>23,173</b>	<b>23,595</b>	<b>(422)</b>	<b>(1.8%)</b>
<b>Net financial position</b>	<b>1,375</b>	<b>16,466</b>	<b>(15,091)</b>	<b>(91.6%)</b>
<b>TOTAL SOURCES</b>	<b>21,798</b>	<b>7,129</b>	<b>14,669</b>	<b>205.8%</b>

At December 31<sup>st</sup>, 2019, non-current assets increased by Euro 7,525 thousand (or 51.3%) from Euro 14,676 thousand at December 31<sup>st</sup>, 2018 to Euro 22,201 thousand. The change was largely attributable to the recognition of Euro 9,753 thousand for the “right of use” asset in tangible assets, following the adoption of the accounting standard IFRS 16 “Leases”

At December 31<sup>st</sup>, 2019, net working capital increased by Euro 6,284 thousand (or +174,9%) from December 31<sup>st</sup>, 2018—largely because of the increased amount of trade receivables, as a result of the higher revenues from services rendered on behalf of third parties provided in 2019, as well as in tax receivables, which were offset by the decline in payables to suppliers and the increased provisions for risks.





At December 31<sup>st</sup>, 2019, the net financial position was down Euro 15,091 thousand (or -91.6%) from Euro 16,466 thousand at December 31<sup>st</sup>, 2018 to Euro 1,375 thousand. The decrease was attributable to the cash flows used in operating activities to support research and development during the period as well as the impact of applying the new accounting standard IFRS 16 “Leases”, which required the recognition of finance lease payables totaling Euro 8,529 thousand in current and non-current financial payables. Net of the effects arising from the adoption of the above-mentioned standard, the net financial position would have amounted to Euro 9,904 thousand at December 31<sup>st</sup>, 2019, compared to Euro 16,466 thousand at December 31<sup>st</sup>, 2018.

<i>(amounts Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018
Cash on hand	3	8
Other cash	9,901	15,499
Cash equivalents	-	-
<b>A. Total cash and cash equivalents</b>	<b>9,904</b>	<b>15,507</b>
<b>B. Current financial receivables and other financial assets</b>	<b>-</b>	<b>959</b>
Liabilities to financial leasing entities (IFRS16)	(1,204)	-
<b>C. Current financial debt</b>	<b>(1,204)</b>	<b>-</b>
<b>D. Net current financial position (A+B+C)</b>	<b>8,700</b>	<b>16,466</b>
Liabilities to financial leasing entities (IFRS16)	(7,325)	-
<b>E. Non-current financial debt</b>	<b>(7,325)</b>	<b>-</b>
<b>F. Net financial position (D+E)</b>	<b>1,375</b>	<b>16,466</b>
G. IFRS16 effects - current	1,204	-
H. IFRS16 effects - non current	7,325	-
<b>I. I. Net financial position - NO IFRS 16 effects</b>	<b>9,904</b>	<b>16,466</b>

Details about changes in equity from January 1<sup>st</sup>, 2019 to December 31<sup>st</sup>, 2019 are provided in the table below:

<i>(importi in migliaia di Euro)</i>	Capitale Sociale	Riserva sovrapp. azioni	Altre riserve	Riserva rivalut. attuariale	Riserva piani stock options	Utili (perdite) a nuovo	Utile (perdita) del periodo	Totale patrimonio netto
<b>Saldo al 31 dicembre 2018</b>	21.819	61.754	223	(11)	-	(56.067)	(4.123)	23.595
Destinazione risultato esercizio precedente						(4.123)	4.123	-
Utile/(perdita) complessivo del periodo				5			(427)	(422)
<b>Saldo al 31 dicembre 2019</b>	21.819	61.754	223	(6)	-	(60.190)	(427)	23.173

MolMed ha deciso di applicare il principio IFRS 16 prospettivamente dal 1° gennaio 2019, quindi senza restatement dei dati comparativi

## Condensed statement of cash flows:

Below is the condensed statement of cash flows:

<i>(amounts Euro thousand)</i>		2019	2018	Change	Change %
<b>Opening cash and cash equivalents</b>	<b>A</b>	<b>15,507</b>	<b>13,105</b>	<b>2,402</b>	<b>18.3%</b>
Cash flow from operating activities before changes in working capital		2,552	(2,400)	4,952	(206.3%)
Total changes in current assets and liabilities		(7,060)	(711)	(6,349)	893.0%
Total cash flow generated (absorbed) by operating activities	<b>B</b>	<b>(5,746)</b>	<b>(2,948)</b>	<b>(2,798)</b>	<b>94.9%</b>
Total cash flow generated (absorbed) by investing activities	<b>C</b>	143	2,267	(2,124)	(93.7%)
Total cash flow generated (absorbed) by financing activities	<b>D</b>	-	3,083	(3,083)	(100.0%)
<b>Cash flow generated (absorbed) during the period</b>	<b>E=B+C+D</b>	<b>(5,603)</b>	<b>2,402</b>	<b>(8,005)</b>	<b>(333.3%)</b>
<b>Closing cash and cash equivalents</b>	<b>F=A-E</b>	<b>9,904</b>	<b>15,507</b>	<b>(5,603)</b>	<b>(36.1%)</b>



Cash flows from operating activities before changes in net working capital increased year-on-year largely thanks the improved results of the fiscal year, recording a loss of Euro 427 thousand at December 31<sup>st</sup>, 2019 compared to Euro 4,123 thousand at December 31<sup>st</sup>, 2018.

The change was the result of, among other things, the Euro 1,262 thousand effect resulting from the adoption of IFRS 16 “Leases” effective January 1<sup>st</sup>, 2019 and the recognition of Euro 611 thousand in non-monetary costs.

Cash flows used in operating activities increased by Euro 2,798 thousand compared to 2018 because of the increase in trade payables and non-current tax receivables.

Cash flows from investing activities decreased by Euro 2,124 thousand compared to 2018 following the sale of the bond held by the Company and the decreased investments in tangible assets.

Cash flows from financing activities decreased by Euro 3,083 thousand compared to 2018, as MolMed did not raise additional capital during the year.

## *8. Main risks and uncertainties*

### *8.1 Risks associated with external factors*

#### **Business interruption risk for COVID-19 coronavirus**

The spread of the new coronavirus called COVID-19, which occurred in Wuhan, China and subsequently spread to many other countries including Italy has had a significant impact on production and commercial activities and as a consequence also on the relative import / export due to restrictions for the transport of goods and people.

In order to protect its employees and business continuity, the Company has implemented and is implementing high safety and monitoring standards to avoid the spread of COVID-19: in particular, it has promoted working remotely, has increased and strengthened the procedures and sanitary and sanitary facilities. A Crisis Committee was also established for the adoption and management of protective measures aimed at the transposition of the emergency directives issued by the competent Authorities in a constantly changing scenario.

The pharmaceutical factories in Bresso and Olgettina are open and functioning and there was no significant interruption in production or in those related to the supply chain.

Although the Company put in place measures to ensure the protection of its employees and business continuity, it cannot be ensured that these safeguards are able to ensure their effectiveness. In particular, the adoption of hygiene and safety measures cannot exclude that Company employees are infected by the virus. Furthermore, it cannot be excluded that there are interruptions in development and production and R&D activities caused by the absence, in the pharmaceutical workshops, of operators receiving preventive quarantine measures, by delays or suspension of the supply of materials and logistic chains, due to disruption of air traffic and transport.

The aforementioned circumstances could entail the risk for the Company of being unable to promptly satisfy customer orders and conduct its business, with a substantial negative effect on its business, economic, equity and / or financial situation.

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

#### **FROM GENES TO THERAPY**



There is no guarantee that the Company will be able to successfully complete the clinical trial of the experimental product CAR T CD44v6. 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 studies 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 ethics committees 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. Both during R&D and subsequent 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.



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

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.

## **8.2 Strategic and operating risks**

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

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

This facility is 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 Pharmaceutical Manufacturing Facilities are adequate for its current production needs and the business plans envisage revamping activities and an increase in the production capacity aimed at both supporting internal demand and at intensifying the development and manufacturing activities for new gene and cell therapy treatments on behalf of third parties. However, should the Company increase the number of products under development in the future or should it be necessary to manufacture greater quantities of existing products, the GMP facility production capacity might reach saturation point, with consequent possible



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 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 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 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 could 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 staff**

The Company heavily depends on the professional contribution of key scientific 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 addition, the development and operations on behalf of third parties largely depend on the Company's ability to attract and retain its highly qualified scientific 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 staff and experienced top management personnel or to successfully integrate staff who can manage the Company's growth, could 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 and cash flows could be negatively affected.

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

In its research and development activities, 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 introduced a training program to raise awareness among employees about the proper use of the IT resources and applications assigned to them.



### 8.3 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 combines development and manufacturing on behalf of third parties with research and development of proprietary product. This business, in line with biotech companies developing new therapeutic products and that have not reached a balanced income and financial position yet, features 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.

In December, the Company entered into a financing arrangement with the European Investment Bank ("EIB") up to Euro 15,000 thousand 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 Euro 7,500 thousand. The drawdown is subject to the review of predefined specific financial goals and milestones. At December 31<sup>st</sup>, 2019, the Company had not drawn down any tranche.

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 reported a loss since its incorporation, cumulatively amounting to Euro 211,022 thousand. The loss for 2019 was Euro 427 thousand, down Euro 3,696 thousand from the Euro 4,123 thousand loss recorded in the previous year. The change was largely attributable to the impact of revenues associated with the steadily growing services performed on behalf of third parties and the redefining of research and development priorities, which led to abandoning the projects that failed to meet expectations.

Taking account of the above and, in particular, based on the Company's liquidity (of Euro 9,904 thousand at December 31<sup>st</sup>, 2019), the improved results for 2019 compared to the last three-year period, and based on future cash flows 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 up to Euro 15,000 thousand and still unused, the Company deems that the financial resources and equity available are adequate enough to continue its business 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 rates could negatively affect the value of assets, liabilities, or expected cash flows. At December 31<sup>st</sup>, 2019, 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 on 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 concentration risk, currently two single-name counterparties account for nearly 79% of 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.

## **8.4 Legal and Compliance Risks**

### **Risks associated with product liability**

As any entity operating 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.



## 9. Significant events after the reporting period

February 2th, 2020 - MolMed announced that AIFA (the Italian Medicines Agency) has authorized new areas of Bresso site for the GMP manufacturing of viral vectors to be used in clinical trials based on advanced therapies. The availability of these new rooms further increases the manufacturing capacity that MolMed can offer to its current and future clients, in the perspective of the continuous growth of its third-party business of development and GMP manufacturing services in the field of cell & gene therapies.

March 6th, 2020 - MolMed announced the execution of a development and supply agreement with Autolus Therapeutics plc (Nasdaq: AUTL), a clinical-stage biopharmaceutical company developing next-generation programmed T cell therapies for the treatment of cancer. Under the multi-year agreement, MolMed will develop and supply viral vectors for the manufacture of certain Autolus' CAR-T programs for use in clinical trials and potentially for commercial sale.

With reference to the CAR-T CD44v6 clinical trial, since the first enrollments started in the last quarter of 2019, as of today 6 patients have been enrolled, 5 at the IRCCS San Raffaele Hospital in Milan and 1 at the Fakultni Nemocnice S Poliklinikou in Ostrava (Czech Republic). Among them, 1 resulted eligible for treatment and was infused at the end of December at the IRCCS San Raffaele Hospital in Milan at the minimum dosage required by the dose escalation protocol (entry level) of phase I/II.

In December 2019, a new coronavirus strain "(COVID 19) emerged in Wuhan, China and later it spread to many other states including Italy. To contain the spread the national authorities and regional authorities have progressively issued restrictive measures including the limitation of people, which must therefore only take place for proven reasons and, the closure of schools and universities, exercises commercial that do not provide primary services, public gathering places including cinemas, stadiums and theaters. The industrial activities, such as ours, depending on the activity carried out, have not undergone any restrictions except the obligation to establish procedures to safeguard the health of employees. The Company is managing and will continue to manage the contingent situation relating to the COVID 19 emergency, in on the basis of the relative provisions of the central and regional governments. A specific has been created Crisis Committee which has put in place mitigation actions to protect the employees they have affected the increase in sanitary and hygienic procedures and promoted the functioning of work remotely. The facilities of Bresso and Olgettina are open and functioning. At the same time, the Company is evaluating all the initiatives aimed at supporting the continuity of business activities, fundamental for a company like Molmed which operates in the supply of cutting-edge therapeutic products. Of those activities, they have been promptly informed all customers in a perspective of transparency and maximum possible guarantee of the business continuity.

The Crisis Committee is operational for the adoption and management of protection measures aimed at transposition the emergency directives issued by the competent Authorities in a constantly changing scenario.



## 10. *Business outlook*

In line with the trend observed in the last three years, the Company ended 2019 with a significantly smaller loss, i.e. Euro 427 thousand compared to Euro 4,123 thousand in the prior year, while EBITDA amounted to a positive Euro 3,298 thousand—the first time MolMed achieved such a result in the 23 years since its foundation.

This was attributable to the strategic decisions made in recent years, which caused development and manufacturing on behalf of third parties—and the relevant revenues and margins—to grow steadily, as well as to the review of proprietary research projects that led to abandoning first the NGR-hTNF and then the Zalmoxis projects—also because their results did not meet expectations.

Today, the Company is recognized as a leading CDMO at the international level, as showed by the extremely high standing of its customers, their loyalty, and the several projects it works on. This was made possible by MolMed's ability to understand the rising demand of production capacity for viral vectors and genetically engineered cells, leading to an increase in the number of customers and projects as demand continues growing.

Global investments in advanced therapies alone have increased steadily in the 4 years from 2016 through 2019, with more than 1,000 clinical trials—50% of which in oncology—currently under way worldwide. Both these factors cause a mismatch between demand and supply in the development and manufacturing of viral vectors and genetically modified cells, fueling demand and, therefore, the value of companies capable of providing these services in the cell & gene therapy area with high quality standards. Indeed, quality plays a key role—and so does the number of available production spaces, as recently showed by the need to postpone the market launch of products already approved due to manufacturing challenges.

Against this international backdrop, the Company seeks to further increase the number of customers and the relevant projects with respect to both viral vectors and cells in the oncology and rare diseases fields.

In order to offer better services in terms of quantity and quality to current partners and future potential customers, MolMed has been expanding its investments in terms of manufacturing scale and technology supporting development and manufacturing on behalf of third parties.

Given the withdrawal of the CMA for Zalmoxis, MolMed will be able to reassign production spaces as well as human resources previously dedicated to the manufacturing of TK to expand the offerings of the CDMO area.

At the same time, and with the goal of maintaining and strengthening its competitive offerings, the Company plans to expand the number and scale of the services it renders in order to retain the leadership that drove the growth highlighted also by this report.

Proprietary product research will continue and remain focused on CAR therapies—specifically the clinical development of CAR-T CD44v6 in liquid tumors (AML and MM). In light of the regulatory authorizations in Italy and the Czech Republic, the negative responses in Germany and Spain, the Company will consider expanding the clinical centers in the authorized countries as part of the EURECART project to increase the chances of recruiting patients. The application for a clinical trial with CAR-T CD44v6 in solid tumors will be contingent on the efficacy and safety findings of the phase I of the mentioned study in patients with liquid tumors.



