Annual Report as of December 31st, 2018

FROM GENES TO THERAPY

MOLMED S.p.A.
Via Olgettina, 58 - 20132 Milan | Phone +39 0221277.1 - Fax +39 02 21277.325
info@ MolMed.com - www. MolMed.com
Capital € 21, 819,020,83, fully paid - REA no.1506630 - Milan Companies Register, Tax Code and VAT no. 11887610159

MOLMED

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, by combining scientific and research excellence with a clear and solid industrial project

…to therapy

MOLMED

Table of contents

General Company information

Registered office:	Via Olgettina, 58 – 20132 MILAN (MI)
Operating unit:	OpenZone, Via Meucci, 3 - 20091 Bresso (MI), Italy
Tax Code:	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:	MLM
ISIN:	IT0001080248
Reuters Ticker:	MLMD.MI
Bloomberg Ticker:	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 expressions such as "it is possible", "should", "forecast", "it is expected", "it is estimated", "one believes", "one intends", "one plans" "objective" or by the negative use of these expressions or by other variations of these expressions or by the use of comparable terminology.

Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties that are beyond the management's control, including scientific, business, economic and financial factors, which could cause actual results to differ materially from those anticipated 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 and which are ascribable to the Company or parties acting on its behalf, are expressly qualified, in their entirety, by these precautionary statements.

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

Corporate bodies

Chairman	Carlo Incerti
CEO	Riccardo Palmisano
Directors	Alberto Luigi Carletti
	Laura Iris Ferro, *independent*
	Sabina Grossi
	Mario Masciocchi, *independent*
	Alfredo Messina
	Elizabeth Robinson, *independent*
	Raffaella Ruggiero, *independent*
	Didier Trono, *independent*

The Board of Directors, appointed by the Shareholders' Meeting held on April 18, 2016, will remain in charge until the Shareholders' Meeting convened to approve the Financial Statements as of December 31st, 2018.
Riccardo Palmisano is enrolled as "Internal Audit Manager".

Board of Statutory Auditors

Chairman	Riccardo Perotta
Statutory Auditors	Flavia Daunia Minutillo
	Enrico Scio
Substitute Statutory Auditors	Alessia Bastiani
	Giuliana Maria Converti

The Board of Statutory Auditors, appointed by the Shareholders' Meeting held on April 18, 2016, will remain in charge until the Shareholders' Meeting convened to approve the Financial Statements as of December 31st, 2018.

*Control and Risk Management Committee **

Chairman	Mario Masciocchi, *independent*
Members	Sabina Grossi
	Elizabeth Robinson, *independent*

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

Remuneration and Nomination Committee

Chairman	Raffaella Ruggiero, *independent*
Members	Laura Iris Ferro, *independent*
	Didier Trono, *independent*

External Auditors

EY S.p.A.

Scientific Advisory Board

MolMed's Scientific Advisory Board (SAB), chaired by Mr. Claudio Bordignon, is an independent advisory body, peculiar of companies where the quality of projects is determined by the value of their scientific contents. The SAB provides advisory support in the Company's research and development programs.

MolMed's Scientific Advisory Board combines the knowledge and experience of leading international scientific experts. Its membership includes:

- Claudio Bordignon, SAB Chairman and Founder of MolMed - Founding Member of the Scientific Council of the European Research Council, and Honorary Professor of hematology at the University Vita-Salute San Raffaele in Milan (Italy).
- Malcolm K. Brenner, Director of the Center for Cell and Gene Therapy at Baylor College of Medicine, Houston, Texas, USA; Professor of Medicine and Pediatrics at the Fayez S. Sarofim (Baylor College of Medicine), Houston, Texas, USA.
- Gianpietro Dotti, member of the UNC Lineberger Comprehensive Cancer Center, Professor at the department of Microbiology and Immunology at the University of North Carolina School of Medicine, North Carolina, USA;
- Mohamad Mohty, Professor of Hematology at the Department of Medicine of the Pierre and Marie Curie University in Paris and Director of Hematology and Cell Therapy at Saint-Antoine Hospital, Paris, France;
- Miguel-Angel Perales, Oncologist and Deputy Director of the Bone Marrow Transplant Service and Director of the "Adult Bone Marrow Transplantation Fellowship Program" at the Memorial Sloan Kettering Cancer Center, NY, USA.

The professional profiles of the Scientific Advisory Board' memebers are available on the Company website (www. MolMed.com).

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: MLMD.MI). MolMed is a a biotechnology company focused on research, development, production and clinical validation of gene and cell therapies for the treatment of cancer and rare diseases, by combining research and development excellence with a clear and solid industrial project.

Over the years, MolMed has developed a dual business model combininig R&D activities on proprietary products with GMP development and manufacturing services for third parties.

Among the first companies in Europe with authorized facilities for GMP manufacturing of cell and gene therapies, MolMed is currently a consolidated company both in the CDMO area (Contract Development & Manufacturing Organization) - where it boasts important international partnerships and increasing revenues – as well as in the area of proprietary products, where it is able to internally perform all the typical functions of a biotechnology company, from pure research to development, manufacturing, clinical validation, regulatory activities, price negotiation and reimbursement of its own therapies.

MolMed's proprietary product pipeline, diversified in terms of stage of advancement and product type, includes the following:

- **Zalmoxis® (TK)**, a cell-based therapy enabling hematopoietic stem cell transplantation from partially compatible donors, in the absence of post-transplant immunosuppression. Zalmoxis® is currently in a Phase III clinical trial for the treatment of high-risk leukemia,but has already received from the European Commission the Conditional Marketing Authorisation to the market (CMA[1] with the indication *adjunctive treatment in haploidentical Hematopoietic Stem Cell Transplantation (HSCT) of adult patients with high-risk hematological malignancies*). Zalmoxis® is the first cell-based therapy approved in the European Community for this indication. The authorization was obtained through a centralized procedure and is therefore effective for all countries of the European Community. Procedurally, the Company must present a pharmacoeconomic analysis to each European national authority in order to obtain a reimbursement of the sale price and commercialize the product in the different countries of the European Community. In this regard, the Company has already obtained a reimbursement price in Italy and Germany, while France conveyed that submitted Phase I and II data are currently not sufficient to justify a reimbursement by the healthcare system. From a commercial perspective - and following the mutually agreed termination of the Zalmoxis® license and distribution agreement for all EU countries, Switzerland, Turkey and Australia as of November 12, 2018 with Dompé - the Company is evaluating all the possible alternatives, including the granting of new licenses or direct marketing in certain areas of the European Community.
- **CAR-CD44v6**, a project of immuno-gene therapy, potentially effective in certain hematological malignancies and solid tumors, has demonstrated a high degree of efficacy and safety in experimental animal models. On the basis of the positive preclinical data - and also due to the funding obtained from the European Commission for the EURE-CART project - MolMed continued R&D activities on CAR T CD44v6 in 2018, defining its therapeutic positioning and starting the authorization process, successfully finalized in Italy in March 2019, with the authorization from AIFA (Italian Medicines

[1] Detailed recommendations for the use of Zalmoxis®, described in the *Summary of Product Characteristic (SmPC),* are attached to the *European Public Assessment Report* (EPAR), available on the EMA website.

Agency) to start phase I / II clinical trial in hematological tumors, for which the enrollment of the first patient is foreseen in the first half of 2019 . Preparatory studies are also being completed in order to submit the application for authorization to human testing of the same CAR T CD44v6 on solid tumors.

- **Autologous CAR T and allogeneic CAR NK** in preclinical development phase for the development of innovative CARs targeting new antigens, for both hematological and solid tumors.
- NGRhTNF, a therapeutic agent for treating several solid tumours which displays anti-tumour activity through its specific binding to blood vessels feeding the tumour and to the concentration of immune system cells into the tumour mass, involved a large program of advanced clinical development (phases II and III), which involved more than 1,000 patients. In 2018, the complete results of the phase III study with NGR-hTNF in mesothelioma were published in the prestigious oncology journal - The Lancet Oncology and the preliminary data of a phase II study in patients with primary brain lymphoma, were presented at the annual convention of the American Society of Clinical Oncology (ASCO), demonstrating an evident efficacy of the product in this real unmet clinical need. The publication highlighted the efficacy of NGR-hTNF in the treatment of mesothelioma, an asbestos-related tumour, with particular reference to patients with a very dismal, refractory or chemo resistant prognosis.

MolMed also collaborates in cell and gene therapy projects with third parties, providing resources and expertise to support development and manufacturing during preclinical and clinical trials (Phase I-III) and for commercial use. These projects include the development, validation and control strategy of the manufacturing process as well as manufacturing - for clinical and commercial use, according to current GMP – of viral vectors and genetically modified cells.

Due to its consolidated leadership in this field, MolMed in recent years has signed agreements with important market players in the cell and gene therapies industry, both academic and non-profit, 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, manufacturing and technology services for clinical application of gene therapies based on cell transduction with viral vectors.

In particular, MolMed was involved in the development and validation of the manufacturing process and related analytical methods as well as the supply for the compassionate use of Strimvelis™ (CD34 cells + autologous, transduced to express the gene that codes for ADA) of Orchard Therapeutics, and previously of GSK, an ex-vivo gene therapy based on stem cells for the treatment of patients suffering from a very rare pathology named ADA-SCID (Severe Combined Immunodeficiency due to Adenosine Deaminase deficiency) which obtained a marketing authorization from EMA in 2016.

In order to support both its proprietary pipeline and projects for third parties, the Company has also launched an important project to expand production capacity through the construction of a second facility at the Open Zone scientific center located in the municipality of Bresso (Milan). In July 2017, AIFA granted this new facility the status of "Pharmaceutical Company" for the manufacturing of gene investigational therapies. Upon completion of the investments and the authorization process of AIFA for other GMP Manufacturing areas, MolMed will have tripled its production capacity, adding the rooms and spaces of the new production site to those already operational within the San Raffaele Hospital.

FROM GENES TO THERAPY

2. Business activities: research, development and production of cell and gene therapies

2.1 Research and Development: therapies for the treatment of severe and high-risk tumors

MolMed's activities are primarily focused on identification, characterization, and preclinical and clinical development of novel therapies for tumors with very different patterns and levels of incidence: however, they all share the common traits of severity and actual need of new therapeutic options.

MolMed is addressing rare or less-widespread tumors - although with ever-growing incidence because of exposure to environmental conditions that contribute to disease onset - with unmet clinical needs. However, clinical investigation of Molmed therapies includes much more widespread indications, thus having indeed a much wider range of treatments available or in development - such as colorectal, ovarian and non-small cell lung cancer (NSCLC) - but with many patients becoming refractory because of loss of disease control to all standard treatments. For these heavily pre-treated patients with no efficacious treatment lines left, MolMed devotes its efforts to offer a new therapeutic option.

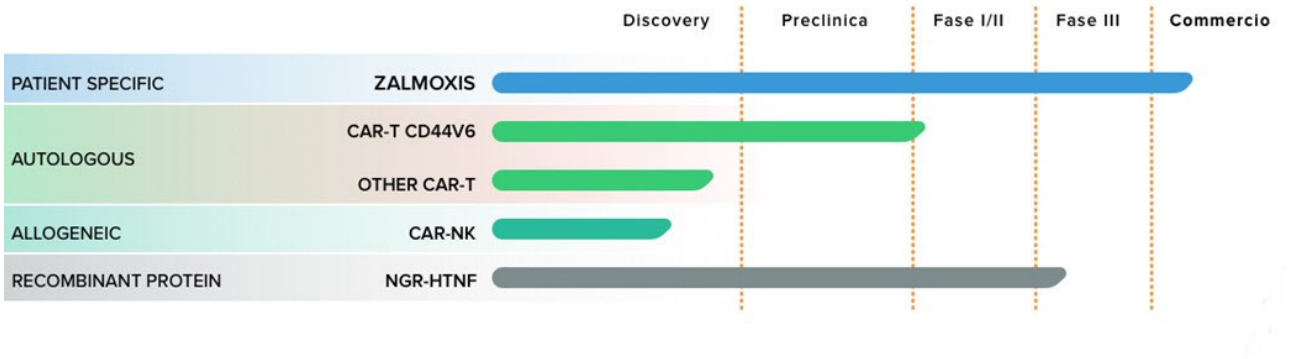


Figure 1. MolMed pipeline at December 31, 2018.

2.2 Zalmoxis® (TK) - A cell-based therapy for the treatment of leukemia

Zalmoxis® is the first patient-specific cell therapy based on engineering of the immune system and used in association with haploidentical HSCT (hematopoietic stem-cell transplantation), in adult patients with leukemia and other high-risk hematological tumors.

HSCT allows to regenerate the hematopoietic and immune system of a leukemic patient, which is severely compromised by the disease and by the radio and pharmaco-therapies endured before the transplant; however, re-infused stem cells need time - several months - in order to give origin to the mature cells characterizing a fully functional immune system. Meanwhile, the patient lacks defenses against infections and leukemic relapses, and it is necessary for him/her to have a substitute protection: in case of full compatibility of the donor, this is provided by the T lymphocytes of the donor which are capable of fighting infections as well as recognizing and eliminating residual cancer cells. However, donor lymphocytes cannot be used as substitute protection if the donor is only partially compatible with the patient given that, in this case, they prove to be a double-edged sword: on the one hand they provide a positive immunotherapeutic effect against

infections and leukemia relapses, but on the other hand, however, they result in very high risk of aggression to the patient's normal tissues, known as Graft versus Host Disease (GvHD); this is the most important and serious side effect in the case of haploidentical transplantation due to the genetic diaparity between patient and donor.

This very serious complication of the transplantation has considerably limited the use of this therapeutic option in all cases of non-full compatibility between donor and patient, which represent half of all leukemic patients.

TK cell therapy was designed in order to allow to keep the protective action of donor T cells, which is vital for the transplant to be really successful, even in the case of partial compatibility between donor and recipient. Zalmoxis® therapy is based on the use of genetically modified T lymphocytes in which a "suicide gene" is inserted. Once infused in patients undergoing a partially compatible donor hematopoietic stem cell transplant, these cells eliminate the use of post-transplant immunosuppressive prophylaxis, thereby favoring rapid immunological reconstitution which can protect against leukemia relapse and the transplant's infectious complications. In the event of the onset of acute GvHD, and at the appearance of the first symptoms, the administration of a simple drug, Ganciclovir, activates the suicide gene, thereby allowing solely for the elimination of the lymphocytes responsible for the aggression and promptly controlling the adverse effect. In this manner, Zalmoxis® allows for the maintenance of all the benefits of immune control performed by the donor's T lymphocytes for the time necessary for the transplant, thereby generating a new, complete and lasting immune system. Zalmoxis®, by significantly increasing long-term survival, therefore makes haploidentical transplantation safer and more effective. In addition, the complete control mediated by the acute GvHD suicide gene system is capable of preventing or almost completely reducing the onset of the more serious - and difficult to treat - form of the disease, chronic GvHD, which is associated with high mortality, very strong reduction in the patient's quality of life and a significant increase in costs for healthcare facilities.