Finally, with respect to the development of the early stage pipeline, the Company has established scientific milestones, with results expected in the first quarter of 2020, that allow assessing whether to continue with the projects as well as the potential for their transfer to clinical practice.

### *11. Proposal for allocation of losses for the year*

As shown by 2019 Financial Statements, accompanied by this Report and the Notes, the Company reported a loss of Euro 427 thousand, which is proposed to be carried forward.



## Financial Statements at December 31<sup>st</sup>, 2019

### 12. Statement of financial position

(amounts in Euro thousand)

	Note	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018
<b>ASSETS</b>			
Tangible assets	1	18,971	11,701
Intangible assets	2	423	546
Financial assets	3	206	210
Tax receivables	4	2,601	1,719
Other assets	5	0	500
<b>TOTAL NON-CURRENT ASSETS</b>		<b>22,201</b>	<b>14,676</b>
Inventories	6	1,830	1,718
Trade receivables and other commercial assets	7	9,911	5,470
Tax receivables	8	2,528	1,742
Other receivables and sundry assets	9	992	622
Other financial assets	10	-	959
Cash and cash equivalents	11	9,904	15,507
<b>TOTAL CURRENT ASSETS</b>		<b>25,165</b>	<b>26,018</b>
<b>TOTAL ASSETS</b>		<b>47,366</b>	<b>40,694</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
Capital		21,819	21,819
Share premium reserve		61,754	61,754
Other reserves		217	212
Retained earnings (accumulated losses)		(60,190)	(56,067)
Profit (loss) for the period/year		(427)	(4,123)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	12	<b>23,173</b>	<b>23,595</b>
Liabilities for pensions and employee severance indemnity (TFR)	13	150	143
Trade payables	14	-	200
Financial debts	15	7,325	-
Other liabilities	16	2,944	3,611
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>10,419</b>	<b>3,954</b>
Provision risk	17	611	-
Trade payables	18	8,230	9,620
Financial debts	19	1,204	-
Tax payables	20	87	-
Other liabilities	21	3,642	3,525
<b>TOTAL CURRENT LIABILITIES</b>		<b>13,774</b>	<b>13,145</b>
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		<b>47,366</b>	<b>40,694</b>



### 13. Income statement

<i>(amounts in Euro thousand)</i>			
	Note	Year 2019	Year 2018
Revenues from sales	21	34,338	28,447
Other revenues	22	1,934	1,433
<b>Total operating revenues</b>		<b>36,272</b>	<b>29,880</b>
Purchases of raw materials and consumables	23	(6,965)	(5,867)
Costs for services	24	(11,729)	(11,717)
Costs for use of third-party assets	25	(87)	(1,507)
Personnel costs	26	(14,012)	(12,902)
Other operating costs	27	(181)	(105)
Amortization and depreciation	28	(3,533)	(1,647)
<b>Total operating costs</b>		<b>(36,508)</b>	<b>(33,745)</b>
<b>Operating result</b>		<b>(236)</b>	<b>(3,865)</b>
Financial income		76	48
Financial charges		(181)	(306)
<b>Net financial income (charges)</b>	29	<b>(105)</b>	<b>(258)</b>
<b>Pre-tax result</b>		<b>(341)</b>	<b>(4,123)</b>
Income taxes	30	(87)	-
<b>Profit (loss) for the year</b>		<b>(427)</b>	<b>(4,123)</b>
<i>(amounts in Euro)</i>			
		<b>2019</b>	<b>2018</b>
Basic earnings (loss) per share		0.0009	0.0089



## 14. Statement of comprehensive income

<i>(amounts in Euro thousand)</i>	2019	2018
<b>Profit (loss) for the period</b>	<b>(427)</b>	<b>(4,123)</b>
<b>Other comprehensive income (not subsequently reclassified to the income statement)</b>		
Profit (loss) actuarial	5	2
<b>Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)</b>	<b>5</b>	<b>2</b>
<b>Other comprehensive income (subsequently reclassified to the income statement)</b>		
<b>Total comprehensive income (loss) for the period</b>	<b>(422)</b>	<b>(4,121)</b>

## 15. Statement of cash flows

<i>(amounts in Euro thousand)</i>	2019	2018
Cash and cash equivalents	15,507	13,105
<b>Opening cash and cash equivalents</b> A	<b>15,507</b>	<b>13,105</b>
<b>Cash flow from operating activities:</b>		
Profit (loss) for the year	(427)	(4,123)
Amortization of assets	3,325	1,903
Amortization pro-quota Bresso	(1,262)	-
Depreciation of assets	(333)	(333)
Write down of fixed asset and assets items	542	77
Non monetary costs	611	-
Reversal of non monetary financial income and charges	96	76
<b>Cash flow from operating activities before changes in working capital</b>	<b>2,552</b>	<b>(2,400)</b>
<b>Changes in current assets and liabilities:</b>		
(Increase) decrease in inventories	(112)	36
(Increase) decrease in trade and other receivables	(6,047)	(533)
Increase (decrease) in trade and other payables	(200)	(146)
Increase (decrease) in other liabilities	(701)	(68)
<b>Total changes in current assets and liabilities</b>	<b>(7,060)</b>	<b>(711)</b>
(Increase) decrease in non-current tax receivables	(378)	963
Increase (decrease) in non current trade liabilities	(867)	(800)
Increase (decrease) in other liabilities and TFR paid	7	-
<b>Total cash flow generated (absorbed) by operating activities</b> B	<b>(5,746)</b>	<b>(2,948)</b>
<b>Cash flow from investing activities:</b>		
Net (investment) divestment in tangible assets	(689)	(1,629)
Net (investment) divestment in intangible assets	(127)	(110)
Net (investment) in other financial assets	959	4,006
<b>Total cash flow generated (absorbed) by investing activities</b> C	<b>143</b>	<b>2,267</b>
<b>Cash flow from financing activities:</b>		
Increases in capital and share premium reserve	-	3,108
Other Equity movemenets (share increase cost)	-	(25)
<b>Total cash flow generated (absorbed) by financing activities</b> D	<b>-</b>	<b>3,083</b>
<b>Cash flow generated (absorbed) during the period</b> E=B+C+D	<b>(5,603)</b>	<b>2,402</b>
<b>Closing cash and cash equivalents</b> A+E	<b>9,904</b>	<b>15,507</b>



## 16. Statement of changes in equity

(amounts in Euro thousand)

	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Stock option plan reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
<b>Balance at January 1<sup>st</sup> 2018</b>	21,514	58,976	223	396	(13)	(47,966)	(8,497)	24,633
Allocation of prior year result						(8,497)	8,497	
Personnel costs for stock options 2016-2021				(396)		396		
Capital increase dedicated to SG	305	2,803						3,108
Capital increase expenses capitalized		(25)						(25)
Profit (loss) for the period					2		(4,123)	(4,121)
<b>Balance at December, 31<sup>st</sup> 2018</b>	21,819	61,754	223	-	(11)	(56,067)	(4,123)	23,695

(amounts in Euro thousand)

	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Stock option plan reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
<b>Balance at January 1<sup>st</sup> 2019</b>	21,819	61,754	223	(11)	-	(56,067)	(4,123)	23,695
Allocation of prior year result						(4,123)	4,123	
Profit (loss) for the period				5			(427)	(422)
<b>Balance at December, 31<sup>st</sup> 2019</b>	21,819	61,754	223	(6)	-	(60,190)	(427)	23,173





## Notes

### 1. General information

MolMed's Financial Statements, as approved by the Board of Directors on March 16<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").

The statements have been prepared on the basis of the revised version of IAS 1 – Presentation of Financial Statements, as approved by Regulation 1274/2008 issued by the European Commission on December 17<sup>th</sup>, 2008 and effective since January 1<sup>st</sup>, 2009.

The financial statements format adopted is consistent with the one indicated in IAS 1. In particular, the statement of financial position has been prepared by classifying assets and liabilities as current and non-current; the income statement has been prepared by classifying costs by nature. This type of presentation is deemed to be suitable to represent the Company's business.

The statement of cash flows has been prepared by recognizing the financial flows based on the "indirect method", as indicated by IAS 7.

In compliance with the requirements of Consob Resolution no. 15519 of July 27<sup>th</sup>, 2006 as to the format of financial statements, specific supplementary statements have been provided, separately recording transactions with related parties and non-recurring transactions so as not to compromise the overall readability of the statements.

Amounts included in these Financial Statements are in thousands of Euro, unless otherwise indicated. The Euro is the Company's functional currency.

### 2. Accounting standards and basis of measurement

#### General principles

The Company's Financial Statements have been prepared on a historical cost basis, adjusted as required to measure some financial instruments, and on a going concern basis.

#### Going concern

The Company's dual business includes development and manufacturing on behalf of third parties as well as research and development activities in relation to proprietary products. This business, in line with biotech companies developing new therapeutic products and that have not reached a balanced income and financial position yet, features 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.



In the sector 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. 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.

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 reported a loss since its incorporation.

The loss for 2019 was Euro 427 thousand, decreased by Euro 3,696 thousand from the Euro 4,123 Euro loss recorded in the previous year. The decreased loss, which has been constantly reducing over the last three years, was largely attributable to the growth in services on behalf of third parties, which caused revenues from development and manufacturing on behalf of third parties to rise by 41.8%. 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 to realize it.

Finally, in accordance with the plan for the next three years approved by the Board of Directors in December 2019, the Company will carry on the clinical development of its main proprietary product as well as expand the business on behalf of third parties. 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.

As disclosed in the Report on Operations, in December, the Company entered into a financing arrangement with the European Investment Bank ("EIB") up to Euro 15,000 thousand 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 Euro 7,500 thousand. Each tranche may be divided into two sub-tranches. The drawdown is subject to the review of predefined specific financial goals and milestones. At December 31<sup>st</sup>, 2019, the Company did not draw down any tranche.

Considering the above, and based on the Euro 9,904 thousand in cash and cash equivalents at December 31<sup>st</sup>, 2019, the year-on-year improvement in the result for the period, and the future cash flows estimated in the next three-year plan as well as the on the Euro 15,000 thousand 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, which, combined with the cash flows expected from development and manufacturing services on behalf of third parties, guarantee that it will continue as a going concern for a foreseeable period of at least 12 months following the date the financial statements are authorized for issue. 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 date the financial statements are authorized for issue.

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.

### Tangible assets

Net of accumulated depreciation and any impairment losses, tangible assets are recognized at acquisition cost, including directly attributable ancillary costs. Costs subsequently incurred for improvement and transformation of tangible assets are capitalized only if they increase the reliably measurable future economic benefits. Maintenance or repair costs that did not generate any significant and measurable increase in the production capacity or the useful life of the assets are fully recognized in profit or loss.

Depreciation, recognized in profit or loss, is calculated taking account of the usage, purpose, and technical or commercial obsolescence of the assets, based on their remaining life. The depreciation rates below apply:

■ General and laboratory plant and machinery	10-30%
■ laboratory equipment	10-20%
■ office electronic equipment	20%
■ office furniture and equipment	12%
■ leasehold improvements	8.33%

Depreciation starts when assets are ready for use. Depreciation rates are reviewed annually and changed if the current estimated useful life is different from that estimated previously.

Leasehold improvements are capitalized as part of the item to which they refer and are depreciated over their estimated useful life or, if shorter, over the lease term.

As of January 1<sup>st</sup>, 2019, the Company has applied the new standard IFRS 16 “Leases”. For more details, please refer to the following paragraph **“Accounting standards, amendments and interpretations applicable on or after January 1<sup>st</sup>, 2019”**.

### Intangible assets

Separately acquired intangible assets are initially recognized at cost, while those acquired in business combinations are recognized at their fair values at the acquisition date. After initial recognition, intangible assets are carried at cost less accumulated amortization and any accumulated impairment losses. Internally generated intangible assets, except for development costs, are not capitalized and are recognized in profit or loss as incurred.

The useful life of intangible assets is assessed as finite or indefinite. Intangible assets with a finite useful life are amortized over their useful life and tested for impairment whenever there is any indication of a potential impairment loss. The amortization period and the amortization method for an intangible asset with a finite useful life is reviewed at least at each financial year-end. Changes in the estimated useful life of, or the pattern of consumption of the future economic benefits associated with, the asset are recognized by changing the amortization period or amortization method, as appropriate, and are considered changes in accounting estimates. The amortization charges of intangible assets with a finite useful life are recognized in profit or loss in the cost category that is consistent with the function of the intangible asset.

Intangible assets with an indefinite useful life are not amortized, but are tested for impairment annually at both the individual and cash-generating unit level. The measurement of the indefinite useful life is reviewed annually to determine whether this assessment remains sustainable, otherwise, the change from indefinite to finite useful life is applied prospectively.



An intangible asset is derecognized on disposal (that is, the date on which the acquirer obtains control of it) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising from the derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in profit or loss.

### **Goodwill**

Goodwill—equal to the difference between the cost of the acquisition and the fair value of the assets, liabilities and contingent liabilities identified by the acquirer on the acquisition date—is classified as an asset with an indefinite useful life and is initially recognized at cost.

After the acquisition date, goodwill is not amortized, but it is tested for impairment annually or more frequently, if an indication of impairment exists. If the recoverable amount is lower than the carrying amount, the value of the assets is reduced to its recoverable amount. If goodwill is allocated to a cash-generating unit partially subject to sale/disposal, the relevant goodwill is considered for determining any gain/loss deriving from the transaction.

### **Other intangible assets**

Other intangible assets are recognized at their historical acquisition cost, including directly attributable ancillary costs, or based on the costs directly incurred for their generation. They are amortized on a straight-line basis over their expected useful life, estimated at ten years, except for certain costs regarding concessions, licenses and software, which are amortized over five years.

### **Concessions, licenses and trademarks**

These assets concern costs incurred under license and sub-license agreements on intellectual property used to develop the Company's products. They are amortized on a straight-line basis over their expected useful life (estimated at ten years).

### **Patents and intellectual property rights**

Patents acquired in exchange for consideration are initially recognized at acquisition cost and amortized on a straight-line basis over their expected useful life (estimated at ten years).

### **Research and development costs**

Research costs are recognized in profit or loss in the period in which they are incurred. Internally-generated costs arising from the development of new products are classified as intangible assets and recognized only if the entity can demonstrate the following:

- the technical feasibility of completing the intangible asset and the intention to complete it, so that it will be available for use or sale;
- its ability to use or sell the intangible asset;
- how costs incurred will generate probable future economic benefits— as far as this point is concerned, the entity can demonstrate the existence of a market for the output of the intangible asset or, if it is to be used internally, the usefulness of the intangible asset;
- the availability of adequate technical and financial resources to complete the development and to use or sell the output of the intangible asset;
- its ability to measure reliably the expenditure attributable to the intangible asset during its development.

Taking account of the Company's business and the objective characteristics of its experimental activities, research and development costs are entirely expensed in the year they are incurred. Research and development costs cannot be capitalized based on the current development phase of MolMed's products.



## Financial assets

At initial recognition, financial assets are recognized at fair value and classified into one of the following categories depending on their nature and the purpose for which they were acquired:

- (a) Financial assets at amortized cost
- (b) Financial assets at fair value through profit or loss;
- (c) Financial assets at fair value through other comprehensive income (OCI).