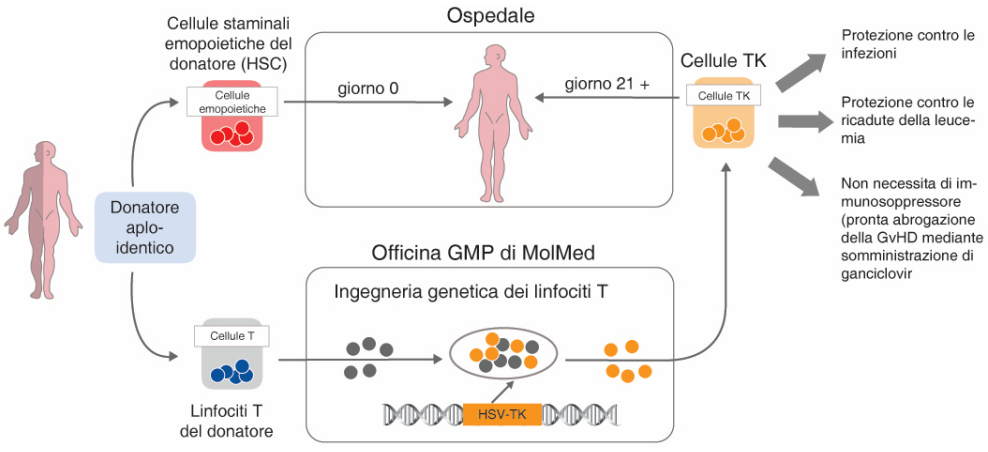


Figure 2. Synthesis of the TK therapy procedure in hematopoietic cell transplantation from a partially compatible donor

On August 18th, 2016, the European Commission, following the recommendation expressed by the CHMP on June 23rd, 2016, granted a Conditional Marketing Authorization (CMA) to Zalmoxis®, based on efficacy and safety data relating to patients enrolled in the Phase I/II of trial TK007[2], and in the randomized Phase III TK008, currently in progress. Trial TK008 is conducted in adult patients with high-risk acute leukemia subjected to haplo-transplant in major European countries as well as the United States and Israel. The study aims to demonstrate the therapeutic efficacy and tolerability of the investigational medicinal product, and compares the results of the haplo-transplant with or without the addition of TK cells, with a randomization of 3 to 1 in favor of Zalmoxis®. The primary objective of the study is disease-free survival evaluated in a population of 170 patients; secondary objectives include overall survival, reduced mortality related to the haplo-transplant procedure, the safety profile and quality of life of patients (study ID in www.clinicaltrials.gov: NCT00914628).

The cumulative data[3], collected on over 130 patients treated with TK technology during the various academic studies, showed that - in the Phase I/II trial - this therapeutic approach is able to guarantee an effective control of acute GvHD.

In addition, an analysis conducted on the first 24 patients treated with Zalmoxis® in the Phase III trial TK008 revealed an additional increase in survival rates and an inverse correlation between the administered cell dose and the probability of leukemic relapse: disease free survival at one year (primary objective of the study) of 74%, higher than the default target of 52% in the Zalmoxis® arm and the 30% for the control arm[4]. It should also be noted that, with regard to the secondary objective of the study, i.e. overall survival (OS), 85% of patients in the TK arm were alive after one year (100% in the case of patients who had attained immune reconstitution), a value that increases to 86% for disease-free survival at one year. The therapeutic effect of TK cells was further confirmed by a very low rate of leukemic relapse after one year (16% - which was zeroed out in patients who received higher doses of Zalmoxis®) and by a very low mortality not linked to leukemic relapse (10% - which was zeroed out in patients who had attained immune reconstitution).

To support the EMA's evaluation process for the Conditional Market Authorization within the realm of the Phase I/II trials and the preliminary data of the Phase III trial, patients treated with Zalmoxis® (n = 37) were compared, in a ratio of 1 to 4, with control patients subjected to haploidentical transplantation (n = 140) contained in the Register of the European Group for Blood and Marrow Transplantation (EBMT), and whose reporting demographic or disease characteristics were comparable to those of patients treated with Zalmoxis® (pair-matched analysis).

These analyses established – on the basis of clinically significant objectives (overall survival, non-relapse mortality and chronic GvHD) – the clinical benefit obtained in patients treated with Zalmoxis® compared to controls taken from the EBMT registry. Up to this point, there had been no available registered therapies or standard treatment options that were capable of controlling the two problems that account for the majority of deaths not due to relapse – namely opportunistic infections and GvHD – as well as increasing survival rates after a haploidentical transplantation.

In addition, Zalmoxis® was granted Orphan Drug designation both in the European Union and in the United States. Key publications concerning Zalmoxis® are available at MolMed's website (www.molmed.com).

[2] *Ciceri, Bonini et al, Lancet Oncology 2009;10:489-500*
[3] *European Society for Blood & Marrow Transplantation* (EBMT) *Tandem Meetings* 2013, Salt Lake City (USA), 13-17 February 2013
[4] *ASCO 2014*

2.3 CAR CD44v6

MolMed's CAR CD44v6 immuno-gene therapy project belongs to the CAR-T family: T lymphocytes armed with chimeric receptors that have demonstrated high anti-tumor potential. It was acquired by the Company in 2015 by exercising an existing option with the San Raffaele Hospital (OSR).

In the field of adoptive cell immunotherapy, the engineering of T lymphocytes with receptors targeted against tumor antigens represents an effective strategy to rapidly generate a large number of tumor-specific T lymphocytes. In particular, the use of chimeric antigen receptors (CAR) currently represents an innovative therapeutic strategy that has already been clinically validated for safety and efficacy. Most clinical studies so far conducted have used specific CARs for the CD19 antigen, expressed exclusively by B lymphocytes and by the tumors derived from them.

Compared to these CARs, MolMed's CAR CD44v6 is an original receptor which is characterized by a variety of factors:

- high therapeutic potential because it recognizes the variant 6 (v6) of the CD44 antigen (CD44v6), expressed in several hematological malignacies (acute myeloid leukemia and multiple myeloma) as well as many epithelial tumors (breast, lung colon, pancreas, head/neck cancer);
- a peculiar space structure between the outer and inner part of the protein, i.e. between the portion targeted to the antigen and the portion responsible for activating the intracellular signal – currently the subject of a patent application – which allows for improvement of the interaction and selection of the target antigen, thereby allowing the CAR to function as a highly performing receptor and eliminating the need to include a separate marker gene;
- a low toxicity profile due to the combination with MolMed's suicide gene HSV-TK Mut2.

CAR CD44v6 therapy involves isolating the T cells of a patient with a tumor expressing the CD44v6 antigen, and then modifying them in vitro with a retroviral or lentiviral vector in order for them to express CAR CD44v6 as well as the HSV-TK Mut2 suicide gene (fig. 4). The presence of CAR CD44v6 will allow the lymphocytes to recognize and kill the tumor cells while - in the case of adverse reactions - HSV-TK Mut2 will allow for the elimination of the cells expressing CAR CD44v6. After being engineered, the T cells expressing the CAR are expanded in vitro until the therapeutic dose is obtained and are then infused into the patient. Prior to the infusion, the patient is subjected to lymphodepleting chemotherapy, i.e. treatment with drugs which, by eliminating part of his/her T lymphocytes, create the space necessary for the T lymphocytes expressing CAR CD44v6 to engraft and remain in circulation.

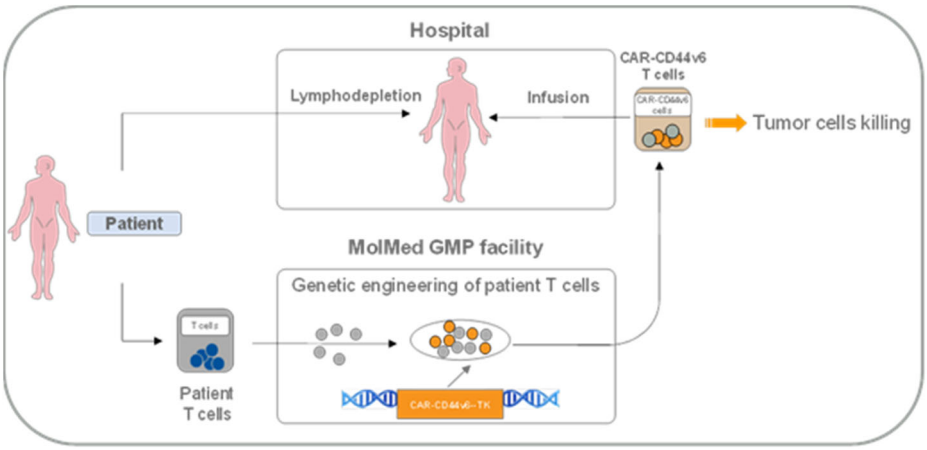


Figure 4. Synthesis of the therapeutic procedure of the CAR CD44v6 project

The lymphocytes infused in vivo into the patient will then be guided by CAR CD44v6 to the tumor site where they will be able to exercise their cytotoxic function by destroying the neoplastic cells. If adverse reactions occur, such as the recognition of the patient's normal tissues, the HSV-TK Mut2 suicide gene will be activated to kill the lymphocytes by administering Ganciclovir. This proprietary technology makes it possible to limit the risks typically associated with the immuno-gene therapy for tumors.

With regard to leukemia, preclinical results confirmed the efficacy and reported a better safety profile of the CAR-T CD44v6 lymphocytes compared to the CAR-T CD19 lymphocytes; even more significant are the results for solid tumors, as shown in a model of human pulmonary adenocarcinoma which reported interesting and very promising properties for the CAR-CD44v6 project. In particular, the T lymphocytes express the CAR CD44v6 very efficiently, and migrate preferentially towards the tumor site where they exert remarkable cytotoxic potential on the tumor cells: the analysis carried out immediately after the treatment showed that, in the tumor lesions, the neoplastic cells were almost completely eliminated and replaced by CAR-T lymphocytes.

The recorded preclinical results confirm that CAR-CD44v6 T lymphocytes may be used also in the treatment of solid tumors in the future; starting from these data, it will be possible to correctly outline the potential of the project and its place in therapy as well as more effectively define the development path to follow in order to initiate experimentation in humans.

The CAR-CD44v6 T lymphocytes will also be used in clinical cancer immunotherapy trial for which the EURE-CART project (EURopean Endeavor for Chimeric Antigen Receptor Therapies) – of whic MolMed is leading coordinator – obtained, at the end of 2016, a European financing totaling Euro 5,903 thousands, within the funding allocation for new therapies for chronic diseases of the "Horizon 2020" research and innovation framework program. The main expected impact of EURE-CART implementation is the establishment of CAR-T-cell therapy as ultimate personalised therapy, capable of defeating neoplastic diseases.. For this purpose, a multi-center Phase I/IIa clinical trial is planned in order to demonstrate the safety and efficacy of immunotherapy based on CAR-T CD44v6 lymphocytes in acute myeloid leukemia and multiple myeloma. EURE-CART will involve a Consortium of prestigious partners from five different countries of the European Union, all leaders in their respective areas of clinical, scientific and industrial activity.

2.4 New products (autologous and allogeneic CARs)

In 2018, the Company stipulated new strategic agreements in order to meet the objective of expanding and building its own CAR oncology pipeline capable of targeting solid and liquid tumors with new original targets as well as allogeneic therapies; as a result, and unlike autologous therapies, cells were transplanted from a donor to a different recipient.

One of the main advantages of these therapies is that they can be produced and administered in an "off-the-shelf" manner without the need for matching with an individual patient: starting from a single batch obtained from the cells of the healthy donor's immune system, they are capable of treating a large number of cancer patients.

The CAR T CD44v6 is part of autologous therapies, those currently most widespread in the field of CAR gene immunotherapy, whereby the cells of the immune system are taken and engineered to transport specific antigens expressed by the tumor and transfused in the same patient. Autologous therapies are still the most widespread because they avoid incurring the risk of adverse reactions against the host.

Allogeneic CARs, on the other hand, exploit a physiological mechanism of action because they naturally recognize the diseased cells and cause their death without the need for customization; they are therefore more standardized and less expensive.

In particular, the allogeneic CAR that MolMed is developing - jointly with Glycostem - is based on NK (Natural Killer) cells of the innate immune system, which are able to mediate the anti-tumor effect without the risk of developing the graft versus host disease.

3. GMP development and production activities on behalf of third parties

Over the years, MolMed has developed specific expertise in the cell and gene therapy field, including the use of stem cells and lymphocytes for various diseases, ranking the Company among the key players at an international level.

MolMed carries out customized activities on behalf of third parties for projects in this field, offering high-level expertise to develop, produce and validate experimental therapies, from the pre clinical stage to Phase III clinical trials, 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 leader in terms of capacity and experience in clinical production according to current Good Manufacturing Practices (cGMPs, the good production standards required by regulatory authorities for medicinal products for human use) for viral vectors and genetically modified cells.

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 methods from the lab to GMP production. In this context, the company constantly works in two areas; on the one hand, implementing a technological platform for large-scale, transient, semi-stable and stable production of retroviral and lentiviral vectors, while on the other automating cell transduction and quality control processes. These process improvements allow for both an increase in production capacity and improvement in the output of the process,

in addition to increasing competitive advantage and differentiation, thereby expanding the portfolio of partners and maintaining the role of technological co-developer.

GMP production

MolMed holds the status of Pharmaceutical Company (Officina farmaceutica), granted in 2003 by the Italian healthcare authority AIFA (Italian Medicines Agency), and runs two in-house GMP facilities formally authorized for the production of cell and gene-based therapies for clinical use, and qualified to support all stages of therapy development, from preclinical development to Phase III trials.

The facility located within the San Raffaele Science Park retains an authorization granted by AIFA as of December 2015 to manufacture Zalmoxis® and Strimvelis™ for commercial purposes.

The facility, which includes various sterile rooms dedicated to GMP production, plus a separate Quality Control laboratories area, with a total surface area of approximately 1,500 m2, currently satisfies the regulatory requirements of the European Union (EMA) and the United States (FDA) for the production of clinical-grade sterile investigational medicines.

In 2018 - following the various submissions of authorization packages relating to the GMP Manufacturing area of the Bresso site, which occurred between the end of 2017 and the beginning of 2018 - authorization was granted from the competent authorities for the GMP Manufacturing area relating to Stream 1 (approx. 600 sq. m) of the new Bresso facility and for the production of viral vectors and genetically modified cells relating to therapies for both clinical research and commerce.

Besides manufacturing Zalmoxis® for its own Phase III clinical trial, MolMed's GMP facilities also provide production services in gene and cell therapy to third parties. Provision of such services often also includes the relevant regulatory support activities. These service activities allow the Company to optimise its manufacturing capacity and to build and maintain strategic collaborations.