A financial asset is derecognized when the rights to the cash flows arising from it expire and the Company has substantially transferred all the risks and rewards of ownership as well as control of the asset.

### (a) Financial assets at amortized cost

Financial assets are classified into this category when the asset is held within a business model whose objective is to collect contractual cash flows and the latter give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortized cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in profit or loss when the asset is disposed of, modified, and revalued.

Financial assets at amortized cost include loans receivable. Assets at amortized cost are classified in the statement of financial position under "Financial assets at amortized cost" as current or non-current assets depending on whether their contractual life is less or greater than 12 months from the reporting date.

### (b) Financial assets at fair value through profit or loss

The financial assets classified into this category consist of securities held for trading as acquired to be sold in the short term.

Financial assets recognized through profit or loss are initially measured at fair value and the relevant ancillary costs are recognized immediately in profit or loss. Subsequently, such financial assets at fair value through profit or loss are measured at fair value. The assets in this category are classified as current. Gains and losses from the fluctuation in the fair value of financial assets at fair value through profit or loss are presented in profit or loss in the line items "Financial income" and "Financial charges" in the period in which they are recognized.

### (c) Financial assets at fair value through other comprehensive income (OCI)

Financial assets are classified into this category when the asset is held within a business model whose objective is to collect cash flows by both collecting contractual cash flows and selling the asset itself.

In addition, the cash flows must be solely payments of principal and interest on the principal amount outstanding. All financial assets in this category are recognized at fair value, and gains or losses arising from their measurement are recognized in a reserve within equity; they are recognized through profit or loss in the line items "Financial income" and "Financial charges" only when the financial asset is actually disposed of.

The fair value of quoted financial instruments is based on the current bid price; these instruments are categorized within Level 1 of the fair value hierarchy. If the market for a financial asset is not active (or refers to unquoted securities), the Company defines fair value using valuation techniques in line with the requirements for Level 2 and Level 3, depending on whether market inputs are observable or unobservable.

When making measurements, the Company priorities market information rather than internal information specifically related to the nature of the business in which the Company operates. In measuring Financial assets at fair value through other comprehensive income (OCI), the Company uses the simplified approach applicable to assets that have low credit risk. At each reporting date, the Company assesses whether the instrument has low credit risk by using all information that is available without undue cost or effort. In making this assessment, the Company monitors the credit rating of the debt instrument on a continuing basis. If there is evidence of a



deterioration in the counterparty's credit standing, the Company recognizes all credit losses expected over the remaining life of the exposure.

In certain cases, the Company may consider a financial asset to be no longer recoverable when internal or external information indicates that the Company is unlikely to fully recover the outstanding contractual amounts, including when considering any collateral held by the Company. Therefore, the financial asset is derecognized when there is no reasonable expectation of recovering the contractual cash flows.

### **Receivables**

Receivables are initially recognized at par value (equal to the fair value of the transaction). They are then measured at amortized cost, net of any impairment losses recognized in profit or loss, if evidence shows that impairment has occurred. Credit losses are recognized based on expected credit losses (ECLs). Expected credit losses are based on the difference between the contractual cash flows that are due and the cash flows that the Company expects to receive, discounted at an approximation of the original effective interest rate.

In particular, measurement at amortized cost of short-term trade receivables, for which the time component is not significant, is equal to the par value, net of any impairment losses.

### **Inventories**

Inventories are recognized at the lower of cost and net realizable value arising from the market trend. Acquisition cost is calculated based on the weighted average cost. The carrying amount of inventories is adjusted to take account of obsolete and slow-moving stocks, based on their expected usage and estimated realizable value.

### **Cash and cash equivalents**

Cash and cash equivalents are recognized, depending on their nature, at par value (i.e. the fair value) or amortized cost. Cash includes cash on hand.

### **Derecognition of financial instruments**

A financial asset is derecognized when the rights to the cash flows arising from it expire and all risks and rewards of ownership are substantially transferred or in the event that the asset is considered not recoverable after exhausting all collection procedures. An entity removes a financial liability from its statement of financial position when its obligation is extinguished. Receivables sold as a result of factoring transactions are derecognized only when all risks and rewards of ownership have been substantially transferred to the factor. The Company continues to recognize receivables factored with or without recourse that do not meet this requirement, even though it formally sold them; in this case, it recognizes a financial liability of the same amount for the advance payment received.

### **Employee benefits**

Employee severance indemnity (TFR) is determined using an actuarial method; the amount of the benefits earned by employees during the period is recognized in profit or loss as part of personnel costs, while the notional financial cost the Company would incur for a loan of the same amount as the TFR is recognized as net financial income (charges). Actuarial gains and losses reflecting the effects of changes in the actuarial assumptions used are recognized in other comprehensive income, taking account of the average remaining working life of employees.

Under IAS 19, the employee severance indemnity is considered as a "defined benefit plan", and the related liability to be recognized in the financial statements is determined through an actuarial calculation, using the Projected Unit Credit Method. Costs arising from the increase in TFR present value (as the period for payment



of benefits gets closer) are recognized as part of "Personnel costs".

Effective since January 1<sup>st</sup>, 2007, the 2007 Budget Law, and the relevant implementation decrees, introduced significant changes in employee severance indemnity (TFR) regulations, including the choice for employees to allocate their post-employment benefits either to supplementary pension schemes or to the fund managed by INPS, the Italian social security agency.

As a result, the Company's contributions to the INPS fund and to the supplementary pension schemes are classified as "defined contribution plans" under IAS 19, while allocations to TFR are classified as "defined benefit plans".

Liabilities relating to post-employment benefits recognized in the statement of financial position as a defined benefit plan represent the present value of the defined benefit plan adjusted to include any actuarial gains and losses.

### **Stock option plans**

The Company grants additional benefits to the Chairman, CEO and specific categories of employees and consultants through stock option plans.

In accordance with IFRS 2 – Share-based Payments, these plans are granted as part of the beneficiaries' remuneration package whose cost is equivalent to the fair value of stock options at the grant date and is recognized in profit or loss on a straight-line basis starting from the grant date through the vesting period, with a corresponding entry in equity. Any subsequent changes in fair value do not have any effect on the initial measurement.

Personnel costs include stock options by virtue of their remuneration nature.

### **Financial payables**

Financial payables, consisting of liabilities arising from finance leases, are initially recognized at cost, equal to the fair value of the amount received, net of any ancillary costs. Subsequently they are measured at amortized cost, based on the effective interest rate.

### **Payables**

Trade and other payables are recognized at amortized cost, which is normally equivalent to the par value, due to the nature and due dates of payables.

### **Provisions for risks and charges**

Allocations include liabilities arising from current (legal or implicit) obligations, relating to a past event, in relation to which a disbursement will be made that can be reliably estimated. If it is expected to occur after the following reporting period, the liability is recognized at the present value, determined by discounting expected future cash flows at an interest rate that takes into account the cost of borrowing and the risk of the liability. The provisions are reviewed at each reporting date, and they are adjusted, as needed, to reflect the best current estimate. Any changes are recognized in profit or loss in the period in which they took place.

Risks involving a possible obligation (contingent liabilities) are disclosed in the Notes, but no provision is made.

### **Recognition of revenues and income**

Revenues are recognized when it is probable that the Company will enjoy future economic benefits and their amount can be reliably determined. They are recognized net of discounts, allowances and returns.

Revenues from services are recognized based on the stage of completion of the service only when the result can be reliably estimated.



As part of its operations, the Company enters into agreements with third parties, which may include upfront payments as well as milestone payments or royalties relating to the achievement of specific targets or the occurrence of events specified by the agreement. For the purpose of recognizing revenues arising from third-party agreements, the Management has to identify each individual revenue defined under the agreement and the relevant time period for recognition. Revenues relating to upfront payments that are not subject to reimbursement are fully recognized in profit or loss at the execution date only if the Company is not committed to a further performance obligation. Revenues relating to milestone payments based on achievement of specific development objectives are fully recognized when the right to such payment arises. Royalties are recognized as revenues in the period when the right to receive them arises.

Revenues arising from government grants are recognized when it is reasonably certain that they will be received. This takes place when the subsidized project is approved by the relevant public sector bodies. Such revenues are recognized based on the costs actually incurred as a percentage of the total costs budgeted for the subsidized research projects.

### **Recognition of costs and charges**

Costs are accounted for when they concern goods and services purchased or used during the reporting period or when they have no identifiable future benefits.

### **Financial income and charges**

Interest income and charges are accounted for on an accrual basis, based on interests accruing on the net value of the relevant financial assets and liabilities, using the effective interest rate.

Financial charges are accounted for on an accrual basis and recognized in profit or loss as incurred.

Financial income is accounted for on an accrual basis, based on the effective rate of return.

### **Income taxes**

Income taxes include all taxes calculated on the basis of the Company's taxable income.

Income tax expense pertaining to the reporting period is determined based on the legislation in force. Income taxes are recognized in profit or loss, 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 profit or loss, 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<sup>th</sup>, 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 profit or loss, 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.

### **Foreign currency transactions**

Transactions in currencies other than the Euro are initially recognized at the exchange rate at the transaction date. Monetary assets and liabilities are translated at the exchange rate in effect at the end of the reporting period. Exchange differences arising from the settlement of monetary items and from their translation at year-end rates differing from those measured upon initial recognition are recognized in profit or loss.

### **Earnings per share**

Basic earnings per share shall be calculated by dividing profit or loss attributable to ordinary equity holders of the Company (the numerator) by the weighted average number of ordinary shares outstanding (the denominator) during the reporting period. Diluted earnings per share are calculated by adjusting profit or loss attributable to ordinary equity holders and the weighted average number of shares outstanding (the denominator) to take into account the effects of all dilutive potential ordinary shares. A potential ordinary share is a financial instrument or any other contract that may entitle its holder to ordinary shares.

### **Use of estimates**

In compliance with IFRSs, the preparation of the financial statements and related notes requires Management to make estimates and assumptions that can impact the amounts of assets and liabilities recognized and the disclosure of contingent assets and liabilities at the end of the reporting period.

The estimates and assumptions used are based on experience and other factors that are considered as significant. Future results could differ from such estimates. Estimates and assumptions are reviewed periodically, and the effects of any changes are immediately recognized in profit or loss in the relevant period, if they have an impact on this period only, or in future years, if they impact both the current reporting period and future periods.

Furthermore, the preparation of the financial statements requires Management to apply accounting principles and methods that, in some cases, are based on difficult and subjective assumptions and assessments arising from past experience and on assumptions which are considered as realistic and reasonable according to circumstances. The application of such estimates and assumptions has an impact on the amounts recognized in the statement of financial position, income statement, statement of cash flows and disclosed in the report.

A description of critical estimates requiring subjective judgments, assumptions and estimates involving issues that are uncertain by nature is provided further on. Changes in the conditions underlying the judgments, assumptions and estimates adopted might have a major impact on future results since there is the risk that significant adjustments to the carrying amount of assets and liabilities may emerge in periods following the



reporting period.

### **Impairment of assets**

Tangible and intangible assets are impaired when specific events or changes in circumstances suggest that the carrying amount is not recoverable. Impairment is calculated by comparing the carrying amount and the relevant recoverable amount, calculated as the higher of fair value—net of disposal costs—and the value in use determined by discounting the expected cash flows arising from the use of the asset. The expected cash flows are determined based on the information available at the time of measurement, based on subjective judgments regarding the trends of future variables.

Management periodically reviews the carrying amount of non-current assets held and used, and that of assets to be disposed of, when events and circumstances suggest such a review. This is performed by using estimates of expected cash flows arising from the use or disposal of the asset, and suitable discount rates to calculate the present value. If a non-current asset has been impaired, the Company recognizes an impairment equal to the difference between the carrying amount of the asset and its estimated recoverable amount arising from use or disposal, determined based on the most recent business plans.

### **Deferred taxes**

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. Recoverability of deferred taxes mainly depends on the recognition of a future taxable profit allowing to use them within the relevant deadlines. In preparing the financial statements, Directors did not find sufficient evidence to consider recoverability as probable. Therefore, no prepaid taxes were recognized. Judgment is required for this assessment since changes in the assumptions could have a material impact on the recognition of deferred tax assets.

### **Amortization/depreciation**

Intangible and tangible assets with a finite useful life are amortized/depreciated on a straight-line basis over their estimated useful life. Their estimated useful life is determined by Directors when assets are acquired or completed. The actual economic life may differ from the estimated useful life. The Company periodically assesses any technological changes, market conditions and forecasts of future events that may impact useful life. Such periodical updates may change the amortization/depreciation period, as well as the amortization/depreciation amounts recognized in future periods.



## Accounting standards, amendments and interpretations applicable on or after January 1<sup>st</sup>, 2019

- **IFRS 16 – Leases** (issued on January 13<sup>th</sup>, 2016), replacing IAS 17 – Leases; IFRIC 4 – Determining Whether an Arrangement Contains a Lease; SIC-15 – Operating Leases – Incentives and SIC-27 – Evaluating the Substance of Transactions in the Legal Form of a Lease.

The new standard provides a new definition of lease and applies a control model (right of use) to distinguish between a lease and a service contract based on the following: identification of the asset, the right to substitute it, the right to obtain substantially all of the economic benefits from use of the identified asset and the right to direct the use of the underlying asset.

The Company adopted IFRS 16 using the modified retrospective approach with a date of initial application of January 1<sup>st</sup>, 2019. Under this approach, the standard is applied retrospectively with the cumulative effective of initially applying the standard recognized at the date of initial application. The Company elected to use the practical expedient for transition allowing to apply the requirements of the standard only to contracts that at the date of initial application were previously identified as leases under IAS 17 and IFRIC 4. In addition, the Company used the exceptions proposed by the standard for leases that, at the date of initial application, have a lease term of 12 months or less and do not contain a purchase option (“short-term leases”) and leases for which the underlying asset is of low value (“low-value assets”).

The Company has recognized right-of-use assets and lease liabilities for all contracts previously classified as operating leases, except for short-term leases and leases of low-value assets. The right-of-use asset for most leases was recognized on the basis of the carrying amount as if the standard had always been in use, but discounted using an incremental borrowing rate at the date of initial application.

Lease liabilities were recognized at the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application.

In addition, the Company applied the available practical expedients, specifically:

- It applied a single discount rate to a portfolio of leases with reasonably similar characteristics;
- It relied on its assessment of whether leases are onerous immediately before the date of initial application;
- It applied the exemption for short-term leases for which the lease term ends within 12 months of the date of initial application;
- It excluded initial direct costs from the measurement of the right-of-use asset at the date of initial application;
- It used hindsight, such as in determining the lease term if the contract contains options to extend or terminate the lease.



Below are the impacts of applying the above standard on the Company's financial position and financial performance.