4. A key factor: intellectual property

The field of cell and gene therapies develops innovative treatments based on biotechnology. In this context, patents and know-how are instruments of primary importance for the protection and enhancement of knowledge and innovation. Due to the peculiar nature of the industry, inventions that can be protected through a patent involve technical applications of biology such as therapeutic genes or variants of genes existing in nature that have therapeutic or diagnostic applications, processes for the production of genetically modified cells, gene transfer technologies such as viral vectors, proteins and processes for their production. The granting of patents allows for exclusive marketing - for the entire duration of the patent (twenty years from registration) - of therapies developed based on these inventions. The protection of know-how, in addition, allows one to build up a wealth of knowledge concerning processes and operating methods that are particularly relevant in production by indirectly offering an additional exclusive tool. The Company aims to obtain market exclusivity and freedom to operate in the most important pharmaceutical markets as well as in emerging markets worldwide. MolMed retains rights to a patent portfolio in order to protect its products and technologies - which includes patents and patent applications, either owned or licensed from third parties - and constantly performs activities aimed at increasing and consolidating its patent portfolio. In particular, the Company directly follows the entire process leading to the granting of a patent in countries of interest, starting from the filing of a patent application for a new invention, subsequently the procedure for examining the validity

requirements in the territories where it is expected, and finally the granting and subsequent maintenance of patents. The rights to new inventions can arise from both internal research activities, as in the case of patents recently granted in the packaging cell line for the production of lentiviral vectors, and from the acquisition of new research projects that can enrich the pipeline of products in development, such as the CAR-CD44v6 product.

As of December 31, 2018, MolMed holds rights as the owner or licensee on 20 patent families and a priority patent application for a new invention, totaling 472 granted patents and filed patent applications, i.e. 421 granted patents and 51 filed patent applications. MolMed's patent portfolio includes:

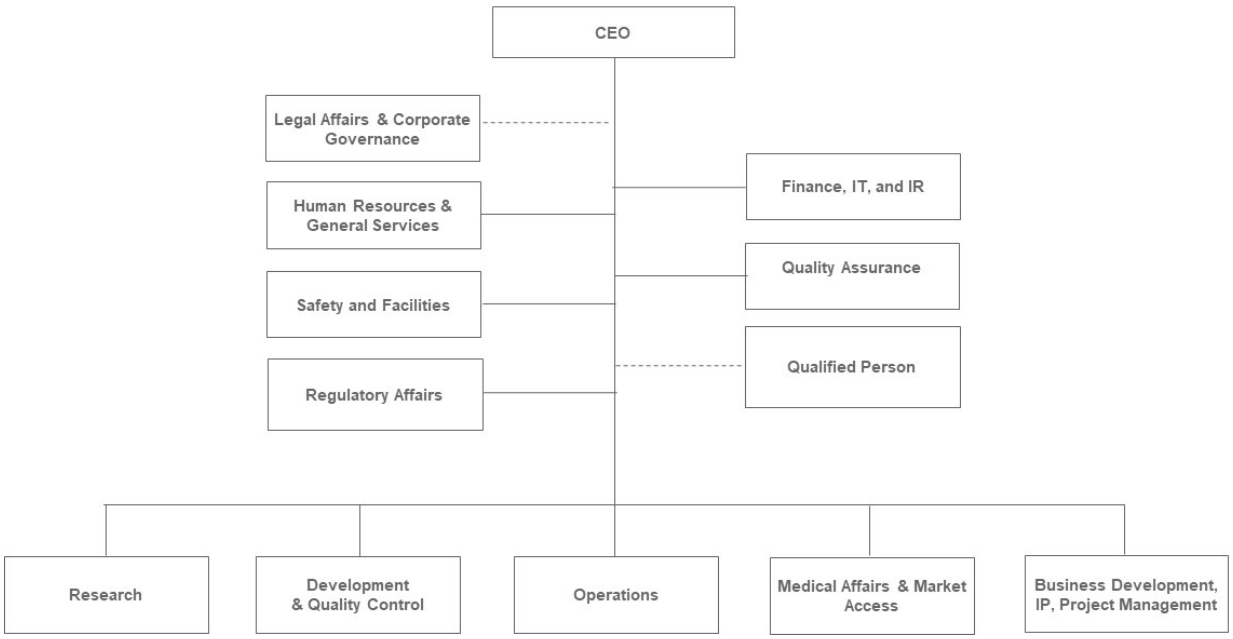
- 3 families of patents (89 granted patents and one filed patent application) in the name of MolMed or acquired under license from third parties which protect the key elements of the Zalmoxis® product, including the patent on the effective and safe variants of the TK gene and relevant production processes. In addition, MolMed has filed a request for the Supplementary Patent Protection Certificate on the variant of the Herpes Simplex Thymidine Kinase gene used in the Zalmoxis product. The certificate has so far been granted in 9 countries, including Italy;
- 4 patent families (162 granted patents and 9 filed patent applications) in the name of MolMed or acquired under license from third parties to protect the NGR-hTNF molecule as well as its use at low doses alone or in combination with other drugs, or for mesothelioma therapy, and the recombinant system for drug production;
- 3 patent families (33 granted patents, 19 filed national patent applications and a new international PCT patent application) regarding the Chimeric Antigen Receptors (CARs) technology, in particular CARs containing new S.p.A.cer molecules between the portion targeted to the antigen and the portion responsible for the activation of the intracellular signal, CARs containing optimized S.p.A.cer structures, and a process for the production of genetically modified cells;
- 6 patent families acquired under license and a new priority patent application jointly owned with third parties (52 granted patents and 13 filed patent applications) regarding production processes and products based on allogeneic therapies with NK cells;
- 3 patent families in the name of MolMed (75 granted patents and 9 filed patent applications) pertaining to semi-stable and stable packaging cell lines for the production of lentiviral vectors and production methods based on their use;
- 1 family of patents comprising 10 granted patents which refer to molecules capable of concentrating within tumor vessels.

5. Human Resources

Highly qualified and specialized personnel constitute a fundamental element for maintaining competitiveness in a high-tech global field which is subject to continuous and rapid innovation such as that of advanced therapies, and where know-how is particularly significant along with intellectual property.

The total personnel of MolMed as of December 31, 2018 is composed of 206 employees (9 executives, 193 middle managers and employees and 4 workers) in which 66.5% are women. About 80% of the staff has a

degree and 22% have a post-graduate degree.
The management team of MolMed includes a team of professionals with large experience, thereby ensuring the Company a considerable wealth of scientific, industrial and managerial skills:



6. *MolMed and the environment and health & safety*

Both the Company's facilities and operations shall comply with stringent environmental and work safety regulations. These regulations govern, for example: air polluting emissions; release of harmful substances into the water and on or under the soil surface; storage and disposal of waste and hazardous materials.

The Company has adopted safety procedures for the management and disposal of waste in accordance with Italian Legislative Decree no. 81/2008 and Italian Legislative Decree no. 206/2001 on management of Genetically Modified Microorganisms (GMMs). Staff members are provided with specific training and comply with procedures aimed at minimizing the risk of biological contamination.

In compliance with the provisions of Article 37 of Italian Legislative Decree no. 81/2008 and pursuant to the procedures indicated by the State-Regions Agreement of December 21, 2011, periodic training courses on safety issues have been implemented for all employees, distinguishing general training from specific training.

In performing its activity, the Company uses chemical and biological agents according to specific risk assessments pursuant to Italian Legislative Decree no. 81/2008. Staff uses personal protective equipment in line with the industry-standard practices.

Special waste is disposed of in compliance with current regulations (Italian Legislative Decree no. 152/2006), based on specific procedures, with the support of a specialized and authorized firm. The Company has also adopted the waste traceability control system (SISTRI) according to the directives of the Italian Ministry of

Environment and has appointed a certified consultant for the transport of dangerous goods (ADR) according to Legislative Decree no. 35/2010.

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.

7. 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 report on corporate governance, to which reference should be made, is available on the Company's website (www.molmed.com) and is stored in the centralized storage mechanism 1INFO-STORAGE according to the terms set by applicable regulations.

7.1 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 directors' appointment and replacement... and amendments to company by-laws, if different from supplementary applicable law and regulations")* is provided in the section of the corporate governance report devoted to the board of directors (Chapter 4).

7.2 Organization, Management and Control Model (pursuant to Italian Legislative Decree 231/2001)

In order to clearly and transparently define the set of values that serve as its foundation to reach its institutional objectives, MolMed has adopted an organization, management and control model pursuant to Legislative Decree no. 231/2001; the latter is regularly updated to reflect changes in applicable legislation (the "**Model**").

MolMed's decision to adopt the Model was based on the conviction that - although the provisions of Legislative Decree no. 231/2001, it should be noted, specify the Model and therefore the code of ethics as an optional and non-mandatory element - it may constitute a valid instrument for awareness amongst all employees of the Company and all parties who work in the name and on behalf of the Company or who have relations with the

latter (i.e.: customers, suppliers, partners, collaborators of different types), thereby prompting them to implement correct and appropriate behavior in the performance of their activities so as to prevent the risk of commission of the offences referred to in Legislative Decree 231/2001.

The Company – at the time of adoption of the Model - has set up a supervisory body, currently with a Board composition, characterized by the prerequisites of autonomy, independence and professionalism in addition to having inspection and control powers and the functions provided for by the Model.

Since the adoption of the Model, the Company has periodically implemented training activities on the contents of the Model which are considered fundamental elements for the correct implementation and effective application of the Model by all employees and collaborators.

The Company also prepared the anti-corruption guidelines following the recent introduction of private-field corruption offenses among the predicate offenses included in Italian Legislative Decree no. 231/2001.

The Model is constantly updated, also with the help of external consultants, for the purposes of both implementing the regulatory changes and taking into account changes in the organizational structure that have an impact on the Model itself.

Both the public version of the Model (to which reference is made for more information) and the anti-corruption guidelines are available to the public in the "investors" section, "corporate governance / documents" section of the Company's website.

7.3 Transactions with related parties

MolMed has adopted the procedures for executing transactions with related parties (the "RPT Procedures") which govern the approval and management of transactions with related parties pursuant to Article 4 of Consob regulation no. 17221/2010 in relation to transactions with related parties. 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 (RPTC): it was deemed suitable to carry out such duties by virtue of its composition, competencies and nature.

Procedures are available on the Company's website under the "Investors/Corporate Governance/Documents" section.

Information on transactions with related parties is presented below in **Note 32** of the Explanatory Notes, to which reference is made.

1. Report on operations

1.1 Summary of activities performed in 2018

Zalmoxis® (TK)

Following the conditional marketing authorization issued on August 18, 2016, and renewed on July 27, 2018 - which allows MolMed to market Zalmoxis® in the 28 EU Member States and the European economic area as an additional treatment during haploidentical Hematopoietic Stem Cell Transplantation (HSCT) in adult patients with high-risk hematologic tumors - the activities necessary for its introduction into European markets continued during 2018.

In particular, the procedure for defining the price and reimbursement in Italy was completed and, on February 14th, 2018, Zalmoxis® was declared reimbursable by the national healthcare system starting from March 29th at an ex factory reimbursement price (VAT excluded) of Euro 149,000 per infusion, gross of legal deductions and including a lump sum reimbursement per patient as well as a safeguard clause on the turnover of the first 24 months (Resolution no. 139/2018 of January 29th, 2018).

In Germany, the public health insurance system (GKV) approved the reimbursement of Zalmoxis® at a price of Euro 130,000 per infusion (ex-factory price excluding VAT). The cost per patient will be based on approved posology - which provides for one to four infusions, until immune-reconstitution is attained - and on clinical experience which indicates an average of infusions per patient of just over two. The agreement effective as of February 15, 2019 follows the authorization granted on January 15th, 2018 and the consequent process of valuation of the drug and price negotiation envisaged by the AMNOG system, with which the Federal Committee G-BA has recognized MolMed's therapy as a benefit for the treatment of adult patients with high relapse risk leukemia who underwent haploidentical Hematopoietic Stem Cell Transplantation (haplo-HSCT).

On November 12th, 2018, MolMed and Dompé, by mutual consent, terminated the license and distribution agreement for Zalmoxis®, and MolMed repurchased the product's marketing rights for all EU countries as well as Switzerland, Turkey and Australia. In addition, and as part of the contract termination agreement, Dompé has paid MolMed an amount equal to Euro 3,000 thousand, equivalent to 100% of the deferred contribution that was contractually due for the year 2018.

During 2018 the Company continued with the enrollment of patients for the TK008 Phase III randomized trial. As of today's date, 83 patients have been enrolled, including 18 patients in 2018 in 34 centers open in 10 countries with 17 active centers that have enrolled at least one patient. The study is conducted in adult patients with high-risk acute leukemia subject to haplo-transplantation in major European countries. The study aims to demonstrate the therapeutic efficacy and tolerability of the investigational product, and compares the results of the haplo-transplant with or without the addition of TK cells, and with a randomization of 3 to 1 in favor of Zalmoxis®. The primary objective of the study is disease-free survival evaluated in a population of 170 patients; secondary objectives include overall survival, decrease of mortality in haplo-transplant procedure, and an improved safety profile and quality of life for patients.

Also during the year, TTY Biopharm Company Ltd, the exclusive licensee for the use, marketing, sale and/or distribution of the product in certain Asian countries (Taiwan, Hong Kong, Singapore, Thailand, Philippines, Vietnam and Malaysia), agreed with T-FDA, the Taiwan Regulatory Agency, to implement a preclinical trial to demonstrate comparability between cells of donors of Asian strains with cells of non-Asian donors. Assessment by the competent regulatory authority, expected by the end of 2019, will - if positive - allow TTY

to submit to T-FDA the registration file necessary for the marketing of the therapy. The inspection visit to the Olgettina facility on the part of TFDA - carried out in collaboration with AIFA (co-inspection) and aimed at the production of Zalmoxis® for its future marketing in Taiwan - was also successfully completed in May. It should be noted that, with respect to the rights conferred to TTY, MolMed will be able to receive up to Euro 13.5 million, including an initial payment and milestones linked to the execution of the authorization processes and the achievement of certain revenue levels. MolMed will be entitled to receive royalties ranging between 10% and 20%, calculated on net annual sales generated in each country covered by the agreement.

With regard to Israel, and after the Israeli Ministry of Health has included the therapy in the national pharmaceutical formulary, Megapharm, the licensee for marketing in Israel, will be in a position to negotiate a reimbursement price for Zalmoxis® with the local agency on the basis of a reference price that will be derived from obtaining at least two final prices in two European countries.

CAR CD44v6

In May 2018, Nature Medicine, one of the most prestigious journals in the international scientific community, published data on the safety profile of CAR-CD44v6, which emerged from a study conducted by researchers of the IRCCS San Raffaele Hospital of Milan on the safety of CAR-T-based immunotherapy in the treatment of tumors, highlighting the extent and potential relapses associated with making CAR-T lymphocyte therapy much safer and manageable. The study, which utilized certain CAR-Ts including MolMed's CAR-T CD44v6 and CAR-T CD19, demonstrated the effectiveness of a strategy for controlling the main adverse effects so far observed in these type of therapies, namely cytokine release syndrome (CRS) and neurotoxicity which require the administration of anakinra, a drug currently on the market for the prevention and treatment of arthritis.

In addition, studies conducted by MolMed on solid tumors (melanoma and lung carcinoma) in murine tumor models - in which the host's immune system is functioning - have shown that CAR-T CD44v6 cells are capable of: i) inhibiting the growth of the primary tumor, thereby significantly prolonging the survival of the treated animals, ii) inhibiting the growth of experimental lung metastases, iii) inducing an immune response towards new antigens expressed by the tumor, thus increasing the effectiveness of the treatment. The set of data that was obtained further supports the use of CAR-T CD44v6 for the treatment of patients with solid tumors expressing CD44v6.

The results of this study were presented in Lausanne on October 17, at the annual congress of the European Society of Gene & Cell Therapy.

On the basis of the positive preclinical data and also due to the funding obtained by the European Commission for the EURE-CART project, MolMed continued R&D activities on CAR T CD44v6 in 2018 with the aim of enhancing the peculiar characteristics of this product, demonstrating its efficacy and safety and correctly defining its therapeutic positioning while initiating the authorization process of the Phase I/II clinical trial in blood tumors.

New products (autologous and allogeneic CAR's)

In 2018, the Company has entered into new strategic agreements that meet the objective of expanding and building a solid CAR pipeline of both autologous and allogeneic original products which are capable of affecting liquid and solid tumors.

On May 31, the Company signed - with the Dutch biotech company Glycostem, focusing on the clinical development of off-the-shelf allogeneic cell immunotherapies based on NK (Natural Killer) cells - a term sheet for the development and production of CAR-NK allogeneic therapies. The contract, finalized on September 28, 2018, provides that the two companies collaborate exclusively in the development and production of NK cells that are genetically modified to recognize three different tumor antigens. Glycostem is responsible for GMP production and the release of the finished product, while MolMed has exclusive rights to use the final product against the payment of relative upfront, milestone and royalty fees. The agreement will allow MolMed to expand its oncological cell & gene therapy pipeline, thereby entering the promising field of allogeneic therapies.

On June 28, the Company undersigned a Master Agreement with AbCheck s.r.o. - a Czech company specializing in the research and optimization of high-quality antibodies - for the development of innovative CARs for new tumor antigens, and whose therapeutic targets are both hematological and solid tumors. On the basis of the agreement, AbCheck will use its own proprietary platform for the research, selection, optimization and production of various human single-chain variable fragments (scFvs) which are capable of specifically recognizing every potential target chosen by MolMed. The scFvs are the fragments of the CAR which, by recognizing and binding to tumor antigens, confer specificity to the CAR itself. The new scFvs, optimized and produced by AbCheck, will allow MolMed to expand its pipeline both in the field of the autologous CAR-T platform and in that of future allogeneic CAR-NK's.

NGR-hTNF:

In 2018, the complete results of the Phase III trial with NGR-hTNF in mesothelioma were published in the prestigious oncology journal, The Lancet Oncology, and the preliminary data of an exploratory Phase II trial in patients with primary cerebral lymphoma were presented at the annual conference of the American Society of Clinical Oncology (ASCO). The publication highlighted the efficacy of NGR-hTNF in the treatment of mesothelioma, a tumor associated with exposure to asbestos, with particular reference to patients with the most unfavorable prognosis, or resistant or refractory to standard chemotherapy treatment.

Nevertheless, in light of the focus and specialization of MolMed in the cell & gene area and considering the decition to allocate the financial resources to the most innovative projects, the Company, while believing in the scientific validity of the NGR-hTNF project, considers it non-priority to continue investing in the NGR-hTNF confirming, in any case, its strategy to research potential industrial or financial partners for a further clinical and productive development of the product.

GMP development and production activities

In 2018, development and production activities continued on behalf of third parties regarding both cancer and rare diseases, with the expansion of both the number of customers and projects. In addition to existing partnerships with GlaxoSmithKline (NYSE: GSK) which, during the period, was replaced by Orchard Therapeutics (Nasdaq: ORTX), Telethon / TIGET, Genenta, Rocket Pharmaceutical (Nasdaq: RCKT), Cellectis

(Nasdaq: CLLS), a partnership with Boston Childern's Hospital was added, as well as new activities on behalf of GSK.

In particular, on April 12, MolMed announced the initiation of a partnership with Orchard Therapeutics, a UK biotechnology company, following the acquisition by the latter of the Tiget/Telethon research product portfolio, which until then was owned by GSK. The takeover of the contract with GSK by Orchard Therapeutics ensures continuity of program development and access for patients to all therapies previously developed and produced for GSK: (i) Strimvelis, the first ex vivo autologous gene therapy for treatment of children suffering from ADA-SCID immunodeficiency, approved by EMA in 2016, (ii) the two programs in advanced clinical trials for registration purposes related to metachromatic leukodystrophy (MLD) and to Wiskott Aldrich syndrome (WAS), and (iii) a program in clinical development on beta thalassemia.

On May 4, MolMed signed a five-year Master Service Agreement - along with the first related Project Agreement - with Boston Children's Hospital for the production of lentiviral vectors to be used in clinical applications for rare diseases. Boston Children's Hospital is one of the most important pediatric institutes in the world in the treatment of complex pathologies, and has important professional associations, including that with Harvard Medical School.

On June 22, Orchard Therapeutics extended the agreement to two additional therapeutic indications, entrusting MolMed with activities related to the production of autologous ex vivo gene therapies for two further indications that were already owned by Orchard, such as mucopolysaccharidosis type IIIA and mucopolysaccharidosis of type IIIB.

On July 13, the Company also undersigned a new three-year agreement with GSK for the development and production of lentiviral vectors targeting clinical applications of GSK's oncology projects.

In 2018, following various submissions of authorization packages relating to the GMP Manufacturing area of the Bresso site - between the end of 2017 and the beginning of 2018 - authorization was granted by the competent authorities of the GMP Manufacturing area relating to Stream 1 (approx. 600 sq. m) of the new Bresso facility for the production of viral vectors and genetically modified cells relating to therapies for both clinical research and commerce.

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 both the production of viral vectors and genetically modified cells.

Intellectual property and protection

In 2018, intellectual property consolidation activities continued nd, in addition, other activities were implemented with the aim of expanding the corporate patent portfolio on new products and for cancer therapy, as well as to protect technologies for the production of vectors for gene therapy.

With regard to Zalmoxis®, a fourth patent was obtained in the USA for the no-splicing variant of the TK gene on which the product is based. The same patent was already granted in all the other territories where the application was originally filed and, as a result, all activities necessary for maintaining these and other granted authorizations - which grant exclusivity rights on the product and its production - were followed in 2018. In addition, the review procedures initiated by the national patent offices of different countries were applied, following the filing of the request for the Complementary Protection Certificate for the patent on the no splicing variant of the HSV-TK gene used in the product. So far, the procedure has resulted in the granting of the

Complementary Protection Certificate in 9 countries, including Italy, and will allow for the extension, in these territories, of the duration of market exclusivity rights on the Zalmoxis® product for up to a maximum of five years beyond the deadline of the patent.

With regard to NGR-hTNF, the activities during 2018 focused on maintaining granted patents that protect the product as well as its use at low doses alone or in combination with other drugs as well as the use of NGR-hTNF for mesothelioma treatment. Furthermore, during the year, activities aimed at obtaining the granting of patent applications still under assessment – and deriving from these families – continued.

In 2018, MolMed carried out activities which aimed to maintain and expand the patent portfolio protecting CAR technology, and in particular included the following: a review procedure was launched – at the European Patent Office, the US Patent Office and in other territories – of the patent application relative to the technology of Chimeric Antigen Receptors (CARs) containing new S.p.A.cer molecules between the portion targeting the antigen and the portion responsible for the activation of the intracellular signal. In addition, a new PCT international patent application was filed in relation to CARs containing optimized versions of the S.p.A.cer molecules.

Following the launch of research activities on the allogeneic technological platform, a new patent application was filed having joint ownership with third parties.

Finally, and in relation to the protection of technologies for the production of viral vectors, MolMed continued in 2018 its activities of maintenance of patents and patent applications concerning the stable packaging cell line for the production of lentiviral vectors for gene therapy, its relative semi-stable intermediate and production processes; it has extended - in markets of primary interest - an international PCT patent application concerning technologies for stable integration of transfer vectors to obtain stable production cell lines.

Organizational chart and human resources

Again in 2018, MolMed invested in its resources in order to guarantee excellence through participation in courses, seminars, congresses and other events, differentiated by professional typology or organizational area. In addition to technical-scientific and quality know how, themes concerning the management of projects, resources and supplies have been studied in depth. Courses were also organized for in-depth study of topics such as national and foreign taxation, IT security and knowledge of the English language. All employees were involved in training on Legislative Decree no. 231/2001 and the GDPR European Privacy Regulation. Personnel have been trained and informed concerning workplace safety, as required by Legislative Decree no. 81/2008.

Environment and workplace safety

In 2018, the Company continued its periodic review and application of safety procedures in the Milan site as well as the application and compliance with safety procedures in the new Bresso site pursuant to Legislative Decree no. 81/2008 and Legislative Decree no. 206/2001 concerning the handling of Genetically Modified Microorganisms (GMMs). For each new GMM introduced in both the Milan and Bresso laboratories, a specific authorization was requested from the Ministry of Health for their use.

In accordance with the obligations of Article 37 of Legislative Decree 81/2008 and the procedures defined by the State-Regions agreement of December 21, 2011, training and update courses on safety were also held in

2018 for employees of the Bresso and Milan sites; these were divided into general and specific training courses.

Infectious or chemical waste was disposed of in compliance with current regulations (Italian Legislative Decree no. 152/2006), based on a specific procedure, with the support of a specialized and authorized firm. During the year, the procedure and management of waste was also adjusted to the new European ADR regulations for the transport of dangerous goods by road.

The Company also maintained a waste traceability control system (SISTRI) for both the Milan and Bresso sites, in accordance with the guidelines of the Ministry of the Environment.

During the year, the Company was subjected to an audit (updating audit) in relation to health and safety in the workplace by PwC (PricewaterhouseCoopers Advisory S.p.A.), an internal audit specifically with regard to the provisions contained in Legislative Decree 81/2008 and its subsequent amendments and supplements as well as Legislative Decree 152/2006 and its subsequent amendments and supplements and/or reference best practices.

At December 31, 2018 there are no environmental issues that might affect the Company's use of its tangible assets.

Communication and Investor Relations

During the year, the Company held numerous meetings with the financial community which were specifically organized in the context of bank conferences in Milan, London, Frankfurt, New York, Boston, and San Francisco. In particular, the Company's management met with investors during industry events such as the ARM Annual Cell & Gene Therapy Investor Day in NYC, the Annual JP Morgan Healthcare Conference in San Francisco, the Annual Wainwright Global Life Sciences Conference in Monaco, Borsa Italiana's Industrial Day and Mediobanca's Small & Mid Cap Conference in Milan as well as during specific road shows in New York and Boston which aimed at meeting specialized investors in the cell & gene field, also to increase the internationalization of the shareholders' base..

In addition, MolMed participated in major international scientific congresses during 2018 and during which it presented posters and abstracts and held symposia on its own proprietary products, in particular CAR T CD44v6 and GMP development and production activities in which MolMed can boast a leading position.

Activities undertaken by the Supervisory Body

As in previous years, the Supervisory Body has monitored company operations in detail, even through targeted audits of company departments. As a result of the conducted supervisory activity and on the basis of information received in the period, no significant critical issues emerged pursuant to Legislative Decree 231/2001. The Supervisory Body also monitored the Compny model update and legislative changes concerning the administrative liability of entities deriving from offences and operating procedures pursuant to Legislative Decree 231/2001.

During the year, the Supervisory Body finally verified that during the year the Company continued to conduct training on Legislative Decree 231/2001 and on its Organizational Model while also and launched a training program on internal and external legislation to prevent market abuse.

Transactions with Related Parties

Detailed information on transactions with related parties is provided in the Notes to the Financial Statements to which reference should be made.

1.2 Other information

Grants and funding schemes

Because of its particular segment of operations, MolMed enjoys some benefits deriving from funding schemes at European, national or local level aimed at supporting and promoting innovation.
From 2017, MolMed has been coordinator of EURE-CART (EURopean Endeavour for Chimeric Antigen Receptor Therapies), an EU co-financed project within the Horizon 2020 – Framework Programme for Research and Innovation, reserved to the new therapies for chronic diseases (including cancer). In this regard, a loan of Euro 5,903 thousand was granted in December, 2016; MolMed holds a share of the total amount of 1,995 Euro thousand which will cover part of R&D costs for a period of 48 months.

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 sensitive 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. For this reason, MolMed has created a system for the protection of personal data that complies with the provisions of current legislation (Reg. (EU) 2016/679 and Legislative Decree no. 196/2003, as most recently updated by Legislative Decree 101/2018), in compliance with the guidelines of the European Data Board Protection and the general authorizations issued by the Guarantor for the protection of personal data, if applicable.
In particular, part of the documentation having an impact even for the protection of personal data was updated during the year, publishing this information on the company Intranet in order to allow employees to have access to constantly updated information.
All disclosures pursuant to Art. 13 and 14 of Reg. (EU) no. 2016/679, the appointments of authorized parties and the legal deeds for the appointment of controllers were also updated.
Finally, the Company has appointed a Data Protection Officer and a designated privacy officer in order to more effectively coordinate and supervise activities related to the protection of personal data.

It should be noted that in 2018 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, 2018, the following shares were held by Directors, General Managers, Statutory Auditors and Executives with strategic responsibilities, 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.