<i>amounts in Euro thousand</i>	January 1 <sup>st</sup> 2019 - IFRS16 First time Adoption	Increase (decrease) of the period	Depreciation	December 31 <sup>st</sup> 2019
Tangible Assets - Right of use	9,587	166		9,753
Effect of depreciation of Right of use			(1,262)	(1,262)
<b>Total Asset</b>	<b>9,587</b>	<b>166</b>	<b>(1,262)</b>	<b>8,491</b>
Lease liability (long term)	8,287	(962)		7,325
Lease liability (short term)	1,300	(96)		1,204
<b>Total liabilities</b>	<b>9,587</b>	<b>(1,059)</b>		<b>8,528</b>

<i>amounts in Euro thousand</i>	IFRS16 Effect 01/01/2019- 31/12/2019
Cost for services (use of third-party assets)	1,355
Depreciation of Right of use	(1,262)
Interest costs	(132)
	<b>(39)</b>

- **IFRIC Interpretation 23 – Uncertainty over income tax treatments** The interpretation addresses the accounting treatment for income taxes when tax treatments involve uncertainty that affects the application of IAS 12. The interpretation does not apply to taxes or levies outside the scope of IAS 12, nor does it specifically include requirements relating to interest or penalties associated with uncertain tax treatments.

The interpretation specifically addresses the following:

- Whether an entity considers uncertain tax treatments separately
- The assumptions an entity makes about the examination of tax treatments by taxation authorities
- How an entity determines taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates
- How an entity considers changes in facts and circumstances.
- An entity shall determine whether to consider each uncertain tax treatment separately or together with one or more other uncertain tax treatments. It should use the approach that better predicts the resolution of the uncertainty.

The interpretation had no impact on the Company's financial statements.

- **Amendments to IAS 19:** they address the accounting when a plan amendment, curtailment or settlement occurs during a reporting period. The amendments specify that when a plan amendment, curtailment or settlement occurs during the annual reporting period, an entity is required to determine current service cost for the remainder of the period after the plan amendment, curtailment or settlement, using the actuarial assumptions used to remeasure the net defined benefit liability (asset) reflecting the benefits offered under the plan and the plan assets after that event. In addition, an entity must determine net interest for the remainder of the period after the plan amendment, curtailment or settlement using: the net defined benefit liability (asset) reflecting the benefits offered under the plan and the plan assets after that event; and the discount rate used to remeasure that net defined benefit liability (asset). These amendments had no impact on the financial statements, as the Company did not register any plan amendment, curtailment or settlement during the reporting period.

- **Amendments to IAS 28: Long-term Interests in Associates and Joint Ventures:** they clarify that an entity applies IFRS 9 to long-term interests in an associate or joint venture to which the equity method is not applied but that, in substance, form part of the net investment in the associate or joint venture (long-term interests). This clarification is relevant because it implies that the expected credit loss model in IFRS 9 applies to such long-term interests. The amendments also clarify that, in applying IFRS 9, an entity does not take account of any losses of the associate or joint venture, or any impairment losses on the net investment, recognized as adjustments to the net investment in the associate or joint venture that arise from applying IAS 28 – Investments in Associates and Joint Ventures. These amendments had no impact on the financial statements, as the Company does not have interests in associates and joint ventures.
- **IAS 12: Income Taxes:** these amendments clarify that the income tax consequences of dividends are linked more directly to past transactions or events that generated distributable profits than to distributions to owners. Therefore, an entity recognizes the income tax consequences of dividends in profit or loss, other comprehensive income or equity according to where the entity originally recognized those past transactions or events. An entity applies those amendments for annual reporting periods beginning on or after January 1<sup>st</sup>, 2019. When an entity first applies those amendments, it applies them to the income tax consequences of dividends recognized on or after the beginning of the earliest comparative period. Since its current practices are in line with these amendments, the Company did not see any impact on its financial statements.
- **IAS 23: Borrowing Costs:** these amendments clarify that an entity treats as part of general borrowings any borrowing originally made to develop a qualifying asset when substantially all of the activities necessary to prepare that asset for its intended use or sale are complete. An entity applies those amendments to borrowing costs incurred on or after the beginning of the annual reporting period in which the entity first applies those amendments. An entity applies those amendments for annual reporting periods beginning on or after January 1<sup>st</sup>, 2019. Earlier application is permitted. Since its current practices are in line with these amendments, the Company did not see any impact on its financial statements.
- **Amendments to IFRS 9 - Prepayments Features with Negative Compensation:** Under IFRS 9, a debt instrument can be measured at amortized cost or at fair value through other comprehensive income, provided that the contractual cash flows are “solely payments of principal and interest on the principal amount outstanding” (the SPPI criterion) and the instrument is classified within the appropriate business model. The amendments to IFRS 9 clarify that a financial asset passes the SPPI criterion regardless of the event or circumstance that causes the early termination of the contract and irrespective of which party pays or receives reasonable compensation for the early termination of the contract. These amendments had no impact on the Company's financial statements.
- **IFRS 11 - Joint Arrangements:** an entity that participates in, but does not have joint control of, a joint operation might obtain joint control of the joint operation in which the activity of the joint operation constitutes a business as defined in IFRS 3. The amendments clarify that the previously held interests in that joint operation are not remeasured. An entity applies those amendments to transactions in which it obtains joint control on or after the beginning of the first annual reporting period beginning on or after January 1<sup>st</sup>, 2019. Earlier application is permitted. This amendment had no impact on the Company's financial statements, as no business combination occurred in which the Company obtained joint control.

- **IFRS 3 - Business Combination:** The amendments clarify that, when an entity obtains control of a business that is a joint operation, it applies the requirements for a business combination achieved in stages, including remeasuring previously held interests in the assets and liabilities of the joint operation at fair value. In doing so, the acquirer remeasures its entire previously held interest in the joint operation. An entity applies those amendments to business combinations for which the acquisition is on or after the beginning of the first annual reporting period beginning on or after January 1<sup>st</sup>, 2019. Earlier application is permitted. This amendment had no impact on the Company's financial statements, as no business combination occurred in which the Company obtained joint control.

Below are the standards and interpretations that had already been issued but were not yet effective at the date of preparing the Company's financial statements. The Company intends to adopt these standards and interpretations, if applicable, as they become effective.

- **IFRS 17 – Insurance Contracts:** In May 2017, the IASB issued IFRS 17 Insurance Contracts (IFRS 17), a comprehensive new accounting standard for insurance contracts covering recognition and measurement, presentation and disclosure. Once effective, IFRS 17 will replace IFRS 4 Insurance Contracts, which was issued in 2005. IFRS 17 applies to all types of insurance contracts (i.e., life, non-life, direct insurance and re-insurance), regardless of the type of entities that issue them, as well as to certain guarantees and financial instruments with discretionary participation features. A few scope exceptions will apply. The overall objective of IFRS 17 is to provide an accounting model for insurance contracts that is more useful and consistent for insurers. In contrast to the requirements in IFRS 4, which are largely based on grandfathering previous local accounting policies, IFRS 17 provides a comprehensive model for insurance contracts, covering all relevant accounting aspects. The core of IFRS 17 is the general model, supplemented by:
  - A specific adaptation for contracts with direct participation features (the variable fee approach).
  - A simplified approach (the premium allocation approach) mainly for short-duration contracts.

IFRS 17 is effective for reporting periods starting on or after January 1<sup>st</sup>, 2021, with comparative figures required. Early application is permitted, provided the entity also applies IFRS 9 and IFRS 15 on or before the date it first applies IFRS 17. This standard does not apply to the Company.

- **Amendments to IFRS 3: Definition of a Business:** In October 2018, the IASB issued amendments to the definition of a business in IFRS 3 Definition of a Business to help entities determine whether an acquired set of activities and assets is a business or not. They clarify the minimum requirements for a business, remove the assessment of whether market participants are capable of replacing any missing elements, add guidance to help entities assess whether an acquired process is substantive, narrow the definitions of a business and of outputs, and introduce an optional fair value concentration test. New illustrative examples were provided along with the amendments. Since the amendments apply prospectively to transactions or other events that occur on or after the date of first application, the Company was not affected by these amendments at the date of initial application.
- **Amendments to IAS 1 and IAS 8: Definition of Material:** In October 2018, the IASB issued amendments to IAS 1 Presentation of Financial Statements and IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors to align the definition of 'material' across the standards and to clarify certain aspects of the definition. The new definition states that information is material if omitting, misstating or obscuring it could reasonably be expected to influence decisions that the primary users of



the financial statements make on the basis of the financial information therein. The amendments to the definition of material are not expected to significantly affect 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 and production of innovative therapies for both its products in the pipeline and for 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 production activity is considered as a whole, the CEO is responsible for all corporate activities. 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 of tangible assets at December 31<sup>st</sup>, 2019 are shown in the table below:

(amounts in Euro thousand)	December 31 <sup>st</sup> , 2018	IFRS 16 Application	Balance at January 1 <sup>st</sup> , 2019	Purchases	Reclassifications	Disposals	Depreciation and write downs	December 31 <sup>st</sup> , 2019
<b>Gross book value</b>								
Plant and machinery	1,824		1,824	30	29	(43)		1,840
Industrial and commercial equipment	10,645		10,645	362	332	(711)		10,628
Leasehold improvements	10,094		10,094	11	14	(64)		10,055
Other tangible assets	2,022		2,022	50		(293)		1,779
Right of use (IFRS16)		9,587	9,587	166				9,753
Ass. under construction and payments on account	397	-	397	236	(375)			258
<b>Total gross book value</b>	<b>24,982</b>	<b>9,587</b>	<b>34,569</b>	<b>855</b>	<b>-</b>	<b>(1,111)</b>	<b>-</b>	<b>34,313</b>
<b>Accumulated depreciation</b>								
Plant and machinery	(630)		(630)			43	(168)	(755)
Industrial and commercial equipment	(5,310)		(5,310)			705	(1,053)	(5,658)
Leasehold improvements	(5,936)		(5,936)			64	(503)	(6,375)
Other tangible assets	(1,406)		(1,406)			293	(180)	(1,293)
Right of use (IFRS16)	-		-			-	(1,262)	(1,262)
<b>Total accumulated depreciation</b>	<b>(13,282)</b>	<b>-</b>	<b>(13,282)</b>	<b>-</b>	<b>-</b>	<b>1,105</b>	<b>(3,166)</b>	<b>(15,343)</b>
<b>Net book value</b>								
Plant and machinery	1,195		1,194	30	29		(168)	1,085
Industrial and commercial equipment	5,335		5,335	362	332	(6)	(1,053)	4,970
Leasehold improvements	4,158		4,158	11	14		(503)	3,680
Other tangible assets	616		616	50			(180)	486
Right of use (IFRS16)		9,587	9,587	166			(1,262)	8,491
Ass. under construction and payments on account	397		397	236	(375)			258
<b>Total net book value</b>	<b>11,701</b>	<b>9,587</b>	<b>21,287</b>	<b>855</b>	<b>-</b>	<b>(6)</b>	<b>(3,166)</b>	<b>18,971</b>

\* The depreciation shown in the table includes the portion relating to leasehold improvements at the site in Bresso, totaling Euro 333 thousand. As detailed in the Notes, this was neutralized in profit or loss following the pro rata reversal of the relevant deferred income, as the costs of said improvements are charged to the site's owner.

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 Manufacturing Facilities 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 of Euro 4,000 thousand, 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 Euro 11,701 thousand at December 31<sup>st</sup>, 2018 to Euro 18,971 thousand at December 31<sup>st</sup>, 2019. Starting from January 1<sup>st</sup>, 2019, after the new standard IFRS 16 "Leases" became effective, the Company included Euro 9,587 thousand worth of Right-of-use assets in tangible assets, divided into the following categories:

- vehicles: Euro 8 thousand;
- car parking spaces at the Bresso and Milan facilities: Euro 34 thousand;
- buildings, offices and laboratories at the Bresso and Milan facilities: Euro 9,545 thousand.

Investments of Euro 855 thousand were made in tangible assets in 2019. They consist in (i) investments to bring new manufacturing facilities online (Stream 2), 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 Euro 362 thousand increase in industrial and commercial equipment.
- the increase in assets under construction and payments on account, for investments in industrial and commercial equipment purchased and delivered but not yet brought into use or tested at December 31<sup>st</sup>, 2019 to the tune of Euro 236 thousand.

In 2019, after taking stock of the assets at the two manufacturing facilities located in via Olgettina and Bresso with the help of a consultancy, the Company derecognized Euro 6 thousand in fully depreciated items of property, plant and equipment, net of their relevant accumulated depreciation.

At December 31<sup>st</sup>, 2019, depreciation amounts to Euro 3,166 thousand, up from Euro 1,750 thousand in 2018 largely because the Company recognized the Right-of-use Asset following the application of the standard IFRS 16 “Leases” and, therefore, the relevant depreciation charges for the period, amounting to Euro 1,262 thousand. The depreciation includes the portion relating to leasehold improvements at the facility in Bresso, totaling Euro 333 thousand. This was neutralized in profit or loss following the pro rata reversal of the relevant deferred income, as the costs of said improvements are charged to the site's owner up to an amount of Euro 4,000 thousand, as provided for by the relevant agreement.

At December 31<sup>st</sup>, 2019, there were no indications of impairment. It should also be noted that there is no collateral on tangible assets.

### Note 2 – Intangible assets

The breakdown and changes in intangible assets at December 31<sup>st</sup>, 2019 are shown in the table below:

(amounts in Euro thousand)	December 31 <sup>st</sup> , 2018	Purchases	Reclassifications	Disposals	Depreciation and write downs	December 31 <sup>st</sup> , 2019
Patents and intellectual property rights	183	36	-	(92)	(41)	86
Concessions, licenses and trademarks	313	91	34	-	(117)	321
Assets under construction	50	-	(34)	-	-	16
<b>Intangible assets</b>	<b>546</b>	<b>127</b>	<b>-</b>	<b>(92)</b>	<b>(158)</b>	<b>423</b>

The purchases of Intangible assets, amounting to Euro 127 thousand, include Euro 91 thousand in software to manage laboratory equipment at the new facility, while amortization charges totaled Euro 158 thousand.

During the year, the Company wrote down the value of patents and trademarks associated with TK and Zalmoxis® by Euro 92 thousand following the withdrawal of the Conditional Marketing Authorization for Zalmoxis.

At December 31<sup>st</sup>, 2019, there are no other intangible assets with an indefinite useful life.

### Note 3 – Financial assets

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

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

Non-current tax receivables increased from Euro 1,719 thousand at December 31<sup>st</sup>, 2018 to Euro 2,601 thousand at December 31<sup>st</sup>, 2019. They consist in VAT tax receivables amounting to Euro 2,601 thousand. VAT receivables regularly accrue to the Company as most invoices are billed to EU and non-EU customers. The Euro 1,519 thousand VAT receivable outstanding at December 31<sup>st</sup>, 2018 was sold to a factoring firm without recourse and collected in June 2019.



At December 31<sup>st</sup>, 2019, the Company conservatively wrote down a Euro 200 thousand receivable arising from withholding taxes in a non-EU country, as the withdrawal of the Conditional Marketing Authorization for Zalmoxis raised doubts as to whether it can be recovered.

#### Note 5 – Other assets (non-current)

“Other non-current assets” decreased to zero, after the amount of Euro 500 thousand paid as an advance on future rents to the owner of the property in the “Open Zone” scientific park in Bresso was reclassified as short-term.