Name	Role	Company in which stake is held	Shares held at December 31, 2017	Shares purchased	Shares sold	Shares held at December 31, 2018
Alfredo Messina	Director	MolMed S.p.A.	1,343,495	-	-	1,343,495

1.3 Performance and financial highlights

(amounts in Euro thousand)	Year 2018	Year 2017	Change	% change
Revenues from sales	28.447	23.000	5.447	23,7%
Other revenues	1.433	987	446	45,2%
Total operating revenues	**29.880**	**23.987**	**5.893**	**24,6%**
Purchases of raw materials and consumables	(5.867)	(5.393)	(474)	8,8%
Costs for services	(11.717)	(10.807)	(910)	8,4%
Costs for use of third-party assets	(1.507)	(1.472)	(35)	2,4%
Personnel costs	(12.902)	(12.928)	26	(0,2%)
Other operating costs	(105)	(186)	81	(43,5%)
Amortization and depreciation	(1.647)	(1.349)	(298)	22,1%
Total operating costs	**(33.745)**	**(32.135)**	**(1.609)**	**5,0%**
Operating result	**(3.865)**	**(8.148)**	**4.283**	**(52,6%)**
Financial income	48	204	(156)	(76,5%)
Financial charges	(306)	(553)	247	(44,7%)
Net financial income (charges)	**(258)**	**(349)**	**91**	**(26,1%)**
Pre-tax result	**(4.123)**	**(8.497)**	**4.374**	**(51,5%)**
Income taxes	-	-	-	-
Profit (loss) for the year	**(4.123)**	**(8.497)**	**4.374**	**(51,5%)**

Comments on the main income statement items and indicators for the year 2018 are provided below. Further details are provided in the Notes.

Operating revenues

Operating revenues amounted to Euro 29,880 thousand in 2018, compared to Euro 23,987 thousand in 2017, broken down as follows:

- Sales totaling Euro 28,447 thousand, increasing by Euro 5,447 thousand (+23.7%) compared to the prior-year period, and consisting of:
  - ✓ Euro 24,224 thousand revenues arising from development and production activities on behalf of third parties (including 1,016 thousand Euro for milestones), and increasing by Euro 3,724 thousand (+18.2%) compared to prior-year period;
  - ✓ revenues from the Zalmoxis® product equal to Euro 4,223 thousand, consisting of (i) the milestones deriving from the Zalmoxis® license and distribution agreement signed on July 26, 2017 with Dompé Farmaceutici S.p.A. for Euro 4,000 thousand, including Euro 3,000 thousand following the consensual resolution agreement of November 12, 2018 and (ii) the sale of the product under the Aifa fund for Euro 223 thousand.
- Other revenues, amounting to Euro 1,433 thousand and consisting mainly of the tax credit recognized pursuant to the "Decree of May 27, 2015 for the implementation of the tax credit for R&D activities" (Euro 1,041 thousand) as well as research and development grants provided on the basis of the Company's participation in public subsidized financing initiatives (Euro 372 thousand).

Operating costs

Operating costs amounted to Euro 33,745 thousand in 2018, increasing by Euro 1,610 thousand (+5.0% compared to 2017 when they amounted to Euro 32,135 thousand).

This change is primarily due to:

- an increase in costs for services to the tune of Euro 910 thousand (+8.4%) attributable to:
  - ✓ higher external development costs of Euro 1,608 thousand, or 68.5%, increasing from Euro 2,348 thousand in 2017 to Euro 3,956 thousand in the 2018 financial year due to the extension of the proprietary pipeline in the onco-hematological sector;
  - ✓ an increase in maintenance costs totaling Euro 230 thousand, or 25.6%, increasing from Euro 898 thousand in 2017 to Euro 1,128 thousand in 2018 following the revamping of both facilities;
  - ✓ the reduction in license fees and patent costs by Euro 514 thousand (-51.2%) from Euro 1,004 thousand in 2017 to Euro 490 thousand in 2018. 2017 figures included the recognition of the second milestone tranche amounting to USD 500 thousand (Euro 422 thousand) concerning the development of Zalmoxis®, after the Conditional Marketing Authorization (CMA) was granted;
  - ✓ market access costs, decreasing by 643 thousand Euro (-71.1%) from 904 thousand Euro in 2017 to 261 thousand Euro in 2018, mainly due to pricing and reimbursement advisory services in relation to Zalmoxis® ended in 2017.
- Increase in costs for raw materials and consumables by Euro 474 thousand (+8.8%), from Euro 5,393 thousand in 2017 to Euro 5,867 thousand in 2018, mainly due to the continuation of the industrial development of the products in the pipeline.

Operating result

Operating result for the year 2018 improved by 52.6% compared to the prior year. The operating loss amounted to Euro 3,865 thousand, down by Euro 4,283 thousand from the Euro 8,148 thousand loss recognized in 2017. This improvement is mainly attributable to the more-than-proportional increase in operating revenues in 2018 compared to the increase in operating costs (+24.6% vs +5.0%).

It should be noted that, based on the Company's operations and the objective characteristics of the activities performed, research and development costs are fully expensed as incurred. MolMed's financials are peculiar to the business model of biotech companies developing new products that have not reached a balanced income and financial position yet. This typical feature leads to a high incidence of costs for services and personnel, costs directly linked to R&D activities for products whose economic return is expected in future years.

Net financial income and charges
The Company's financial activities generated a negative result of Euro 258 thousand, a Euro 91 thousand improvement compared to the previous year, mainly due to lower fees on the installments provided for by the SEF agreement (for further details, reference should be made to **Note 26** of this Report).

Profit (loss) for the period

As a result of the above, the Company recognized a loss of Euro 4,123 thousand in 2018 compared to a loss of Euro 8,497 thousand in 2017, showing a +51.5% improvement on the previous year.

Equity and financial results

The following table shows the Company's equity and financial results, reclassified based on sources and uses of funds:

(amounts Euro thousand)	December 31, 2018	December 31, 2017
Non-current assets		
Fixed assets and other non-current assets	14,676	15,918
Total non-current assets	**14,676**	**15,918**
Net working capital		
Inventories	1,718	1,754
Trade receivables and other commercial assets	5,470	4,896
Tax receivables	1,742	1,079
Other receivables and current assets	622	1,326
Trade payables	(9,620)	(9,766)
Other liabilities	(3,525)	(3,927)
Total net working capital	**(3,593)**	**(4,638)**
Non-current liabilities		
Other non-current liabilities	(3,954)	(4,758)
Total non-current liabilities	**(3,954)**	**(4,758)**
TOTAL USES	**7,129**	**6,522**
Shareholders' equity	**23,595**	**24,633**
Net financial position	**16,466**	**18,111**
TOTAL SOURCES	**7,129**	**6,522**

Non-current assets

Non-current assets at December 31, 2018 and December 31, 2017 are detailed in the table below:

(amounts Euro thousand)	December 31, 2018	December 31, 2017	Change	% change
Tangible assets	11,701	11,860	(159)	(1.3%)
Goodwill	-	77	(77)	(100.0%)
Intangible assets	546	589	(43)	(7.3%)
Financial assets	210	210	0	0.0%
Tax receivables	1,719	2,182	(463)	(21.2%)
Other assets	500	1,000	(500)	(50.0%)
Total non-current assets	**14,676**	**15,918**	**(1,242)**	**(7.8%)**

Non-current assets amounted to Euro 14,676 thousand at December 31, 2018.

In 2018 investments in intangible and tangible assets amounted to Euro 1,739 thousand and they are broadly offset by amortization/depreciation for the reporting period.

Consisting of VAT credits, Tax receivables decreased by Euro 463 thousand, from Euro 2,182 thousand at December 31, 2017 to Euro 1,719 thousand at December 31, 2018.

Other non-current assets include an advance on future rents paid in 2013 to the owners of the property located in the “Open Zone” scientific park in Bresso (Milan) that belongs to the Zambon pharmaceutical group. The Euro 500 thousand decrease compared to the prior year is due to the fact that pursuant to the lease agreement, starting from 2018 and for the two following years, the advance payment of Euro 1,500 thousand made by the lessee shall be repaid by the lessor through a reduction in three annual lease fees to the tune of Euro 500 thousand. Given the above, an amount of Euro 500 thousand was reclassified under current assets and an equal amount was used to reduce the lease fee due for the 2018 financial year.

Net working capital

Net working capital at December 31, 2018 and December 31, 2017 is broken down as follows:

(amounts Euro thousand)	December 31, 2018	December 31, 2017	Change	% change
Inventories	1,718	1,754	(36)	(2.1%)
Trade receivables and other commercial assets	5,470	4,896	574	11.7%
Tax receivables	1,742	1,079	663	61.4%
Other receivables and current assets	622	1,326	(704)	(53.1%)
Trade payables	(9,620)	(9,766)	146	1.5%
Other liabilities	(3,525)	(3,927)	402	10.2%
Total net working capital	**(3,593)**	**(4,638)**	**1,045**	**22.5%**

Net working capital at December 31, 2018 was negative to the tune of Euro 3,593 thousand, improving by Euro 1,045 thousand (+22.5%) compared to December 31, 2017 (negative to the tune of Euro 4,638 thousand).

Inventory were essentially unchanged, from Euro 1,754 thousand at December 31, 2017 to Euro 1,718 thousand at December 31, 2018.

FROM GENES TO THERAPY

The increase in receivables from customers and commercial activities - totaling Euro 574 thousand or 11.7% - is mainly ascribable to the normal trend of commercial dynamics.
The increase in current tax receivables of Euro 663 thousand (+ 61.4%) is mainly linked to the recognition of the tax credit for R&D pursuant to the Ministerial Decree of 27 May 2015 - for an amount equal to Euro 1,041 thousand - and the reclassification from short to long term of a tax credit linked to withholding taxes on sales to foreign customers.

The Euro 704 thousand decrease in Other receivables and current assets (-53.1%) is primarily due to the reduction in receivables relating to grants for subsidized projects at a European level following payments received in the year.

Trade payables remained almost unchanged compared to the end of the previous year and reported a change of Euro 146 thousand (+ 1.5%).

The increase in other liabilities amounting to Euro 402 thousand, from Euro 3,927 thousand at December 31, 2017 to Euro 3,525 thousand at December 31, 2018, is primarily due to the combined effect of the following:

- ✓ a decrease of Euro 683 thousand for the payment of 40% of the pre-financing due to the partners of the EURE-CART funded project, and in which MolMed is the coordinator. For further details, reference should be made to the Notes;
- ✓ an increase of Euro 412 thousand due to the booking of the short-term portion of the payable due to Mr. Bordignon following recognition of the non-competition agreement provided for in the contract, and whose payment was divided into installments over 24 months. For further details, reference should be made to the Notes.

Non-current liabilities

The table below shows the items included in non-current liabilities:

(amounts Euro thousand)	December 31, 2018	December 31, 2017	Change	% change
Liabilities for pensions and employee severance indemnity (TFR)	143	147	(4)	(2.7%)
Trade payables	200	1,000	(800)	(80.0%)
Other liabilities	3,611	3,611	-	0.0%
Total non-current liabilities	**3,954**	**4,758**	**(804)**	**(16.9%)**

Non-current liabilities decreased by Euro 804 thousand, from Euro 4,758 thousand at December 31, 2017 to Euro 3,954 thousand at December 31, 2018. This change in mainly due to the Euro 800 thousand decrease in Non-current trade payables, after the deferred income relating to the GSK's up-front payment pursuant to the agreement signed on March 19, 2015 was reclassified as a short-term payable.

Equity and capital transactions

Details about changes in shareholders' equity from January 1, 2018 to December 31, 2018 are provided in the table below:

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2018	**21,514**	**58,976**	**223**	**396**	**(13)**	**(47,966)**	**(8,497)**	**24,633**
Allocation of prior year result	-	-	-	-	-	8,497	8,497	-
Other variations - stock options, Plan 2016-2021	-	-	-	396	-	396	-	-
Capital increase dedicated to SG	305	2,803	-	-	-	-	-	3,108
Capital increase expences capitalized	-	25	-	-	-	-	-	25
Profit (loss) for the year	-	-	-	-	2	-	4,123	4,121
Balance at December, 31 2018	**21,819**	**61,754**	**223**	**-**	**(11)**	**(56,067)**	**(4,123)**	**23,595**

Further details about changes in shareholders' equity are provided in the Notes.

Net financial position

(amounts Euro thousand)	December 31, 2018	December 31, 2017
Cash on hand	8	12
Other cash	15,499	13,093
Cash equivalents	-	-
A. Total cash and cash equivalents	**15,507**	**13,105**
B. Current financial receivables and other financial assets	**959**	**5,006**
Finance lease payables	-	-
Current financial Debts	-	-
C. Current financial debt	**-**	**-**
D. Net current financial position (A+B+C)	**16,466**	**18,111**
Finance lease payables	**-**	**-**
Non current financial Debts	-	-
E. Non-current financial debt	-	-
F. Net financial position (D+E)	**16,466**	**18,111**

Net financial position was positive to the tune of Euro 16,466 thousand at December 31, 2018. It only consists of cash and cash equivalents and current financial receivables, since no financial debt is recognized.

2. Main risks and uncertainties

2.1 Risks associated with external factors

Commercial risks

The Company does not have its own sales network and, for this reason, has transfedded to Dompé the licence to market Zalmoxis®. During the year, the Company consensually terminated the existing agreement with Dompé for the licensing and distribution of Zalmoxis® in all European Union countries as well as Switzerland, Turkey and Australia. In the absence of its own sales network, the Company may find it difficult to identify a partner interested in marketing the product; in this case, the Company may not be able to successfully launch and market Zalmoxis® in the EU, and this could have a significantly negative effect on the Company's activities, financial conditions, operating results and future growth prospects.

The conditional marketing authorization for Zalmoxis was obtained through a centralized procedure and is therefore valid for all countries of the European Community. Procedurally, the Company will have to present the pharmaco-economic analysis to the various European national authorities in order to obtain recognition of reimbursement of the price and so as to be able to implement a commercial launch in the various countries of the European Community. The Company has developed an economic drug analysis based on knowledge of the product and its benefits as well as of the reference market and is presenting the request for reimbursement and price in the primary countries of the European Community. The Company has already obtained the reimbursement in Italy and Germany while France considered the presented data of the Phase I and II studies as not currently sufficient to justify the reimbursement. If were to encounter unexpected delays and difficulties in obtaining approval for the Zalmoxis price and reimbursement, launch and growth prospects could be negatively affected.

In addition, and following the initial approval of prices and reimbursements, the eventual price decreases and changes in reimbursement levels can be triggered by multiple factors, including reference price systems and the publication of discounts by third-party payers or authorities from other countries. If one of these events occurs, the revenues forecasted by Zalmoxis would suffer negative consequences, with an impact on financial conditions, operating results and future growth prospects.nDue to efforts to ensure containment of healthcare expenditures, one or more countries of the European Community may not support our estimated level of government price and reimbursement for Zalmoxis, particularly in light of the budget crises of some EU countries that would have a negative impact on the forecasted revenues of Zalmoxis, with an impact on financial conditions, operating results and future growth prospects.

In the case of Zalmoxis®, the possibility could arise in which - despite having received the necessary approvals from the competent authorities, as well as the guaranteed price - the number of patients that will effectively access the therapy is lower than expected, thereby generating a significant negative effect on the Company's activities, financial situation, results of operations and future growth prospects.