#### Note 6 – Inventory

Inventory at December 31<sup>st</sup>, 2019 is broken down as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% change
Processing materials	667	543	124	22.8%
Reagents	958	1,095	(137)	(12.5%)
General materials	205	80	125	156.3%
<b>Total inventories</b>	<b>1,830</b>	<b>1,718</b>	<b>112</b>	<b>6.5%</b>

Consisting of reagents and materials used in the Company's laboratories, inventory increased by Euro 112 thousand, from Euro 1,718 thousand at December 31<sup>st</sup>, 2018 to Euro 1,830 thousand at December 31<sup>st</sup>, 2019. Such increase was due to the higher purchase of materials in relation to increasing manufacturing volumes.

#### Note 7 – Trade receivables and other commercial assets

The breakdown of trade receivables and other commercial assets at December 31<sup>st</sup>, 2019 is as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% change
Trade receivables	4,433	4,140	293	7.1%
Prepayments	506	518	(12)	(2.3%)
Invoices to be issued	4,972	812	4,160	512.3%
<b>Total trade receivables and other commercial assets</b>	<b>9,911</b>	<b>5,470</b>	<b>4,441</b>	<b>81.2%</b>

The Euro 9,911 thousand increase in trade receivables and other commercial assets 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 Euro 278 thousand.

#### Note 8 – Tax receivables (current)

Tax receivables at December 31<sup>st</sup>, 2019 are broken down as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% Change
VAT receivables	700	522	178	34.1%
Tax credit R&D costs	1,826	1,041	785	75.5%
Withholding taxes	2	179	(177)	(98.9%)
<b>Total tax receivables</b>	<b>2,528</b>	<b>1,742</b>	<b>786</b>	<b>45.1%</b>

Current tax receivables equal to Euro 2,528 thousand, and reported an increase of Euro 786 thousand compared to Euro 1,742 thousand at the end of the prior year. This variance is mainly related to the recognition



of Euro 1,826 thousand of tax credit for R&D pursuant to the Ministerial Decree of 27 May 2015 for the year 2019, as well as Euro 700 thousand in VAT receivables.

The Company recognizes as current tax receivables only the amount of VAT credits that may offset other taxes under Italian tax law, as well as VAT credits for which refunds were requested in previous years and which are expected to be collected within the next 12 months (including interests). The remaining VAT credits are recognized as part of non-current tax receivables, in relation to which reference should be made to **Note 4**.

### Note 9 – Other receivables and sundry assets

Other receivables and sundry assets at December 31<sup>st</sup>, 2019 are broken down as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% change
Accrued research and development grants	450	312	138	44.2%
Prepayments relating to costs not pertaining to the period	352	310	42	13.5%
Other receivables	190	-	190	100.0%
<b>Total other receivables and sundry asset</b>	<b>992</b>	<b>622</b>	<b>370</b>	<b>59.5%</b>

Other receivables and sundry assets amounted to Euro 992 thousand at December 31<sup>st</sup>, 2019, thus increasing by Euro 370 thousand (or 59.5%) compared to the amount of Euro 622 thousand recognized at December 31<sup>st</sup>, 2018. They primarily consist of:

- Euro 450 thousand in accrued public sector research and development grants, related to the Eurecart research project. The costs incurred and reported were audited by an independent auditor and presented to the European Community in February 2020. The previous report and the relevant certification had been presented in the second half of 2018. The receivables are fully recoverable, as the Company has already received the government grants for the research project. Pending their set-off against the work carried out, the grants already received are presented separately in the line item Other Liabilities (**Note 21**) in the statement of financial position;
- Euro 352 thousand in prepayments to suppliers:
  - ✓ operating costs incurred for contracts with “advanced billings” and maintenance and assistance fees for information services and other minor amounts (Euro 330 thousand);
  - ✓ insurance premium costs (Euro 22 thousand).
- Accrued income largely associated with an insurance payout.

### Note 10 – Other financial assets

This line item amounted to zero at December 31<sup>st</sup>, 2019. The decrease recorded from December 31<sup>st</sup>, 2018 is attributable to the disposal of the corporate bonds held by the Company in December 2019: at the end of the prior year, these securities were measured at Euro 959 thousand.

### Note 11- Cash and cash equivalents

Cash and cash equivalents are broken down as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% change
Bank and post office accounts	9,901	15,499	(5,598)	(36.1%)
Cash on hand	3	8	(5)	(62.5%)
<b>Total cash and cash equivalents</b>	<b>9,904</b>	<b>15,507</b>	<b>(5,603)</b>	<b>(36.1%)</b>



At December 31<sup>st</sup>, 2019, cash and cash equivalents amounted to Euro 9,904 thousand (Euro 15,507 thousand at December 31<sup>st</sup>, 2018), including Euro 9,901 thousand of bank deposit accounts and Euro 3 thousand of cash on hand.

### Note 12 – Shareholder’s Equity

Shareholders’ equity at December 31<sup>st</sup>, 2019 totaled Euro 23,173 thousand. Its breakdown is as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% change
Share capital	21,819	21,819	-	0.0%
Share premium reserve	61,754	61,754	-	0.0%
<i>Other reserves:</i>				
Actuarial valuation reserve	(6)	(11)	5	(45.5%)
Other	223	223	-	0.0%
Retained earnings (accumulated losses)	(60,190)	(56,067)	(4,123)	7.4%
Profit (loss) for the year	(427)	(4,123)	3,696	(89.6%)
<b>Total shareholders’ equity</b>	<b>23,173</b>	<b>23,595</b>	<b>(422)</b>	<b>(1.8%)</b>

### Share capital

At December 31<sup>st</sup>, 2019, the fully subscribed and paid-in share capital amounted to Euro 21,819 thousand and consisted of 463,450,672 ordinary shares with no par value.

Shareholder	No. of shares	%
Fininvest S.p.A. (*)	107,173,138	23.12
H-Invest S.p.A. (*)	7,071,534	1.53
H-Equity S.r.l. (**)	6,039,692	1.30
Market (***)	343,166,308	74.05
<b>Total</b>	<b>463,450,672</b>	<b>100.00</b>

\* based on the Company’s figures at October 25<sup>th</sup>, 2018

\*\* based on the Company’s figures at April 12<sup>th</sup>, 2018

\*\*\* based on the Company’s figures at December 13<sup>th</sup>, 2019

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



### Share premium reserve

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

### Other reserves

Other reserves are broken down as follows:

#### a) Actuarial valuation reserve

The Actuarial valuation reserve was negative to the tune of Euro 6 thousand at December 31<sup>st</sup>, 2019, with a Euro 5 thousand change compared to the previous year.

#### b) Other reserves

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

- a Euro 45 thousand reserve for unexercised rights relating to the 2014 share capital increase including income arising from the sale of such rights;
- a Euro 178 thousand 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 Euro 60,190 thousand at December 31<sup>st</sup>, 2019. The Euro 4,123 thousand change compared to the period ended December 31<sup>st</sup>, 2018 is attributable to the recognition of the loss for 2018 as accumulated losses, as per the Shareholders' Meeting resolution of April 30<sup>th</sup>, 2019.

### Main equity items

<i>(amounts in Euro thousand)</i>	<b>Balance at December 31<sup>st</sup>, 2019</b>	<b>Purpose of use</b>	<b>Amount available</b>
<b>Reserves</b>			
-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)	(60,190)	-	-

Key:

A: for share capital increase

B: for coverage of losses

C: for distribution to shareholders

### Note 13 – 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 Euro 150 thousand at December 31<sup>st</sup>, 2019 (Euro 143 thousand at December 31<sup>st</sup>, 2018). Changes in the period are as follows:



(amounts in Euro thousand)

	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018
<b>Opening balance</b>	<b>143</b>	<b>147</b>
Uses	-	(6)
Financial loss	2	-
Actuarial (gain)/loss	5	2
<b>Total liabilities for pensions and employee severance indemnity (TFR)</b>	<b>150</b>	<b>143</b>

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.

Pursuant to IAS 19, the Employee severance indemnity was measured using the methods described below, as provided for by the recent relevant provisions introduced by the National Association of Actuaries together with the competent bodies—OIC (Italian Accounting Body), Assirevi, (Italian Association of Auditors), and ABI (Italian Banking Association)—for companies with more than 50 employees.

Under IAS 19, at December 31<sup>st</sup>, 2019, the Iboxx Corporate AA discount rate was used with seven to ten years duration. Specifically, the Company chose an instrument with a term comparable to the duration of the group of employees concerned. The calculation method can be broken down as follows:

- projection for each staff member employed at the measurement date, of the employee severance indemnity accrued at December 31<sup>st</sup>, 2006 and revalued at the measurement date;
- calculation for each staff member of the probability-based payments concerning the employee severance indemnity that must be made should an employee leave the Company due to dismissal, resignation, disability, death and retirement, and also in the case of request of early payments;
- discounting, at the measurement date, of each probability-based payment.

More specifically, the following assumptions were adopted:

- Annual discount rate: 0.37%
- Annual inflation rate: 1.20%
- TFR annual increase rate: 2.40%
- Demographic assumptions
- Mortality rate: RG48 table
- Disability: INPS tables by age and sex
- Retirement age: 100% fulfillment of General Compulsory Insurance (AGO) requirements

Annual turnover and TFR advance payments

- Advance payment frequency, %: 3.00%
- Turnover frequency: 4.00%

Further disclosure required by the Amendments to IAS 19 is shown below:

hypothesis variation						
TFR	turnover frequency		inflation rate		discount rate	
	-1%	1%	+ 1/4 %	- 1/4 %	+ 1/4 %	- 1/4 %
150	150	149	151	147	146	152

Below is the amount of the contribution for the subsequent reporting period and the average financial duration for defined benefit plans:



- Cost service: 0
- Plan duration: 8.1

#### Note 14 – Trade payables (non-current)

Non-current trade payables decreased to zero at December 31<sup>st</sup>, 2019 from Euro 200 thousand at December 31<sup>st</sup>, 2018. In previous years, they consisted of the deferred income relating to GSK's upfront payment arising from the agreement signed on March 19<sup>th</sup>, 2015, taken over by Orchard Therapeutics in 2018, and recognized in the income statement over the term of the relevant agreement. During the year, the payable was reclassified into current liabilities.

#### Note 15 – Financial payables (non-current)

Non-current financial payables of Euro 7,325 thousand were recognized at December 31<sup>st</sup>, 2019, 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 16 – Other liabilities (non-current)

Other non-current liabilities amounted to Euro 2,944 thousand at December 31<sup>st</sup>, 2019. Their breakdown is as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% change
Project pre-financing payments	964	964	-	100%
Other debts	-	333	(333)	(100.0%)
Deferred income relating to the Bresso facility	1,980	2,314	(334)	(14.4%)
<b>Total other liabilities</b>	<b>2,944</b>	<b>3,611</b>	<b>(667)</b>	<b>(18.5%)</b>

The item mainly consists of:

- Deferred income relating to the Bresso facility to the tune of Euro 1,980 thousand. 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 of Euro 4,000 thousand, shall be borne by the property's 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 Euro 333 thousand, representing the depreciation for the next 12 months, as current liabilities.

The Euro 333 thousand decrease in the period is due to the reclassification of the depreciation relating to the January-to-December 2019 period from long to short term.

- Project pre-financing payments to the tune of Euro 964 thousand. The amount is related to the pre-financing payment that MolMed (as project coordinator) received on December 22<sup>nd</sup>, 2016 in relation to the EURE-CART project funded by the European Union, within the Horizon 2020 – Research and





Innovation Framework Programme. The project funding will cover a portion of R&D costs relating to the CAR-T project over a period of 48 months. The item has not changed compared to the end of the previous year.

At December 31<sup>st</sup>, 2019, the item Other payables decreased to zero, since the Euro 333 thousand payable due to the former Chairman, Mr. Bordignon, was reclassified among other current payables, instead of being recognized as non-current liabilities at December 31<sup>st</sup>, 2018. Further details are provided in the **Note 21**.

### Note 17 - Provisions for risks and charges (current)

The provisions for risks and charges amounted to Euro 611 thousand at December 31<sup>st</sup>, 2019, compared to zero at the end of the prior year. They consisted of:

- restructuring risk provision: it is associated with the restructuring of certain business functions formally launched in December 2019 and totals Euro 551 thousand;
- commercial risk provision: it was set aside for a contingent liability associated with the insolvency proceedings of a supplier that directors deemed likely to occur and totals Euro 60 thousand.

Below are the changes occurred during the period:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018
<b>Opening balance</b>	-	-
write-off (used)	-	-
Provison	611	-
<b>Provison for risk and charges (current)</b>	<b>611</b>	-

### Note 18 – Trade payables

Trade payables amounted to Euro 8,230 thousand at December 31<sup>st</sup>, 2019, compared to Euro 9,620 thousand at December 31<sup>st</sup>, 2018, and are broken down as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% change
Trade payables	6,226	7,547	(1,321)	(17.5%)
Deferred income concerning revenues pertaining to future periods	2,004	2,073	(69)	(3.3%)
<b>Total trade payables</b>	<b>8,230</b>	<b>9,620</b>	<b>(1,390)</b>	<b>(14.5%)</b>

At December 31<sup>st</sup>, 2019, payables to suppliers included Euro 5,472 thousand due in Italy, Euro 590 thousand due in other European Union countries and Euro 164 thousand due in other countries (mainly in USD).

Deferred income mainly refers to revenues from gene and cell therapy services to be provided by the Company in 2020. The line item was essentially unchanged compared to the end of the prior year and mainly consisted of:

- deferred income of Euro 200 thousand arising from the agreement signed with GSK and taken over by Orchard Therapeutics in 2018. The agreement and its subsequent amendments provide for the recognition of deferred income relating to the up-front payment recorded in the income statement over the duration of the agreement;



- Euro 1,804 thousand in deferred income 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 profit or loss as revenues when the service will be rendered.

#### Note 19 – Financial payables (current)

Current financial payables of Euro 1,204 thousand at December 31<sup>st</sup>, 2019 consist in the current portion of the payables recognized after the adoption of IFRS 16 “Leases” starting from 2019, as better previously described in paragraph 2 Accounting standards and basis of measurement.

#### Note 20 – Tax payables (current)

Current tax payables amounted to Euro 87 thousand at December 31<sup>st</sup>, 2019 and represented the Company's IRAP liability for the year 2019.

#### Note 21 – Other liabilities

This item is broken down as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018	Change	% change
Amounts due to employees for holidays and bonuses	1,408	1,474	(66)	(4.5%)
Amounts due to social security institutions	676	551	125	22.6%
Tax payables	382	360	22	6.1%
Other payables	755	762	(7)	(0.9%)
Deferred income (Bresso)	421	378	43	11.3%
<b>Total other liabilities</b>	<b>3,642</b>	<b>3,525</b>	<b>117</b>	<b>3.3%</b>

Amounts due to employees for salaries, holiday and bonus pay decreased by Euro 66 thousand, from 1,474 thousand Euro at December 31<sup>st</sup>, 2018 to Euro 1,409 thousand at December 31<sup>st</sup>, 2019.

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 December 2019, paid to the authorities the following month.

Other payables were in line with December 31<sup>st</sup>, 2018 and mainly consisted of:

- Euro 266 thousand in payables for third-party contributions associated with the funds received from the European Community for the EURECART project, which exceeded expectations.
- 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 Euro 800 thousand 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 Euro 367 thousand residual payable net of the installments already paid.

Accrued liabilities and deferred income mainly relate to the current amount of Euro 333 thousand: the depreciation for the next 12 months of an amount equal to Euro 4,000 thousand, 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 Euro 4,000 thousand, 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

### Notes 22 – Revenue from contracts with customers

(amounts Euro thousand)	Year 2019	Year 2018	Change	% change
Revenues from development and manufacturing activities	34,338	24,224	10,114	41.8%
- of wich milestones	1,350	1,016	334	32.9%
Revenues from Zalmoxis <sup>®</sup>	-	4,223	(4,223)	(100.0%)
<b>Total operating revenues</b>	<b>34,338</b>	<b>28,447</b>	<b>5,891</b>	<b>20.7%</b>

Sales revenues amounted to Euro 34,338 thousand at December 31<sup>st</sup>, 2019, based on recognition at a point in time, increasing by Euro 5,891 thousand (or 20.7%) compared to the previous year.

In particular, the expansion of the customer base and the growing volume of services rendered to customers already present in previous years, generated an increase of Euro 10,114 thousand (or 41.8%) in revenues from development and manufacturing activities on behalf of third parties, from Euro 24,224 thousand at December 31<sup>st</sup>, 2018 to Euro 34,338 thousand at December 31<sup>st</sup>, 2019. The change was attributable to Euro 9,977 thousand (98.6%) in revenues arising from the expansion of the business on behalf of existing customers, for which the Company worked on a growing number of projects, and Euro 137 thousand (1.4%) in revenues arising from preliminary activities carried out on behalf of new customers, whose economic benefits will become more apparent in 2020.

This increase was offset by the shortfall in revenues from Zalmoxis<sup>®</sup> following the termination of the licensing and distribution agreement with Dompé Farmaceutici S.p.A., which had contributed for Euro 4,223 thousand in the previous year.

4.4% of sales revenues were generated in Italy (compared to 5.7% in 2018), 83.3% in the European Union (compared to 83.3% in 2018) and 7.9% in non-EU countries (compared to 10.9% in 2018).

### Note 23 – Other income

This item mainly consists of public sector research and development grants and is broken down as follows:

(amount i Euro thousand)	Year 2019	Year 2018	Change	% change
Contribution for founded projects	139	372	(233)	(62.6%)
Tax credit R&D cost	1,665	1,040	625	60.1%
Other revenue	130	21	109	519.0%
<b>Total other income</b>	<b>1,934</b>	<b>1,433</b>	<b>501</b>	<b>35.0%</b>

At December 31<sup>st</sup>, 2019, other income, recognized as part of operating revenues and amounting to Euro 1,934 thousand (compared to Euro 1,433 thousand in 2018), mainly consists of:

- Euro 139 thousand income relating to research and development grants the Company received based on its participation in public-sector subsidized projects (EureCART project);



- Euro 1,826 thousand in income deriving from the tax credit pursuant to the “May 27<sup>th</sup>, 2015 Decree enacting the research and development tax credit”, including Euro 160 thousand related to adjustment to the tax credit for the prior year recognized based on the clarifications provided by the Italian Revenue Agency with Circular no. 8 of April 10<sup>th</sup>, 2019;
- Euro 130 thousand in other revenues, including mainly Euro 119 thousand recognized insurance payout.

#### Note 24 – Purchases of raw materials and consumables

This item is broken down as follows:

<i>(amounts in Euro thousand)</i>	Year 2019	Year 2018	Change	% change
Processing materials	1,988	2,011	(23)	(1.2%)
Reagents	3,815	3,011	804	26.7%
General laboratory materials	1,162	665	497	74.7%
<b>Total purchases of raw materials and consumables</b>	<b>6,965</b>	<b>5,687</b>	<b>1,278</b>	<b>22.5%</b>

Costs for raw materials and consumables, which largely consist of materials and reagents used in manufacturing and development activities, rose from Euro 5,687 thousand at December 31<sup>st</sup>, 2018 to Euro 6,965 thousand at December 31<sup>st</sup>, 2019. The Euro 1,278 thousand increase (+22.5%) is mainly due to growing services and manufacturing activities on behalf of third parties and to the increase in the development of products in the pipeline.



### Note 25 – Costs for services

This item is broken down as follows (figures at December 31<sup>st</sup>, 2019 and December 31<sup>st</sup>, 2018):

<i>(amounts in Euro thousand)</i>	Year 2019	Year 2018	Change	% change
Outsourced development costs	3,490	3,956	(466)	(11.8%)
Consultancy and technical fees	842	692	150	21.6%
License and patents consultancy fees	351	490	(139)	(28.3%)
Maintenance	1,289	1,308	(19)	(1.5%)
Transport and storage of laboratory materials	506	535	(30)	(5.5%)
Utilities	1,145	1,139	6	0.6%
Directors and statutory auditors' fees	420	391	28	7.3%
Audit	78	77	1	1.3%
Legal, administrative and managerial fees	835	669	166	24.8%
Listing consultancy fees and other listing costs	68	149	(81)	(54.2%)
Supervisory board fees	165	96	69	71.4%
Communications agency fees	174	261	(87)	(33.3%)
IT assistance and other IT costs	503	435	68	15.6%
Other general and administrative costs	1,090	995	96	9.6%
Travel, staff training and other personnel costs	773	704	69	9.8%
<b>Total costs for services</b>	<b>11,729</b>	<b>11,897</b>	<b>(168)</b>	<b>(1.4%)</b>

Costs for services declined from Euro 11,897 thousand at December 31<sup>st</sup>, 2018 to Euro 11,729 thousand at December 31<sup>st</sup>, 2019. The Euro 168 thousand decrease was mainly associated with the following:

- outsourced development costs decreased by Euro 466 thousand or 11.8%, from Euro 3,956 thousand in 2018 to Euro 3,490 thousand in 2019. The decline was largely attributable to the lower spending on pre-clinical research for the development of the proprietary pipeline;
- consultancy and technical fees increased by Euro 150 thousand or 21.6%, from Euro 692 thousand in 2018 to Euro 842 thousand in 2019 as a result of the increase in clinical and regulatory consultancy services associated with the multicentric phase I/II clinical trial in patients with acute myeloid leukemia (AML) and multiple myeloma (MM);
- license fees decreased by Euro 139 thousand or 28.3%, from Euro 490 thousand in 2018 to Euro 351 thousand in 2019. In line with recent strategic corporate changes, the Company decided not to invest any further to maintain patents on NGR-TNF and the relevant vascular targeting area;
- legal and administrative consultancy and services increased by Euro 166 thousand or 24.8%, from Euro 669 thousand in 2018 to Euro 835 thousand in 2019, largely for one-off consultancy services associated with the participation in the project funded by the Italian Ministry of Economic Development to support spending on research into chimeric antigen receptors;
- other general and administrative costs increased by Euro 96 thousand or 9.6%, from Euro 995 thousand in 2018 to Euro 1,090 thousand in 2019, largely due to increased cleaning costs as facilities were used more often.

### Note 26 – Costs for use of third-party assets

Costs for use of third-party assets decreased from Euro 1,507 thousand at December 31<sup>st</sup>, 2018 to Euro 87 thousand at December 31<sup>st</sup>, 2019. The Euro 1,420 thousand decrease was mainly due to the adoption of IFRS 16 as of January 1<sup>st</sup>, 2019, which generated the reclassification of lease costs for Euro 1,355 thousand and



the recognition of depreciation and financial charges for Euro 1,262 thousand. The remaining amount recognized at December 31<sup>st</sup>, 2019 was related to leases with a term of less than a year and “low-value assets”.

### Note 27 – Personnel costs

These costs are broken down as follows:

<i>(amounts in Euro thousand)</i>	Year 2019	Year 2018	Change	% change
Wages and salaries	10,058	10,199	(141)	(1.4%)
Social security contributions	2,807	2,446	361	14.8%
Defined contribution plans	564	227	337	148.5%
Stock option costs	551	-	551	100.0%
Other personnel costs	32	30	2	6.7%
<b>Total personnel costs</b>	<b>14,012</b>	<b>12,902</b>	<b>1,110</b>	<b>8.6%</b>

Personnel costs increased by Euro 1,110 thousand compared to the previous year (8.6%), from Euro 12,902 thousand in 2018 to Euro 14,012 thousand in 2019.

In 2018, personnel costs included Euro 800 thousand in one-off compensation awarded to the former Chair of the Board of Directors after his resignation in September 2018.

The increase in personnel costs was mainly attributable to the rising average number of employees, up from 199 in 2018 to 215 in 2019, and the Euro 551 thousand provision set aside for the restructuring of the organizational structure launched in December 2019.

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

At December 31<sup>st</sup>, 2019, the actual number of employees was 213 (compared to 206 in 2018), while in 2019 the average number of employees was 215 (199 in the first half of 2018). The breakdown by position is as follows:

	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018
Executives	8	9
Middle management	33	33
Clerical staff	169	160
Technicians	3	4
<b>Total</b>	<b>213</b>	<b>206</b>

### Note 28 – Other operating costs

The item “Other operating costs” of Euro 182 thousand at December 31<sup>st</sup>, 2019 is broken down below and compared with figures at December 31<sup>st</sup>, 2018.



(amounts in Euro thousand)	Year 2019	Year 2018	Change	% change
Printed and promotional materials	2	2	-	-
Stationery	18	13	5	38.5%
Entertainment costs	38	18	20	111.1%
Membership fees	57	50	7	14.0%
Books and magazines	16	8	8	100.0%
Other costs	51	14	37	264.3%
<b>Total other operating costs</b>	<b>182</b>	<b>105</b>	<b>77</b>	<b>73.3%</b>

### Note 29 – Amortization, depreciation and impairment

This item amounted to Euro 3,533 thousand in 2019, increasing by Euro 1,886 (+114.5%) thousand compared to the previous year (Euro 1,647 thousand). Such change is mainly due to:

- the recognition of depreciation on leased assets to the tune of Euro 1,262 thousand, after the adoption of the new IFRS 16 “Leases” starting from January 1<sup>st</sup>, 2019;
- the impairment of receivables associated with Zalmoxis®, since the Company believes that the withdrawal of the Conditional Marketing Authorization with the European Medicines Agency raised doubts as to whether they can be recovered;
- the impairment of patents and trademarks relating to NGR-TN and the Supplementary Protection Certificate of Euro 92 thousand after the Conditional Marketing Authorization was withdrawn.

This item was recognized net of the relevant depreciation on leasehold improvements at the facility in Bresso totaling Euro 333 thousand and charged to the site’s lessor. This was neutralized in profit or loss following the pro rata reversal of the relevant deferred income. For further details, reference should be made to **Note 16**.

(amounts in Euro thousand)	Year 2019	Year 2018	Change	% change
Amortization of tangible assets	158	153	5	3.3%
Amortization of intangible assets	3,166	1,750	1,416	80.9%
Pro-quota amortization Bresso	(333)	(333)	-	0.0%
Write-downs	542	77	465	603.9%
<b>Totale ammortamenti e svalutazioni</b>	<b>3,533</b>	<b>1,647</b>	<b>1,886</b>	<b>114.5%</b>



### Note 30 – Financial income and charges

This item is broken down as follows:

<i>(amounts in Euro thousand)</i>	Year 2019	Year 2018	Change	% change
<b>FINANCIAL INCOME:</b>				
Interest and other financial income	75	32	43	134.4%
Exchange gains	2	16	(14)	(87.5%)
<b>Total financial income</b>	<b>77</b>	<b>48</b>	<b>29</b>	<b>60.4%</b>
<b>FINANCIAL CHARGES:</b>				
Exchange losses	(9)	(14)	5	(35.5%)
Financial charges IFRS16 "Leases"	(132)	-	(132)	(100.0%)
Other charges	(41)	(292)	251	(86.0%)
<b>Total financial charges</b>	<b>(182)</b>	<b>(306)</b>	<b>124</b>	<b>(40.5%)</b>
<b>Total financial income (charges)</b>	<b>(105)</b>	<b>(258)</b>	<b>153</b>	<b>(59.3%)</b>

The Company's financial activities generated a negative result of Euro 105 thousand at December 31<sup>st</sup>, 2019, improving by Euro 153 thousand on the prior year. This change is mainly attributable to the decrease in financial charges. In the previous year, they included the fees paid in May 2018 following subscription for shares as provided for by the SEF agreement entered into with Société Générale (fifth and last installment of Euro 155 thousand).

### Note 31 – Income taxes

At the reporting date, the Company recognized Euro 83 thousand in provisions for the Italian regional tax on productive activities (IRAP) and reported no taxable income for the purposes of the Italian corporate income tax (IRES).

The Company did not recognize any tax credit that could arise from calculation of deferred taxes on temporary differences deductible in future years. At December 31<sup>st</sup>, 2019 the tax losses to be carried forward totaled Euro 211,022 thousand and the theoretical deferred tax assets totaled Euro 50,645 thousand. Pursuant to reference accounting standards, the Company will recognize deferred tax assets only if it is likely that such amounts will be recovered through future taxable income.

The following table provides a summary of the temporary differences at December 31<sup>st</sup>, 2019 and 2018:

<i>(amounts in Euro thousand)</i>	31.12.2019			31.12.2018		
	Temporary differences amount	Rate	Tax effect	Temporary differences amount	Rate	Tax effect
Maintenance in exceeds	1,327	24.00%	319	1,004	24.00%	241
Other temporary differences	801	24.00%	192	131	24.00%	31
Bad Debt provision	279	24.00%	67	29	24.00%	7
Start up losses	1,552	24.00%	372	1,552	24.00%	372
Tax losses carried forward	207,063	24.00%	49,695	205,999	24.00%	49,440
<b>Total deferred tax assets</b>	<b>211,022</b>		<b>50,645</b>	<b>208,715</b>		<b>50,092</b>
Other temporary differences	-	24.00%	-	-	24.00%	-
<b>Total deferred tax liabilities</b>	<b>-</b>		<b>-</b>	<b>-</b>		<b>-</b>





### Note 32 – Basic and diluted earnings (loss) per share

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

<i>(amounts in Euro)</i>	2019	2018
Basic earnings (loss) per share	(0.0009)	(0.0089)

As required under IAS 33, diluted earnings (loss) per share take into account the effects of all dilutive potential ordinary shares.

The calculation of the basic earnings (loss) per share is based on the net loss in 2019 and 2018, of respectively Euro 427 thousand and Euro 4,123 thousand, and on the weighted average of the ordinary shares outstanding in the two periods equal to no. 463,450,672.

## 3. Other notes

### Note 33 – Net financial position

The net financial position, based on the format provided for by Consob Communication 6064293 of July 28<sup>th</sup>, 2006, is provided below. The effects arising from the adoption of IFRS 16 “Leases” are shown separately.