Regulatory risks

The conditional marketing authorization obtained from the European Commission (CMA5 with the indication hematological malignancies) for Zalmoxis requires the conduct of a Phase III clinical study for the treatment of high-risk leukemia and recruitment of a defined number of patients. We may not be able to fulfill the obligations imposed as part of the marketing authorization for Zalmoxis. Failure to comply with these requirements may result in the suspension, variation or withdraw of the marketing authorization for Zalmoxis in the EU. It is also possible that new adverse events or safety problems emerge from the ongoing clinical trial and from the data generated in that study; this could affect conclusions on the safety of Zalmoxis. Any complications associated with the use of Zalmoxis would seriously damage revenue forecasts as well as potential future growth.

Risks associated with products in the clinical development stage

The Company has still not completed the development of its products that are currently in the clinical trial stage. With regard to Zalmoxis®, a Phase III clinical trial is currently underway for the treatment of high-risk leukemia. A clinical trial is expensive and time consuming and the results are uncertain. A failure to demonstrate safety and efficacy in clinical trials would require us to halt development; this could significantly and negatively affect our business activities, financial conditions, operational results and growth prospects.

Clinical tests can take many years to complete and failure can occur at any time during the clinical trial process. Any errors or delays in completing clinical trials could significantly affect the maintenance and growth of Zalmoxis® markets, which could negatively affect the Company's business, financial conditions, results and overall growth prospects.

No guarantee can be given that the Company will successfully complete the clinical trial of the Zalmoxis® medicinal product and the experimental CAR CD44v6 product.

Clinical studies may be delayed or stopped for a variety of reasons, including: delays or failures to obtain regulatory authorization to start a trial due to safety concerns, regulators or failure to comply with regulatory guidelines; delays in obtaining clinical materials or in producing sufficient quantities for use in tests; delays in obtaining the approval of clinical trial protocols by ethics committees; delays in patient recruitment; failure of the clinical trial or its management not in compliance with the applicable legislation; unexpected security problems; inability to adequately monitor patients during or after treatment or at multiple study sites; inability of those responsible for clinical trials to correctly carry out their activities, also in terms of compliance with applicable regulations or the expected timing; or lack of sufficient funds to complete the tests. Any incapacity on the part of the Company to comply with the product development program or to complete the clinical studies on schedule may have a substantial negative effect on its activity, economic, patrimonial and / or financial situation.
The experimental products under development could still prove to be ineffective or cause side effects during clinical trials and may not receive the necessary approvals from the competent authorities or may not be obtained at the right times for marketing them. Furthermore, it could happen that non-randomized Phase II studies, which ended positively, do not give the same positive results in later stages of development. Clinical studies can be suspended at any time by decision of the Company, or the competent authorities, in the case, for example, where it is believed that patients are exposed to high health risks. Even after approval by the competent authorities, a product could prove to be unsafe or not have the expected effects (for example, side

[5] Detailed recommendations for the use of Zalmoxis®, described in the *Summary of Product Characteristic (SmPC),* are attached to the *European Public Assessment Report* (EPAR), available on the EMA website.

effects could emerge after being placed on the market, or due to an effective efficacy of the inferior product compared to to what emerged in the experimental phases), or not in any case accepted by the subjects operating on the market (which could favor competing products) or, in general, for other reasons that cannot be controlled by the Company, preventing its use on a large scale scale or forcing them to withdraw from the market. Any incapacity on the part of the Company to comply with its own product development program or to complete clinical studies on schedule may have a substantial negative effect on the activity and on the economic, patrimonial and / or financial situation of the Company.

MolMed relies on contract reserach organizations, CROs, or other third parties for the design, management, monitoring and management of its clinical studies. If these subjects do not carry out their activities in accordance with the contractual indications, clinical protocols or regulatory requirements, the quality or accuracy of the data produced may be compromised. These circumstances, together with the need to replace one of these subjects during the course of the study, could lead to significant delays in clinical studies. The Company would therefore not be able to comply with its product development program or to complete clinical studies on schedule and this could have a substantial negative effect on the activity and on the economic, patrimonial and / or financial situation of the Company.

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 significant inancial resources, investment budget and better in-licensing opportunities with regards to new products and technologies in respect of the Company.

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 MolMed. 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 and larger 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 reference to the business part of development and production services for third parties, the investments put in place by international players in the field of gene and cellular therapies are progressively more consistent and such as to jeopardize the Company's ability to compete in this sector and to maintain the expected growth rates of the specific turnover.

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 significant 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 production 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.

2.2 Strategic and operating risks

Risks associated with research, clinical and preclinical trials, and production

The Company conducts research, preclinical and clinical studies relating to its products as well as production activities of both its own products and third-party products, based on collaboration agreements. The Company's strategy therefore includes the maintenance and stipulation of further collaboration agreements with third parties for the conduct of clinical studies, the development and production of the drug.

Furthermore, the Company uses third parties to carry out some research activities, preclinical and clinical studies as well as production activities. These subjects could fulfill, in whole or in part, their contractual obligations in a manner that is not adequate to the requests, also in terms of compliance with the expected times and the required quality standards, with consequent delays in the completion of preclinical and clinical studies and effects. negative relationships with their customers. The occurrence of these circumstances could have negative effects on the activity and on the economic, equity and / or financial situation of the Company.

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 license and supply agreements

As part of its operations, the Company has entered into several license agreements with different companies 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 the Company'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 reliance on key personnel

The Company heavily depends on the professional contribution of key scientific and managerial 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 future sale of new products will largely depend on the Company's ability to attract and retain its highly qualified scientific staff and other senior 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, successfully integrate or retain qualified scientific staff or other senior personnel, could have an adverse effect on its business, and financial position, results of operations, and cash flows.

Risks associated with reliance on key suppliers

For some production and development activities, the Company relies on unique suppliers that may not be able to replace quickly in case of need. If, for any reason, these suppliers were not able to provide the requested services or materials, or to do so on time, this could lead to the Company failing to fulfill the contractual obligations assumed with third parties and / or regulatory provisions with negative effects on the activity and on the economic, equity and / or financial situation of the Company.

FROM GENES TO THERAPY

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

MolMed owns one GMP manufacturing facility formally authorized by the Italian Medicines Agency (AIFA), for the production of genetically modified cell therapy products to be used in clinical trials. Besides supplying TK cell therapy for its own clinical trials, at the GMP facilities MolMed provides cell therapy services to selected customers and partners. In addition, MolMed performs research and development activities in 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 regulations, that may prevent the Company from performing its research and development activities and treating patients as part of clinical trials, and promptly processing its customers' orders. In addition, although the Company has taken out relevant insurance, the negative impact of such events might not be fully covered by the policies that the Company has entered into or may exceed the indemnity limits. Should these circumstances occur in the future, they could have negative effects on the Company's business and financial position, results of operations, and cash flows. The Company's GMP facilities are adequate for its current production needs and the business plans envisage an increase in the production capacity aimed at both supporting domestic demand and intensifying the development and production activities for new cell and gene 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 produce 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 has mitigated it by constantly expanding its facilities and production capacity in 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 civil liability related to product trials, production and sale

To date, the Company has never been involved in legal action for its trial, production and commercialization activities. Nonetheless, the Company is exposed to civil liability risks related to its current and future clinical trials, production and sale of therapeutic products for human use. 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 the Company face legal proceedings, be liable for compensation, and be forced to pay damages exceeding the indemnity limits provided for by its insurance policies, it 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 and be sentenced to pay compensation for any damage caused to third parties.
Should these circumstances occur in the future, the Company's business and its financial position, results of operations and cash flows could be negatively affected.

FROM GENES TO THERAPY

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 legislative and regulatory 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 in the future, the Company's business and its financial position, results of operations and cash flows could be negatively affected.

2.3 Financial risks

Risks associated with funding research and development activities

The Company's business model, typical of 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. The Company may not be able to find adequate financial resources necessary for its operations.
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. Notably, the loss for 2018 was 4,123 thousand Euro, down 4,374 thousand Euro from the 8,497 thousand Euro loss recorded in the previous year. This trend is primarily the consequence of the impact of revenues linked to increasing activities carried out on behalf of third parties and the milestones received on the Zalmoxis® commercial license on the 2018 financial year.

Taking account of the above and, in particular, based on the Company's net financial position (positive to the tune of Euro 16,466 thousand at December 31, 2018), the improved results for 2017 compared to 2017, and based on future cash flows projected by the 2019-2021 business plan, 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.

Notwithstanding, it cannot be ruled out that the Company may in the future need to resort to additional financial resources, accessible through financing by means of risk capital or debt capital, or through the stipulation of further collaboration agreements, the use of sponsored research or other means. The Company has generated losses since its establishment and expects to continue to incur significant costs for research and development of its pipeline. There is no certainty that the Company will become profitable in the long run. Even if the Company markets, directly or indirectly, Zalmoxis®, this could have a very limited market such as not to allow it to generate sufficient revenues to finance its business.

The Company cannot guarantee to be able to arrange and / or find the financial resources to a satisfactory extent for its own needs. In particular, the loan contracts could include obligations such as c.d. financial and

non-financial covenants that could have the effect of restricting the Company's operational flexibility. In the event that adequate funds are not available, the Company may be forced to delay, reorganize or cancel research and development programs, or to enter into financing, licensing or collaboration agreements at unfavorable conditions or renounce rights to certain products which otherwise it would not have renounced, with negative effects on the activity and on the economic, patrimonial and / or financial situation of the Company.

Currency and interest rate risk

At December 31, 2018, 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. The Company has no financial payables or receivables. Interest rate risk exclusively concerns financial instruments used to manage liquidity such as bank accounts, corporate bonds and other short-/medium-term cash instruments.

3. Significant events after the reporting period

Opinion of the TranS.p.A.rency Commission of the Haute Autorité de Santé (HAS) on the reimbursability of Zalmoxis® in France

On January 15, 2019, the Company announced that the TranS.p.A.rency Commission, a body of the French Haute Autorité de Santé (HAS), expressed an unfavorable opinion on the reimbursability of Zalmoxis® as per the indications authorized by EMA (European Medicines Agency). The Commission concluded that the data of the Phase I and II studies are not currently sufficient to justify reimbursement by the French healthcare service.

Germany confirms the reimbursability of Zalmoxis® at a price of Euro 130,000 per infusion.

On February 4, 2019, the Company announced that the German public healthcare insurance system (GKV) approved the reimbursement of Zalmoxis® at a price of Euro 130,000 per infusion (ex-factory price net of VAT). The cost per patient will be based on the approved posology which provides for 1 to 4 infusions up to the attainment of immuno-reconstitution, and on clinical experience, which reports an average number of infusions per patient slightly above two. The agreement, effective as of February 15, 2019, followed the authorization granted in February 2018 and the consequent process of assessing the value of the drug and the price negotiation envisaged by the AMNOG system with which the Federal Committee G-BA recognized the therapy of MolMed as a benefit for the treatment of adult patients with high-risk relapse leukemia who underwent haploidentical Hematopoietic Stem Cell Transplantation (haplo-HSCT). Due to this agreement, valid for the next 24 months, Zalmoxis® will not only be prescriptible in the two transplant centers that were so far authorized but also in all bone marrow transplant centers operating in Germany.

Renewal and extension of the partnership with Genenta Science in the field of oncology

On March 7th, 2019, the Company renewed and extended its partnership contract in the field of oncology, stipulated in March 2016 with Genenta Science, a biotechnology company operating in the development of new generation gene therapies based on transcriptional and mirRNA control; MolMed has collaborated with this firm by successfully validating the analytical and manufacturing methods of Genenta's proprietary product, TEMferon, an innovative gene therapy for cancer treatment.
Following approval from AIFA (Italian Medicines Agency) of the IMPD (Investigational Medicinal Product Dossier) file for the initiation of clinical trials with TEMferon in patients with multiple myeloma and glioblastoma multiforme (TEM-MM-101 and TEM-GBM-001), Genenta entrusted MolMed with the exclusive supply of modified cells for use in human trials. The objective of these clinical trials is to demonstrate the safety of TEMferon and its clinical efficacy in these two indications, thereby supporting the potential development of this product in a wide range of tumors.

Extension of partnership with Rocket Pharma in the field of rare genetic diseases to three new therapeutic indications

On March 13th, 2019, the Company renewed and extended - to three new therapeutic indications - the partnership initiated in February 2017 with Rocket Pharmaceuticals Ltd, 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 production of a gene therapy for the treatment of Fanconi anemia - Rocket Pharma will entrust MolMed with activities related to the production of lentiviral vectors for three new therapeutic indications: LAD-1 (leukocyte adhesion deficiency syndrome), PKD (pyruvate-kinase deficiency syndrome) and IMO (infantile malignant osteopetrosis).

4. *Business outlook*

During 2019 the Company has forecasted the continuation of the enrollment of patients in the randomized Phase III TK008 registration study for the treatment of high-risk leukemia for Zalmoxis® while awaiting to identify a new partner with whom to start the commercial development of the product in the shortest possible time period or pursue direct marketing in certain territories of the European Community.

With reference to the CAR CD44v6 project, the Company plans to start clinical trials on humans with the activation of the first Phase I/II clinical study in blood tumors (AML and MM) within the first half of 2019. In this regard, the authorization process for the clinical trial, started in the third quarter of 2018, and that obtained in Italy the authorization from AIFA to the start of phase I / II clinical trial on multiple myeloma and acute myeloid leukemia, is expected to continue also in other European countries. Preparatory studies are also being completed to submit the application for authorization to human testing of the same CAR T CD44v6 in relation to solid tumors.

The business plan also provides to develop the new product portfolio of the CAR platform with the continuation of development activities started with the agreement - in thefirst half of 2018 - with Glycostem and AbCheck s.r.o., and aimed at expanding the proprietary pipeline in the onco-hematological area. The Company plans to develop new CARs on new therapeutic targets, also due to the introduction of innovative technological platforms and through the search for new partnerships and new opportunities aimed at strengthening internal preclinical research capacities.

In 2019 MolMed will gradually continue to bring the new facility in Bresso operational, in line with the current improving trend in existing and future partnerships. Even on the basis of the new areas that are available, business development activities will be increased with the objective of extending ongoing partnerships and forging new ones for the development and production of cell & gene therapy products performed on behalf of third parties.

Taking account of the above and, in particular, based on the Company's net financial position (positive to the tune of Euro 16,466 thousand at December 31, 2018), the improved results for 2017 compared to 2017, and based on future cash flows projected by the 2019-2021 business plan, 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.

5. *Proposal for allocation of losses for the year*

As shown by 2018 Financial Statements, accompanied by this Report and the Notes, the Company reported a loss of Euro 4,123 thousand, which is proposed to be carried forward.