<i>(amounts Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018
Cash on hand	3	8
Other cash	9,901	15,499
Cash equivalents	-	-
<b>A. Total cash and cash equivalents</b>	<b>9,904</b>	<b>15,507</b>
<b>B. Current financial receivables and other financial assets</b>	<b>-</b>	<b>959</b>
Liabilities to financial leasing entities (IFRS16)	(1,204)	-
<b>C. Current financial debt</b>	<b>(1,204)</b>	<b>-</b>
<b>D. Net current financial position (A+B+C)</b>	<b>8,700</b>	<b>16,466</b>
Liabilities to financial leasing entities (IFRS16)	(7,325)	-
<b>E. Non-current financial debt</b>	<b>(7,325)</b>	<b>-</b>
<b>F. Net financial position (D+E)</b>	<b>1,375</b>	<b>16,466</b>
G. IFRS16 effects - current	1,204	-
H. IFRS16 effects - non current	7,325	-
<b>I. I. Net financial position - NO IFRS 16 effects</b>	<b>9,904</b>	<b>16,466</b>

At December 31<sup>st</sup>, 2019, the net financial position was down Euro 15,091 thousand (or -91.6%%) from Euro 16,466 thousand at December 31<sup>st</sup>, 2018 to Euro 1,375 thousand. The decrease was attributable to the cash flows used in operating activities as well as to the impact of applying the new accounting standard IFRS 16 “Leases”, which required including finance lease payables totaling Euro 8,529 thousand in current and non-current financial payables. Net of the effects arising from the adoption of the above-mentioned standard, the net financial position would have amounted to Euro 9,904 thousand at December 31<sup>st</sup>, 2019, compared to Euro 16,466 thousand at December 31<sup>st</sup>, 2018.



### Note 34 – Contingent liabilities, commitments, and guarantees

#### Contingent liabilities

With respect to CAR-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. Under the co-development agreement for the CAR pipeline, upon meeting certain goals related to purchases and IP licenses on the targets, the Company shall pay a milestone payment of up to approximately Euro 580 thousand.

Finally, under the agreement for the development of the project CAR-CD44v6 with NK cells, the Company shall pay a milestone payment of up to Euro 11,700 thousand upon the occurrence of particular events such as the beginning and end of the clinical trial, the obtaining of the first approval for the product, and the extension of said approval. In addition, it shall pay royalties of 5% of sales in the countries covered by the patent and 2.5% in those not covered by patents.

Finally, on April 30, 2019, the Board of Directors decided to recognize to the CEO, for the sole case of termination of office due to the hypothesis of good leaver, equal compensation the fixed emolument, equal to Euro 450 thousand per year, for the residual term of office, or until the approval of the financial statements as of December 31, 2021. The following events are good leaver hypotheses: (i) revocation from the office of director without recourse to a subjective just cause; (ii) resignation from the office of director if, without a subjective just cause, the CEO suffers one substantial revocation of the proxies such that its relationship with the Company is substantially altered.

The above conditions had not been met at the reporting date.

### Note 35 – Commitments and guarantees

Commitments and guarantees are broken down as follows:

<i>(amounts in Euro thousand)</i>	December 31 <sup>st</sup> , 2019	December 31 <sup>st</sup> , 2018
Guarantees	365	439
<b>Total guarantees and commitments</b>	<b>365</b>	<b>439</b>

Guarantees mainly include bank guarantees issued for the payment of real estate leases.

### Note 36 – Transactions with related parties

At December 31<sup>st</sup>, 2019, no transaction with related parties were recorded.

### Note 37 – Share-based payments

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

### Note 38 – Significant non-recurring events and transactions

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

### Note 39 – Transactions resulting from atypical and/or unusual events

Pursuant to Consob Communication of July 28<sup>th</sup>, 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 40 – Fees due to Directors and Statutory Auditors

Pursuant to Article 78 of Consob Regulation 11971/1999 on the provisions governing issuers 1, the following disclosure is provided in relation to the fees paid to the Directors and Statutory Auditors:

Name Surname	Position held	Term of office	Term of office expiry date	Defined Fee	Defined Fee Board of Directors	Fee for presence Board of Directors	Fee for presence Committee	Variable fee		Non monetary fee	Other fee	Total	Fair value Equity fee	Allowance charge end or termination employment relationship
								Bonus and other incentives	Particip. in profit					
<b>DIRECTORS - Board of Directors in charge from April 30, 2019</b>														
Claudio Bordignon	President	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	317	-	-	-	90	-	2	-	409	-	-
Riccardo Palmisano	CEO	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	450	-	-	-	90	-	15	-	555	-	-
Alberto Carletti	Director	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	12	10	-	-	-	-	-	-	22	-	-
Laura Iris Ferro	Director	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	12	10	5	7	-	-	-	-	34	-	-
Sabina Grossi	Director	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	12	10	18	14	-	-	-	-	54	-	-
Mario Masciocchi	Director	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	12	10	24	7	-	-	-	-	53	-	-
Alfredo Messina	Director	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	12	10	-	-	-	-	-	-	22	-	-
Elisabeth Robinson	Director	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	12	9	15	7	-	-	-	-	43	-	-
Raffaella Ruggiero	Director	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	12	10	8	7	-	-	-	-	37	-	-
Didier Trono	Director	01.01.2018-30.04.2019	on approval of 2018 Fin.Statement	4	2	2	1	-	-	-	-	9	-	-
				<b>855</b>	<b>71</b>	<b>72</b>	<b>43</b>	<b>180</b>	<b>-</b>	<b>17</b>	<b>-</b>	<b>1,238</b>	<b>-</b>	<b>-</b>
<b>STATUTORY AUDITORS - Statutory Auditors in charge from April 30, 2019</b>														
Riccardo Perotta	President	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	52	-	-	-	-	-	-	-	-	-	-
Enrico Scio	Statutory Auditor	01.01.2018-30.04.2019	on approval of 2018 Fin.Statement	8	-	-	-	-	-	-	-	-	-	-
Flavio Deamia Minutillo	Statutory Auditor	01.01.2019-31.12.2019	on approval of 2021 Fin.Statement	35	-	-	-	-	-	-	-	-	-	-
Michele Milano	Statutory Auditor	30.04.2019-31.12.2019	on approval of 2021 Fin.Statement	27	-	-	-	-	-	-	-	-	-	-
				<b>122</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>OTHER MANAGERS WITH STRATEGIC RESPONSIBILITIES</b>														

On April 30<sup>th</sup>, 2019, the Board of Directors decided to award the CEO an amount equal to his fixed remuneration, totaling Euro 450 thousand 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.

In addition to the above-mention agreement, no further agreements have been signed by other Directors, and no compensation was paid to Directors resigning from their office in the period.

### Note 41 – Disclosure pursuant to Article 149-duodecies of the Consob Issuers’ Regulations

The table below has been prepared in accordance with Article 149-duodecies of the Consob Issuers’ Regulations. It shows the fees for 2019 and 2018 for the audit services and for other non-audit services provided by External Auditors. No additional services were provided by other entities belonging to the External Auditors’ network.

	Entity that provided the service	Fees for 2019	Fees for 2018
Audit	EY S.p.A.	78 (1)	77 (1)
Certification services	EY S.p.A.	16	-
<b>Total</b>		<b>94</b>	<b>77</b>

(1) Audit of Statutory Financial Statements and limited review of the half-year report and verification that accounting records are properly maintained and reflect accurately operating events

(2) R&D Tax Credit Certification pursuant to the "Decree of 27 May 2015 implementation of the tax credit for research and development"



### Note 42 – 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 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

Since December 2019, the Company has had access to a line of credit up to Euro 15,000 thousand from the European Investment Bank (“EIB”). However, it still has not drawn down any funds, and therefore reported no financial payables due to the EIB at December 31<sup>st</sup>, 2019. Available cash was invested in current account deposits. 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.

The extent of exposure to interest rate risk is measured through a sensitivity analysis, as provided for by IFRS 7. This analysis shows the effects of a given and assumed change in the levels of relevant variables on financial income and charges arising from financial activities and, at times, directly on equity. The sensitivity analysis was carried out on the basis of the following assumptions:

- the analysis was performed by applying reasonably possible changes in the relevant risk variables to the figures of the Financial Statements at December 31<sup>st</sup>, 2019 and 2018, assuming that these figures are representative of the entire year;
- changes in the value of financial assets generated by changes in the benchmark interest rates have an effect on income only when they are recognized at their fair value in compliance with IFRS 9;
- changes in the value of floating rate financial assets generated by changes in the benchmark interest rates have an impact on financial income for the year.

In order to determine the effects of interest rate changes on the income statement and on the statement of comprehensive income, below are the results of a sensitivity analysis, in line with the requirements of IFRS 7, applying parallel, negative and positive shifts to the zero-coupon curves of market rates. The shifts in the zero-coupon curves are equal to +/- 100 basis points.

(amounts in Euro thousand)	FY 2019		FY 2018	
	effect on financial income		effect on the fair value reserve	
Shift compared to zero-coupon	+1%	-1%	+1%	-1%
Effect	99	(99)	-	-



## 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 and concentration risk

Credit risk represents the Company's exposure to potential losses resulting from the counterparty's failure to perform on 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 concentration risk, currently two single-name counterparties account for nearly 79% of 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.

## Classes of financial instruments

In order to provide full disclosure as required by IFRS 7, the following table shows a break-down of the types of financial instruments recorded in the Financial Statements, with an indication of the measurement bases and, in the case of financial instruments at fair value, of the relevant recognition (profit or loss or equity). When applicable, the last two columns of the table list the fair value of the financial instrument at December 31<sup>st</sup>, 2019, and the amount recognized in the relevant reserve.

Class of financial instruments	Measurement criteria for financial instruments in the Statutory Financial Statements					of which fair value reserve
	Financial instruments at fair value through		Financial instruments at amortized cost	Book value at December 31, 2018	Fair value at December 31, 2018	
	profit or loss	equity				
	(1)	(2)	(3)			
<b>Assets</b>						
Cash and cash equivalents	-	-	9,904	9,904	9,904	-
Financial assets	-	-	-	-	-	-
Trade receivables	-	-	9,911	9,911	9,911	-
<b>Liabilities</b>						
Trade payables	-	-	8,230	8,230	8,230	-
Finance lease payables	-	-	-	-	-	-

(1) Financial assets and liabilities measured at fair value with changes recognized in profit or loss

(2) Financial assets available for sale measured at fair value with gain or loss recognized in equity

(3) Loans & receivables and financial liabilities measured at amortized cost

For further details on cash and cash equivalents, and other financial assets, reference should be made to **Notes 10** and **11**.

## Fair value hierarchy

In relation to the financial instruments recognized at fair value in the statement of financial position, IFRS 7



requires such values to be classified on the basis of a hierarchy of levels which reflects the inputs used in determining the fair value. Levels are broken down as follows:

- Level 1 – quoted prices in active markets for assets or liabilities to be measured;
- Level 2 – inputs other than quoted prices included within Level 1 that are observable either directly (i.e., as prices) or indirectly (i.e., derived from prices);
- Level 3 – inputs that are not based on observable market data.

Financial assets measured at fair value at December 31<sup>st</sup>, 2018 were classified under Level 1.

### **Liquidity risk**

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

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.

Considering the above, and based on the Euro 9,904 thousand in cash and cash equivalents at December 31<sup>st</sup>, 2019, the year-on-year improvement in the result for the period, and the future cash flows estimated in the next three-year plan as well as the on the Euro 15,000 thousand 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, which, combined with the cash flows expected from development and manufacturing services on behalf of third parties, guarantee that it will continue as a going concern for a foreseeable period of at least 12 months following the reporting date. 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 reporting date.

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



*Note 43 – Government grants - Disclosures as per Article 1, paragraphs 125-129 of Italian Law no. 124/2017*

With respect to the transparency and disclosure requirements for government grants, governed by Article 1, paragraphs 125-129 of Italian Law no. 124/2017 as supplemented by the ‘security’ decree-law (no. 113/2018) and the ‘simplification’ decree-law (no. 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 no. 124/2017.

*Note 44 – Significant events after the reporting period*

For further information on significant events after the reporting period, reference should be made to paragraph *3. Significant events after the reporting period*.



### *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.





## *Certification of the Financial Statements pursuant to Article 81-ter of Consob Regulation no. 11971 of May 14<sup>th</sup>, 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 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 Financial Statements for the year ended December 31<sup>st</sup>, 2019;
- measurement of the adequacy of the administrative and accounting procedures used for the preparation of the Financial Statements for the year ended December 31<sup>st</sup>, 2019 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 Financial Statements for the year ended December 31<sup>st</sup>, 2019:
  - 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.
  - d) the Management Report includes a reliable analysis of the Company's performance and results of operations, as well as a description of its situation and the main risks and uncertainties to which it is exposed.

Milan, March 16<sup>th</sup>, 2020

[Signed by]  
Riccardo Palmisano  
CEO

[Signed by]  
Salvatore Calabrese  
Executive Officer responsible for preparing  
company financial reports

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



ANNUAL FINANCIAL REPORT AT  
DECEMBER 31<sup>ST</sup>, 2019

## *Statutory Auditors' Report*

## *Report of the Board of Statutory Auditors to the Shareholders' Meeting of MolMed S.p.A. pursuant to art. 153 of Legislative Decree no. 58/1998 and art. 2429. C.2 of the Italian Civil Code.*

Dear Shareholders,

this Report illustrates the activities carried out by the Board of Statutory Auditors during the year 2019 and up to the current date, in accordance with the requirements of Consob Communication DEM/1025564 dated April 6, 2001, as subsequently amended.

During the year ended December 31, 2019, the Board of Statutory Auditors of MolMed S.p.A. (hereinafter also the "Company") performed the supervisory activities provided for under the law, also in consideration of the principles of conduct recommended by the Italian Councils of Certified Public Accountants and Bookkeepers and the Consob's communications on company audits and activities of the Board of Statutory Auditors.

1. During 2019, the Board of Statutory Auditors acquired the necessary information to perform its general supervisory duties, by attending the meetings of the Board of Directors and the board committees meetings (i.e. the Control and Risk Management Committee, the Related Parties Committee and the Remuneration and Nomination Committee), meetings with the top management, hearings of the Company's management, meetings with the External Auditors, meetings with the Internal Auditors, meetings with the Supervisory Board appointed pursuant to Legislative Decree no. 231/2001, as well as through the analysis of the information flows obtained from the relevant corporate functions, and through the specific audit activities carried out during its own meetings or during those held jointly with the Control and Risk Management Committee.

In relation to transactions with related parties, the Company has adopted a procedure that establish approval and execution requirements. At December 31<sup>st</sup> 2019, no transactions with related parties were recorded.

The Board of Statutory Auditors obtained information from the Directors on the activities undertaken and the most significant transactions carried out at least on a quarterly basis.

Based on the Company bodies' disclosure and as a result of the Board of Statutory Auditors' analyses carried out during its supervisory activities, it was found that the Company's most significant income, financial and equity transactions, aimed at implementing its business plan – specifically as for the

development of its product portfolio and the gene and cell therapy activities performed on behalf of third parties –, are adequately described in the Directors' Report and in the Notes to the Financial Statements.

In particular, with reference to obtaining the financial resources necessary to support the Company's development plan, the Board of Statutory Auditors' point out that on December 18<sup>th</sup> 2019, the Company signed a financing agreement with the European Investment Bank (BEI") for a credit line of up to Euro 15 million over the coming years. The line of credit is subordinated to achieving a set of agreed performance criteria, in support of the Company's development plan for sustainable growth. As of December 31<sup>st</sup>, the Company has not yet benefited from the financing and therefore no financial payables to the BEI have been recognized in the financial statements.

The Board of Statutory Auditors confirmed that the above-mentioned transaction comply with the law, the company by-laws and the principles of good management, having ascertained that it was not manifestly imprudent or risky, with a potential conflict of interest, that it did not conflict with the resolutions of the Shareholders' Meeting or negatively affect the Company's assets.

2. The Board of Statutory Auditors did not find any atypical and/or unusual corporate transactions carried out with third parties or related parties during the year 2019 or after the reporting period. The Board of Statutory Auditors point out that the Company does not hold own shares.
3. On 27<sup>th</sup> 2020, the External Auditors EY S.p.A. have issued their report pursuant to Articles 14 and 16 of Legislative Decree no. 39/2010, in which they certify that the Financial Statements at December 31, 2019 comply with the policies used for their preparation, it has been prepared clearly and provide a true and fair view of the Company's financial position, results of operations and cash flows. According to the External Auditors, the Directors' Report and disclosure pursuant to Article 123-bis, paragraph 4 of the Consolidated Law on Finance (Testo Unico sulla Finanza, TUF), included in the Report on corporate governance and ownership structure, are consistent with MolMed S.p.A's Financial Statements at December 31, 2019. Finally, the External Auditors, in their additional report to the Internal Control Committee and Audit pursuant art. 11 of EU Regulation 537/2014, have identified as key aspects of the audit:
  - a) the presumption of the business as a going concern;
  - b) the recognition of the revenues arising from license and distribution agreements.
4. Pursuant to the provisions of Article 19 of Italian Legislative Decree no. 39 of January 27, 2010, the Board of Statutory Auditors monitored the independence of the external auditors. The fee to EY S.p.A for the

audit in 2019 is Euro 78 thousand. During 2019, MolMed S.p.A. assigned to EY the assignment for the certification of the R&D Tax Credit, pursuant to the Decree of 27 May 2015 "Implementation of the tax credit for Research and Development" for a fee of Euro 16 thousand, and did not confer any assignments to subjects linked to EY by ongoing relationships and/or companies belonging to the EY network. Taking account of the annual statement confirming their independence issued by EY pursuant to art. 17, of Legislative Decree no. 39 of January 27, 2010, modified by Legislative Decree no. 135 of July 17, 2016, and the nature of the engagements conferred on EY and the companies in its network, no evidence or situations emerged such as to lead to the belief that there are risks for the independence of the company engaged for the audit.

During the 2019 financial year, the Board of Statutory Auditors did not receive any reports pursuant to art. 2408 Civil Code, or third party claims. During the year, the Board of Statutory Auditors issued its favorable opinion on the following:

- the resolution adopted by the Board of Directors regarding the appointment of the Manager in charge of preparing the corporate accounting documents pursuant to art. 154 bis, c. 1, of Legislative Decree 58/1998;
- to the compensation attributed to directors with special duties as set forth in art. 2389. c.3;
- the annual audit plan;
- the appointment of the Controlling Body in accordance pursuant to Legislative Decree no. 231/2001, as required by internal regulation.

5. During the year 2019, the Company's Board of Directors held 10 meetings, which were all attended by the Board of Statutory Auditors. The Control and Risk Management Committee met 7 times. The Remuneration and Nomination Committee met 9 times. The Board of Statutory Auditors participated in all the meetings of both committees with at least one member present. The Board of Statutory Auditors held 11 meetings. The Board of Statutory Auditors also took part in the Shareholders' Meeting held on April 30, 2019.

6. The Board of Statutory Auditors obtained information on and monitored compliance with the principles of good management, within the scope of its responsibilities, by attending all the meetings of the Board of Directors, through interviews, direct observations and collection of information during meeting with members of the top management, internal audit and Supervisory Body. With regard to the decision-making

processes of the Board of Directors, the Board of Statutory Auditors verified, also through direct participation in board meetings, that the Directors' decisions complied with the law and the company by-laws, as well as that the resulting resolutions were adequately supported by reliable information, analysis and assessment processes and, if required supported by outside professionals.

The Board of Statutory Auditors carefully monitored the Company's equity and financial position, and encouraged the Board of Directors to consider the most appropriate measure to strengthen it. Finally, it took note of the actions undertaken and completed in this regard as a part of the Company's business plan.

The Board of Statutory Auditors obtained information on, and monitored the adequacy of the Company's organizational structure by collecting relevant information from the management staff responsible for it.

During 2019, the Board of Statutory Auditors took note of the overall assessment of the internal control system by the Internal Audit Manager, who found the internal control system to be adequate and functional in reducing the risk profiles to an acceptable level for the proper operation of business processes. The Board of Statutory Auditors monitored the internal control and risk management system adopted by the Company, by assessing its adequacy through meetings with the Internal Audit Manager, the Executive Officer responsible for preparing company financial reports, the Management and the External Auditors. The Board of Statutory Auditors acknowledge that the Control and Risk Management Committee gave its favorable opinion on the adequacy on the internal control and risk management system.

7. The Board of Statutory Auditors also acquired due information on organizational and procedural activities which were undertaken pursuant to Legislative Decree no. 231/2001. From the information provided by the Supervisory Board, also through its annual Report on the work undertaken, no facts and/or circumstances emerged which are worthy of note.
8. The Board of Statutory Auditors assessed and monitored the adequacy of the administrative/accounting system, as well as its reliability in terms of providing a true and fair view of operating results, by obtaining information from the managers of the relevant corporate departments, examining the Company's documentation and analyzing the results of the activities carried out by the External Auditors EY SpA. The Board of Statutory Auditors acknowledged the statements issued by the Chief Executive Officer together with the Executive Officer responsible for preparing company financial reports regarding the adequacy – in relation to the Company's characteristics – and the actual application of the administrative and accounting

procedures during the preparation of 2019 Financial Statements. Finally, the Board of Statutory Auditors monitored the financial disclosure process, by verifying, also through the information collected from the Company's management, the adequacy and effectiveness of the procedure whereby information is produced and shared with the public.

9. The Board of Statutory Auditors ascertained, through direct assessments and based on information received from the External Auditors EY SpA and the Management, that the Financial Statements and the Directors' Report were drafted in compliance with IAS/IFRS (as well as with relevant rules and regulations). In particular, Directors detailed in the Directors' Report different risks to which the Company is exposed, including those interrupting the activity due to the health emergency related to the spread of the Covid coronavirus 19, as well as the financial ones, indicating in the Notes to the Financial Statements the actions taken to cover the financial needs and to manage the aforementioned emergency.

10. The Board of Statutory Auditors monitored the actual implementation procedures of the corporate governance rules provided for by the Corporate Governance Code prepared by Borsa Italiana's Corporate Governance Committee, which the Company adheres to.

MolMed SpA adopted the criteria established by Borsa Italiana's Corporate Governance Code regarding the independence of Directors. The Board of Directors, based on the information provided by the Directors themselves, verified the existence of the independence requirements of the four non-executive Directors, qualifying as independent.

The Board of Statutory Auditors verified the existence of the independence requirements for its members, pursuant to Article 148, paragraph 3, of the Consolidated Law on Finance, and of those provided for by Borsa Italiana's Corporate Governance Code, as described in the Report on corporate governance.

11. The Board of Statutory Auditors supervised the overall review of the market abuse legislation adopted by the Company as well as the fulfillment of the obligations related to market abuse and internal dealing regulations.

12. The supervisory and control activities carried out by the Board of Statutory Auditors, as described earlier, did not result in further findings to be pointed out in the Report to the Shareholders' Meeting or to be reported to the supervisory and control bodies, nor worthy of mention in this report on the Financial Statements at December 31, 2019.

*The Report of the Board of Statutory Auditors have been translated from those issued in Italy, from the Italian into English language solely for the convenience of international readers.*

13. Given the above, on the basis of the supervisory work undertaken during the year, the Board of Statutory Auditors does not find any grounds to reject approval of the Financial Statements at December 31, 2019 and has no objections to raise regarding the resolution proposals submitted by the Board of Directors about carrying forward the loss for 2019.

14. With regard to the prescription of Law 124/2017 regarding information to be disclosed in the financial statements in relation to any subsidies, contributions, paid offices and in any case economic advantages of any kind received from public administrations, the Board of Statutory Auditors acknowledges that the Company, after having having analyzed his own situation, he judged that he did not fall into any case involving the disclosure of information pursuant to art. 1, c. 125-129, Law 124/2017, as reported in the explanatory notes.

Milan, April 3, 2020

**On behalf the Board of Statutory Auditors**

Riccardo Perotta (Chairman) [Signature]



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



ANNUAL FINANCIAL REPORT AT  
DECEMBER 31<sup>ST</sup>, 2019

## *Independent Auditors' Report*



# **MolMed S.p.A.**

**Financial statements as at December 31, 2019**

**Independent auditor's report pursuant to article 14 of  
Legislative Decree n. 39, dated 27 January 2010, and article  
10 of EU Regulation n. 537/2014**

## Independent auditor's report pursuant to article 14 of Legislative Decree n. 39, dated 27 January 2010 and article 10 of EU Regulation n. 537/2014

(Translation from the original Italian text)

To the Shareholders of  
MolMed S.p.A.

### Report on the Audit of the [Consolidated] Financial Statements

#### Opinion

We have audited the financial statements of MolMed S.p.A. (the Company), which comprise the statement of financial position as at 31 December 2019, and the income statement, the statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the financial statements give a true and fair view of the financial position of the Company as at 31 December 2019, and of its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union and with the regulations issued for implementing art. 9 of Legislative Decree n. 38/2005.

#### Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing (ISA Italia). Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Statements* section of our report. We are independent of the Company in accordance with the regulations and standards on ethics and independence applicable to audits of financial statements under Italian Laws. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

We identified the following key audit matters:

Going concern	Audit Response
<p>The Company's business model foresees mainly the development and manufacturing on behalf of third parties and research and development activities in relation to proprietary products. This business is subject to uncertainties related to the current stage of development of proprietary products as well as products of third parties to whom the Company provides development and manufacturing activities.</p> <p>The assumptions underlying the 2020-2022 business plan, representing the basis supporting the Directors' assessment over the ability of the Company to act as a going concern in the foreseeable future of 12 months starting from the approval date of the financial statements, include both the uncertainties typical of the sector in which the Company operates as well as those embedded in each forecast analysis, mainly concerning the results that it may achieve, as well as the related methodologies and timing.</p> <p>Considering the estimates and assumptions made by the Directors underlying forecast analysis, referred in particular to the adequacy of financial resources and assets to guarantee business operations in the foreseeable future of at least 12 months from the approval of the financial statements by the Board of Directors, we deemed that this matter represents a key audit matter.</p> <p>Financial statements disclosure related to the going concern assessment are reported in the notes to the financial statements at paragraph "Going concern".</p>	<p>The procedures performed to address the key audit matter included, among others, gaining an understanding, also through inquiries with management, of the elements underlying the assessment of the going concern basis of accounting, the analysis of the key assumptions included in the 2020 - 2022 business plan approved by the Board of Directors in December 2019, the analysis of the documents underlying the financial resources available and the assessment of the events occurred after the balance sheet date.</p> <p>Lastly, we assessed the disclosure included in the notes to the financial statements as at 31 December 2019.</p>
<p><b>Recognition of revenues from contracts with customers</b></p>	<p>The procedures performed to address the key audit matter included, among others, the assessment of the accounting treatment adopted by the Company to identify the contractual elements in the transactions and the</p>

---

The recognition of revenues from such contracts requires the Directors to identify the various elements included in the contracts, as well as the timing for their recognition. Considering the judgment required to Directors while performing such assessment, we deemed that this matter represents a key audit matter.

timing for their recognition, through the analysis of the underlying contracts.

Lastly, we assessed the disclosure included in the notes to the financial statements as at 31 December 2019.

Financial statements disclosure related to revenue recognition for such agreements are reported in paragraph "Recognition of revenues and income" within the section "Accounting standards and basis of measurement" of the notes to the financial statements as at 31 December 2019.

---

## **Responsibilities of Directors and Those Charged with Governance for the Financial Statements**

The Directors are responsible for the preparation of the financial statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the European Union and with the regulations issued for implementing art. 9 of Legislative Decree n. 38/2005, and, within the terms provided by the law, for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

The Directors are responsible for assessing the Company's ability to continue as a going concern and, when preparing the financial statements, for the appropriateness of the going concern assumption, and for appropriate disclosure thereof. The Directors prepare the financial statements on a going concern basis unless they either intend to liquidate the Company or to cease operations, or have no realistic alternative but to do so.

The statutory audit committee ("Collegio Sindacale") is responsible, within the terms provided by the law, for overseeing the Company's financial reporting process.

## **Auditor's Responsibilities for the Audit of the Financial Statements**

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with International Standards on Auditing (ISA Italia) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with International Standards on Auditing (ISA Italia), we have exercised professional judgment and maintained professional skepticism throughout the audit. In addition:

- we have identified and assessed the risks of material misstatement of the financial statements, whether due to fraud or error, designed and performed audit procedures responsive to those risks, and obtained audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- we have obtained an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control;
- we have evaluated the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Directors;
- we have concluded on the appropriateness of Directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to consider this matter in forming our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern;
- we have evaluated the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We have communicated with those charged with governance, identified at an appropriate level as required by ISA Italia, regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We have provided those charged with governance with a statement that we have complied with the ethical and independence requirements applicable in Italy, and we have communicated with them all matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with those charged with governance, we have determined those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We have described these matters in our auditor's report.

## **Additional information pursuant to article 10 of EU Regulation n. 537/14**

The shareholders of MolMed S.p.A., in the general meeting held on April 18 2016, engaged us to perform the audit of the financial statements for each of the years ending 31 December 2016 to 31 December 2024.

We declare that we have not provided prohibited non-audit services, referred to article 5, par. 1, of EU Regulation n. 537/2014, and that we have remained independent of the Company in conducting the audit.

We confirm that the opinion on the financial statements included in this report is consistent with the content of the additional report to the audit committee (Collegio Sindacale) in their capacity as audit committee, prepared pursuant to article 11 of the EU Regulation n. 537/2014.

## **Report on compliance with other legal and regulatory requirements**

### **Opinion pursuant to article 14, paragraph 2, subparagraph e), of Legislative Decree n. 39 dated 27 January 2010 and of article 123-bis, paragraph 4, of Legislative Decree n. 58, dated 24 February 1998**

The Directors of MolMed S.p.A. are responsible for the preparation of the Report on Operations and of the Report on Corporate Governance and Ownership Structure of MolMed S.p.A. as at 31 December 2019, including their consistency with the related financial statements and their compliance with the applicable laws and regulations.

We have performed the procedures required under audit standard SA Italia n. 720B, in order to express an opinion on the consistency of the Report on Operations and of specific information included in the Report on Corporate Governance and Ownership Structure as provided for by article 123-bis, paragraph 4, of Legislative Decree n. 58, dated 24 February 1998, with the financial statements of MolMed S.p.A. as at 31 December 2019 and on their compliance with the applicable laws and regulations, and in order to assess whether they contain material misstatements.

In our opinion, the Report on Operations and the above mentioned specific information included in the Report on Corporate Governance and Ownership Structure are consistent with the financial statements of MolMed S.p.A. as at December 31 2019 and comply with the applicable laws and regulations.

With reference to the statement required by art. 14, paragraph 2, subparagraph e), of Legislative Decree n. 39, dated 27 January 2010, based on our knowledge and understanding of the entity and its environment obtained through our audit, we have no matters to report.

Milan, 27 March 2020

EY S.p.A.  
Signed by: Luca Pellizzoni, Auditor

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