Financial Statements at December 31, 2018

1. Statement of financial position

(amounts in Euro thousand)		December 31, 2018	December 31, 2017
ASSETS			
Tangible assets	1	11,701	11,860
Goodwill	2	-	77
Intangible assets	2	546	589
Financial assets	3	210	210
Tax receivables	4	1,719	2,182
Other assets	5	500	1,000
TOTAL NON-CURRENT ASSETS		**14,676**	**15,918**
Inventories	6	1,718	1,754
Trade receivables and other commercial assets	7	5,470	4,896
Tax receivables	8	1,742	1,079
Other receivables and sundry assets	9	622	1,326
Other financial assets	10	959	5,006
Cash and cash equivalents	11	15,507	13,105
TOTAL CURRENT ASSETS		**26,018**	**27,166**
TOTAL ASSETS		**40,694**	**43,084**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Capital		21,819	21,514
Share premium reserve		61,754	58,976
Other reserves		212	606
Retained earnings (accumulated losses)		(56,067)	(47,966)
Profit (loss) for the year		(4,123)	(8,497)
TOTAL SHAREHOLDERS' EQUITY	12	**23,595**	**24,633**
Liabilities for pensions and employee severance indemnity (TFR)	13	143	147
Trade payables	14	200	1,000
Other liabilities	15	3,611	3,611
TOTAL NON-CURRENT LIABILITIES		**3,954**	**4,758**
Trade payables	16	9,620	9,766
Other liabilities	17	3,525	3,927
TOTAL CURRENT LIABILITIES		**13,145**	**13,693**
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY		**40,694**	**43,084**

2. Income statement

(amounts in Euro thousand)	Note	Year 2018	Year 2017
Revenues from sales	18	28,447	23,000
Other revenues	19	1,433	987
Total operating revenues		**29,880**	**23,987**
Purchases of raw materials and consumables	20	(5,867)	(5,393)
Costs for services	21	(11,717)	(10,807)
Costs for use of third-party assets	22	(1,507)	(1,472)
Personnel costs	23	(12,902)	(12,928)
Other operating costs	24	(105)	(186)
Amortization and depreciation	25	(1,647)	(1,349)
Total operating costs		**(33,745)**	**(32,135)**
Operating result		**(3,865)**	**(8,148)**
Financial income		48	204
Financial charges		(306)	(553)
Net financial income (charges)	26	**(258)**	**(349)**
Pre-tax result		**(4,123)**	**(8,497)**
Income taxes	27	-	-
Profit (loss) for the year		**(4,123)**	**(8,497)**

(importi in Euro)	Esercizio 2018	Esercizio 2017
Utile/(perdita) base/diluito per azione	(0.0089)	(0.0194)

3. Statement of comprehensive income

(amounts in Euro thousand)	Year 2018	Year 2017
Profit (loss) for the year	**(4,123)**	**(8,497)**
Other comprehensive income (not subsequently reclassified to the income statement)		
Profit (loss) actuarial	2	-
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	2	-
Total comprehensive income (loss) for the year	**(4,121)**	**(8,497)**

4. Statement of cash flows

(amounts in Euro thousand)		December 31, 2018	December 31, 2017
Cash and cash equivalents		13,105	19,701
Opening cash and cash equivalents	**A**	**13,105**	**19,701**
Cash flow from operating activities:			
Profit (loss) for the year		(4,123)	(8,497)
Amortization of assets		1,903	1,682
Amortization pro-quota Bresso		(333)	(333)
Depreciation of assets		77	-
Non monetary costs		-	151
Reversal of non monetary financial income and charges		76	(113)
Cash flow from operating activities before changes in working capital		**(2,400)**	**(7,110)**
Changes in current assets and liabilities:			
(Increase) decrease in inventories		36	(687)
(Increase) decrease in trade and other receivables		(533)	3,260
Increase (decrease) in trade and other payables		(146)	(2,760)
Increase (decrease) in other liabilities		(68)	(1,319)
Total changes in current assets and liabilities		**(711)**	**(1,506)**
(Increase) decrease in non-current tax receivables		963	40
Increase (decrease) in non current trade liabilities		(800)	(800)
Increase (decrease) in other liabilities and TFR paid		-	(1,089)
(Increase) decrease in other financial activities		-	1
Total cash flow generated (absorbed) by operating activities	**B**	**(2,948)**	**(10,464)**
Cash flow from investing activities:			
Net (investment) divestment in tangible assets		(1,629)	(1,746)
Net (investment) divestment in intangible assets		(110)	(211)
Net (investment) in other financial assets		4,006	(5,005)
Total cash flow generated (absorbed) by investing activities	**C**	**2,267**	**(6,962)**
Cash flow from financing activities:			
Increases in capital and share premium reserve		3,108	10,893
Other Equity movemenets (share increase cost)		(25)	(63)
Closing cash and cash equivalents	**D**	**3,083**	**10,830**
Cash flow generated (absorbed) during the period	**E=B+C+D**	**2,402**	**(6,596)**
Closign cash and cash equivalents	**A+E**	**15,507**	**13,105**

5. Statement of changes in equity

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2017	**20,313**	**49,347**	**223**	**251**	**(13)**	**(34,096)**	**(13,876)**	**22,149**
Allocation of prior year result	-	-	-	-	-	(13,876)	13,876	-
Personnel costs for stock options 2016-2021	-	-	-	151	-	-	-	151
Other variations - stock options, Plan 2016-2021	-	-	-	(6)	-	6	-	-
Capital increase dedicated to SG	1,201	9,692	-	-	-	-	-	10,893
Capital increase expences capitalized	-	(63)	-	-	-	-	-	(63)
Profit (loss) for the year	-	-	-	-	-	-	(8,497)	(8,497)
Balance at December, 31 2017	**21,514**	**58,976**	**223**	**396**	**(13)**	**(47,966)**	**(8,497)**	**24,633**

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2018	**21,514**	**58,976**	**223**	**396**	**(13)**	**(47,966)**	**(8,497)**	**24,633**
Allocation of prior year result	-	-	-	-	-	8,497	8,497	-
Other variations - stock options, Plan 2016-2021	-	-	-	396	-	396	-	-
Capital increase dedicated to SG	305	2,803	-	-	-	-	-	3,108
Capital increase expences capitalized	-	25	-	-	-	-	-	25
Profit (loss) for the year	-	-	-	-	2	-	4,123	4,121
Balance at December, 31 2018	**21,819**	**61,754**	**223**	**-**	**(11)**	**(56,067)**	**(4,123)**	**23,595**

6. Statement of Financial Position pursuant to Consob resolution no. 15519 of July 27, 2006

(amounts in Euro thousand)	Notes	December 31, 2018	December 31, 2017
ASSETS			
Tangible assets	1	11,701	11,860
Goodwill	2	-	77
Intangible assets	2	546	589
Financial assets	3	210	210
Tax receivables	4	1,719	2,182
Other assets	5	500	1,000
TOTAL NON-CURRENT ASSETS		**14,676**	**15,918**
Inventories	6	1,718	1,754
Trade receivables and other commercial assets	7	5,470	4,896
Tax receivables	8	1,742	1,079
Other receivables and sundry assets	9	622	1,326
Other financial assets	10	959	5,006
Cash and cash equivalents	*32*	15,507	13,105
of which with related parties	11	-	*24*
TOTAL CURRENT ASSETS		**26,018**	**27,166**
TOTAL ASSETS		**40,694**	**43,084**
LIABILITIES AND SHAREHOLDERS' EQUITY		-	-
Capital		21,819	21,514
Share premium reserve		61,754	58,976
Other reserves		212	606
Retained earnings (accumulated losses)		(56,067)	(47,966)
Profit (loss) for the year		(4,123)	(8,497)
TOTAL SHAREHOLDERS' EQUITY	12	**23,595**	**24,633**
Liabilities for pensions and employee severance indemnity (TF	13	143	147
Trade payables	14	200	1,000
Other liabilities	15	3,611	3,611
TOTAL NON-CURRENT LIABILITIES		**3,954**	**4,758**
Trade payables	16	9,620	9,766
Other liabilities	17	3,525	3,927
TOTAL CURRENT LIABILITIES		**13,145**	**13,693**
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY		**40,694**	**43,084**

7. Income Statement pursuant to Consob resolution no. 15519 of July 27, 2006

(amounts in Euro thousand)	Note	Year 2018	Year 2017
Revenues from sales	18	28,447	23,000
Other revenues	19	1,433	987
Total operating revenues		**29,880**	**23,987**
Purchases of raw materials and consumables	20	(5,867)	(5,393)
Costs for services	21	(11,717)	(10,807)
Costs for use of third-party assets	22	(1,507)	(1,472)
Personnel costs	23	(12,902)	(12,928)
Other operating costs	24	(105)	(186)
Amortization and depreciation	25	(1,647)	(1,349)
Total operating costs		**(33,745)**	**(32,135)**
Operating result		**(3,865)**	**(8,148)**
Financial income		48	204
Financial charges		(306)	(553)
Net financial income (charges)	26	**(258)**	**(349)**
Pre-tax result		**(4,123)**	**(8,497)**
Income taxes	27	-	-
Profit (loss) for the year		**(4,123)**	**(8,497)**

Notes

1. General information

MolMed's Financial Statements for the year ended December 31, 2017 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 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, 2008 and effective since January 1, 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 order to provide a better view of flows, some comparative figures recognized in the statement of cash flows have been reclassified.

In compliance with the requirements of Consob Resolution no. 15519 of July 27, 2006 as to the format of financial statements, specific supplementary statements have been provided, separately recording significant 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

As is common knowledge, the Company's business model, typical of 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 services and personnel, costs directly connected to research and development and to testing activities. At this stage of development, there is no strict correlation between costs and revenues and return for these activities is not certain and in

any case it is expected in forthcoming years.

It should also be noted that the Company operates in a highly competitive sector and must compete daily with companies whose size, stage of product development and financial resources are larger and more attractive in capital markets. In addition, the Company is subject to some uncertainties associated with the sector in which it operates (notably, the current product trial stage) regarding both the results that it may actually achieve, and the relevant methods and timings. Taking account of the peculiarities of the sector in which the Company operates and although it obtained the required authorizations for Italy and Germany from the relevant authorities, it should be noted that some uncertainties persist both in relation to the number of patients that can be treated in a context of evolving alternative therapies in clinical practice and in relation to the result of negotiations over pricing and reimbursement in relation to the Company's products that may actually be different from management's expectations in terms of profitability.

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. Notably, the loss for 2018 was Euro 4,123 thousand, down Euro 4,374 thousand from the Euro 8,497 thousand loss recorded in the previous year.

During the year, the contribution of services for third parties was more significant than that attained in the previous year, reporting an increase in revenues from development and production activities on behalf of third parties of 18.2%, despite this increase, management believes that there is still untapped potential on which it is currently working on and which could contribute more to generating positive cash flows.

During 2018 and in the first months of 2019,

- as regards Zalmoxis® it is also worth noting that:
  - on January 16, 2018, the Company announced that Dompé filed the product dossier pursuant to AMNOG (*Gesetz zur Neuordnung des Arzneimittelmarkt*, Act on the Reform of the Market for Medicinal Products) with the German Federal Joint Committee (*Gemeinsamer-Bundesausschus*, G-BA) concerning Zalmoxis®. Following this submission and simultaneous disclosure of the sale price concerning LauerTaxe®, Zalmoxis® can be prescribed and reimbursed in Germany (since January 15). The proposed sale price is Euro 163,900 per infusion (ex-factory price, VAT excluded).

  - on February 14, 2018, the relative Resolution no. 139/2018 of January 29, 2018 was published in the Official Journal of the Italian Republic in relation to the reimbursability and the price of Zalmoxis®, indicated as an additional treatment in haploidentical stem cell transplantation (HSCT) in adult patients with high-risk hematologic malignancies. The supply of Zalmoxis® on the basis of the agreement with AIFA (Italian Medicines Agency) provides for an ex factory reimbursement price (excluding VAT) of Euro 149,000 per infusion, gross of legal deductions and including a flat fee reimbursement per patient and a safeguard clause on turnover in the first 24 months

  - in February, Dompé exercised the option to develop and sell Zalmoxis® in Switzerland, Turkey and Australia, as allowed by the strategic agreement on the sale and supply of MolMed's therapy entered into with the Company;

- on July 27, 2018, the Company was informed of the decision of the European Commission on the renewal of the Conditional Marketing Authorization for Zalmoxis®. On the same date, EMA informed the Company of the positive opinion issued for the addition of the Bresso workshop as a production as well as a batch control and release site for Zalmoxis®;

- on November 12, 2018, MolMed and Dompé reached a consensual agreement for termination of the Zalmoxis® license and distribution agreement through which MolMed repurchased the product marketing rights for all EU countries as well as Switzerland, Turkey and Australia.

- on January 15, 2019, the TranS.p.A.rency Commission, a body of the French Haute Autorité de Santé (HAS), expressed an unfavorable opinion on the reimbursability of the orphan drug Zalmoxis® and for the indications authorized by EMA (European Medicines Agency). The Commission concluded that the data of the Phase I and II studies is not currently sufficient to justify reimbursement by the French healthcare service.

- on February 4, 2019, the Company announced that the German public healthcare insurance system (GKV) approved the reimbursement of Zalmoxis® at a price of Euro 130,000 per infusion (ex-factory price net of VAT). The cost per patient will be based on the approved posology - which provides for 1 to 4 infusions until immuno-reconstitution is attained – as well as on clinical experience which reports an average of infusions per patient of just over two. The agreement, effective as of February, 15 2019, followed the authorization granted in February 2018 and the consequent process of assessing the value of the drug and the price negotiation envisaged by the AMNOG system with which the Federal Committee G-BA recognized the therapy of MolMed as a benefit for the treatment of adult patients with high-risk relapse leukemia who underwent haploidentical Hematopoietic Stem Cell Transplantation (haplo-HSCT).

- With reference to CAR CD44v6:
  - the Company continued with investments in R&D activities with the objective of enhancing the specific characteristics of this product while demonstrating its efficacy and safety and correctly defining its therapeutic positioning due to the launch of the first Phase I/II clinical study in blood tumors (AML and MM), scheduled for the end of the first half of 2019.

- New products:
  - On May 31, the Company signed - with the Dutch biotech company Glycostem, focused on the clinical development of off-the-shelf allogeneic cell immunotherapies based on NK (Natural Killer) cells - a term sheet for the development and production of CAR-NK allogeneic therapies. The contract, undersigned on September 28, 2018, provides that the two companies collaborate exclusively in the development and production of NK cells that are genetically modified to recognize three different tumor antigens. Glycostem is responsible for GMP production and the release of the finished product while MolMed has exclusive rights to use the final product against the payment of relative upfront, milestone and royalty fees. The agreement will allow MolMed to expand its oncological cell & gene therapy pipeline, thereby entering the promising field of allogeneic therapies;

- On June 28, the Company undersigned a Master Agreement with AbCheck s.r.o. - a Czech company focused on the research and optimization of high quality antibodies - for the development of innovative CARs for new tumor antigens, and whose therapeutic targets are both hematological and solid tumors. On the basis of the agreement, AbCheck will use its own proprietary platform for the research, selection, optimization and production of various human single-chain variable fragments (scFvs) which are capable of specifically recognizing every potential target chosen by MolMed. The scFvs are the fragments of the CAR which, by recognizing and binding to tumor antigens, confer specificity to the CAR itself. The new scFvs, optimized and produced by AbCheck, will allow MolMed to expand its pipeline both in the field of the autologous CAR-T platform and in that of future allogeneic CAR-NK's.

- Within the framework of GMP development and production activities:
  - on April 12, MolMed announced the start of a partnership with Orchard Therapeutics, a UK biotechnology company in the field of gene therapy for rare diseases resulting from the acquisition – on the part of the latter - of the portfolio of rare disease therapies of GSK, and with the aim of strengthening its position as a global leader in gene therapy for rare diseases;

  - on May 4, MolMed undersigned a five-year Master Service Agreement - jointly with the first relative Project Agreement - with Boston Children's Hospital for the production of lentiviral vectors for use in clinical applications for rare diseases. Boston Children´s Hospital is one of the most important pediatric institutions in the world in the treatment of complex pathologies, and retains important partnerships, including that with Harvard Medical School;

  - in the first half of 2018, and following various submissions of authorization packages relating to the GMP Manufacturing area between the end of 2017 and the beginning of 2018, authorization was granted by the competent authorities for the GMP Manufacturing area relative to Stream 1 (approx. 600 sq. m) of the new Bresso Facility for the production of viral vectors and genetically modified cells relating to therapies for clinical research purposes;

  - on July 13, 2018, a three-year agreement was undersigned with GSK - a global pharmaceutical company based on research - for the development and production of lentiviral vectors aimed at clinical applications in the context of GSK's oncology projects.

Finally, the Company, as providen in the Businness Plan 2019-2021 (the Plan), approved by the Board of Director in February 2019, will continue the clinical and industrial development of the Company's main products, notably:

- access to the markets of additional countries for Zalmoxis® and the search for new partners for its marketing;
- carrying on with investments in preclinical 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.

Given the above, and based on the financial position as of December 31, 2018, equal to Euro 16,466 thousand, as well as the improvement in the result for the period compared to the previous year and the future

cash flows forecasted by the Business Plan, the management and the Board of Directors believe that the Company has adequate financial resources and sufficient assets which - together with forecasted cash flows from the performance of development and production services on behalf of third parties - are sufficient to guarantee business operations in the foreseeable future and for at least 12 months from the date of this Report. Management and the Board of Directors therefore believe that the assumption of a going concern is based on reasonable assumptions given that, as of today, there are no significant uncertainties regarding the business continuity of the company.

In particular, it should be noted that, if there is a need to increase expenditure to a greater extent than planned, or if revenues and financial flows turn out to be lower than forecasted, the priority levels of development programs will be reviewed, potentially postponing some of them while also evaluating all options for recourse to sources of external financing or share capital increases as well as commercial licensing.

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 (unchanged from 2016) 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.

Leased assets

Lease agreements are classified as finance leases when all the risks and rewards incidental to ownership are substantially transferred to the lessee. All other leases are considered as operating leases. Assets held under finance leases are recognized as tangible assets at their fair value at the date the agreement was signed or, if lower, at the present value of the minimum lease payments. The corresponding liability to the lessor is recognized in the financial statements as a financial liability. Furthermore, gains from sale and leaseback transactions based on finance leases are deferred over either the lease term or, if shorter, over the remaining life of the asset.
If there is no reasonable certainty that the lessee will obtain ownership by the end of the lease term, the asset shall be fully depreciated over the shorter of the lease term and its useful life.

A lease is classified as an operating lease if it does not substantially transfer all the risks and rewards incidental to ownership. Operating lease payments are recognized in profit or loss on a straight-line basis over the lease term.

Intangible assets

Intangible assets acquired separately are initially recognized at cost, while those acquired through business combinations are recognized at fair value on the acquisition date. After initial recognition, intangible assets are recorded at cost net of accumulated depreciation and any accumulated impairment losses. Intangible assets produced internally, with the exception of development costs, are not capitalized and are recognized in the income statement for the year in which they were incurred.

The useful life of intangible assets is valued as definite or indefinite. Intangible assets with a defined useful life are amortized over their useful life and are subject to a value appropriateness test whenever there are indications of a possible loss in value. The amortization period and the amortization method of an intangible asset with a definite useful life is reconsidered at least at the end of each year. Changes in the expected useful life or in the ways in which the future economic benefits associated with the asset will be realized are recognized by changing the period or the amortization method, as the case may be, and are considered changes in accounting estimates. The amortization rates of intangible assets with a definite useful life are recognized in the profit / (loss) for the year in the cost category consistent with the function of the intangible asset.

Intangible assets with an indefinite useful life are not amortized, but are subjected to an annual impairment test both at the individual level and at the level of the cash flow generating unit. The valuation of the indefinite useful life is reviewed annually to determine whether this attribution continues to be sustainable, otherwise, the change from indefinite useful life to a definite useful life is applied on a prospective basis.

An intangible asset is eliminated at the time of disposal (ie, on the date on which the buyer obtains control) or when no future economic benefits are expected from its use or disposal.

Any profit or loss deriving from the elimination of the asset (calculated as the difference between the net disposal price and the carrying amount of the asset) is included in the income statement.

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. For the sake of prudence, Management deemed it better not to capitalize research and development costs based on the current development Phase of MolMed's products.

Financial assets
At the time of their initial booking, financial assets are recognized at fair value and classified in one of the following categories based on their nature and the purpose for which they were acquired:
(a) financial instruments measured at amortized cost;
(b) financial assets measured at fair value through profit or loss;
(c) financial assets measured 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 risks and rewards of ownership relating to the instrument and its control.

(a) Financial assets measured at amortized cost
Financial assets are classified in this category if the asset is held within the framework of a business model aimed at collecting contractual cash flows and the latter provide for – on specific dates - cash flows that are represented solely by payments of principal and interest on the amount of capital to be repaid.
Financial assets at amortized cost are subsequently valuated by using the effective interest method and are subject to impairment. Profits and losses are booked in the income statement when the asset is sold, modified and revalued.

Financial assets at amortized cost include receivables and receivable loans. Assets at amortized cost are classified in the balance sheet under the item “Financial assets valuated at amortized cost” and are booked under current or non-current assets depending on whether the contractual maturity date is less than or greater than twelve months compared to the financial statement date.

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

Financial assets classified in this category include securities held for trading given that they were acquired for the purpose of being sold in the short term.
Financial assets through profit or loss are initially booked at fair value and the relative accessory costs are immediately recognized in the income statement. Subsequently, these financial assets measured at fair value through profit or loss are valuated at fair value. The assets belonging to this category are classified as current.
Profits and losses deriving from changes in the fair value of financial assets valuated at fair value with an offsetting item in the income statement are reported in the income statement under the items "Financial proceeds" and "Financial charges" for the period in which they are recognized.

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

Financial assets are classified in this category if the asset is held within the framework of a business model which aims at collecting financial flows both through the collection of the contractually defined flows and through the sale of the asset itself. In addition, the financial flows must derive solely from payments of principal and interest on the principal amount to be repaid.
All the financial assets belonging to this category are booked at fair value; valuation gains or losses are booked under a shareholders’ equity reserve; they are only booked to the income statement under the items "Financial proceeds" and "Financial charges" when the financial asset is actually sold.
The fair value of listed financial instruments is based on the current offer price; these instruments belong to Level 1 of the fair value hierarchy. If the market for a financial asset is not active (or refers to unlisted securities), the Company defines the fair value by utilizing valuation techniques that comply with the provisions for Level 2 and Level 3, depending on the observability of market inputs, or the lack thereof.
When calculating valuations, the Company favors the use of market information compared to the use of internal information that is specifically ascribable to the nature of the business in which the Company operates. During the valuation of financial assets measured at fair value through other comprehensive income (OCI), the Company applies the simplified approach that is authorized for low credit risk assets. On each financial statement date, the Company assesses whether the instrument is deemed to have a low credit risk by using all available information that can be obtained without excessive costs or effort. In making this valuation, the Company continuously monitors the credit rating of the debt instrument. If there is evidence of a deterioration in the credit rating of the counterparty, the Company fully books the expected losses that refer to the residual duration of the exposure.
In certain cases, the Company may conclude that a financial asset is no longer recoverable when internal or external information indicates that it is unlikely that the contractual amounts will be fully recovered, even in light of the credit guarantees held by the Company. As a result, the financial asset is cancelled when there is no reasonable expectation of recovery of 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. Losses on receivables are booked in the financial statements on the basis of

expected losses ("expected credit loss" ECL). Expected losses are based on the difference between the contractually due cash flows and the cash flows that the Group expects to receive, discounted at the estimated 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.
Cash equivalents are short-term and highly liquid investments, mainly time deposits, that are readily convertible to known amounts of cash, are subject to a negligent risk of fluctuations and have an original maturity of no more than three months.

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, 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 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 the development of new biopharmaceutical products, the Company enters into license and distribution agreements with third parties, which may include upfront payments for the transfer of rights to products being developed 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 license and distribution 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 and arise from the sale of rights to products being developed under license and distribution agreements to third parties 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 on an accrual basis 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, 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.
For the purpose of preparing the Financial Statements for the year ended December 31, 2018, and, more specifically, of testing tangible and intangible assets for impairment, the Company has taken into account the expected performance for 2019 and future years, arising from the approved business plans and based on the current economic and financial situation. In the current year, the Company has written down the goodwill booked in 2002 following the incorporation of the company Genera S.p.A.

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 deferred 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.

Stock option plans
The Company grants additional benefits to some Senior Managers through stock option plans. In accordance with IFRS 2 – Share-based Payments, these plans are granted as part of the beneficiaries' remuneration package. Stock options granted to employees are measured at fair value at the grant date, based on models that take into account a number of factors—such as option strike price, vesting period, current price of the underlying shares, expected share price volatility, expected dividends and interest rate for a risk-free investment over the option term—at the grant date as well as the probability to achieve the relevant targets for

vesting.
At the end of each reporting period, the fair value of options previously determined is neither reviewed nor updated, but maintained at its original value. At that date, on the contrary, the estimates on the market conditions and future events that could impact the measurement are updated.

Accounting standards, amendments and IFRS interpretations applied as from January 1, 2018

- On May 28, 2014, the IASB published IFRS 15 – Revenue from Contracts with Customers which, together with further clarifications released on April 12, 2016, will replace the standards IAS 18 – Revenue and IAS 11 – Construction Contracts, as well as the interpretations IFRIC 13 – Customer Loyalty Programs, IFRIC 15 – Agreements for the Construction of Real Estate, IFRIC 18 – Transfers of Assets from Customers and SIC 31 – Revenue – Barter Transactions Involving Advertising Services. The standard outlines a single comprehensive framework for entities to be used in accounting for revenue arising from contracts with customers, except for those within the scope of other IASs/IFRSs such as leases, insurance contracts, and financial instruments. The key steps to account for revenue based on this new model are:
  - ✓ identify the contract(s) with a customer;
  - ✓ identify the performance obligations in the contract;
  - ✓ determine the transaction price;
  - ✓ allocate the transaction price to the performance obligations in the contract;
  - ✓ recognize revenue when (or as) the entity satisfies a performance obligation.

  The standard is effective for annual periods beginning on or after January 1, 2018. The application of the new standard did not have significant impacts on its financial position, equity, and disclosure.
- On July 24, 2014, the IASB issued the final version of IFRS 9 – Financial Instruments: recognition and measurement. This standard brings together the results of the IASB's project to replace IAS 39. The new standard is applicable for annual periods beginning on or after January 1, 2018.
  The standard introduces new classification and measurement requirements for financial assets and liabilities. In particular, as far as financial assets are concerned, the new standard introduces a single approach based on the management methods of financial instruments and on the features of contractual cash flows of financial assets in order to determine the measurement bases, thus replacing the provisions of IAS 39.

  With reference to impairment, the new standard requires that the estimate of losses on receivables be made on the basis of the expected losses model (and not on the incurred losses model used by IAS 39) and by using supportable information, available without unreasonable charges or effort , including historical, current and prospective data. The standard requires to apply this impairment model to all financial instruments, that is financial assets measured at amortized cost and at fair value through other comprehensive income, as well as lease receivables and trade receivables.

  Finally, the standard introduces a new hedge accounting model to amend the requirements of the current IAS 39, which were often viewed as too stringent and not capable of reflecting risk management policies. The new issues addressed include:

  - ✓ the increase in transactions eligible for hedge accounting, also including the risks eligible for hedge accounting of non-financial assets/liabilities;

- ✓ changes in the way forward contracts and options are accounted for when they are in a hedge accounting relationship to reduce profit or loss volatility;
- ✓ changes to the hedge effectiveness assessment by replacing the 80-125% criterion with the principle of the "economic relationship" between the hedged item and the hedging instrument; furthermore, entities will no longer be required to perform a hedge effectiveness assessment retrospectively.

The greater flexibility introduced by the new accounting rules is offset by additional disclosure requirements concerning the Company's risk management activities.

The standard was applied as of January 1, 2018 without generating effects on the balance sheet of the company, using the option not to modify the comparatives.

- On June 20, 2016, IASB published the amendment to IFRS 2 "Classification and measurement of share-based payment transactions" (published on June 20, 2016) which contains certain clarifications in relation to the accounting of the effects of vesting conditions in the presence of cash-settled share-based payments, the classification of share-based payments with net settlement characteristics and the accounting of changes to the terms and conditions of a share-based payment that modify the classification from cash-settled to equity-settled. The amendments are effective for annual periods beginning on or after January 1, 2018. The adoption of this amendment had no impact on the Company's Financial Statements.
- On December 08, 2016 the IASB published "Annual Improvements to IFRSs: 2014-2016 Cycle", which partially supplement the existing standards in the context of the annual improvement process of the standards. The most important issues addressed include:
  - ✓ IFRS 1 First-Time Adoption of International Financial Reporting Standards - Deletion of short-term exemptions for first-time adopters. The amendment was applied as of January 1, 2018 and refers to the cancellation of certain short-term exemptions provided for in paragraphs E3-E7 of Appendix E of IFRS 1 given that the benefit of these exemptions is now considered no longer applicable.
  - ✓ IAS 28 Investments in Associates and Joint Ventures – Measuring investees at fair value through profit or loss: an investment-by-investment choice or a consistent policy choice. The amendment clarifies that the option for a venture capital organization or other entity so qualified (such as a mutual fund or similar entity) to measure investments in associates and joint ventures at fair value through profit or loss (rather than through the application of the equity method) is exercised for each individual investment at the time of initial booking. This amendment is effective for annual periods beginning on or after January 1, 2018. The adoption of this amendment had no impact on the Company's Financial Statements.
  - ✓ IFRS 12 Disclosure of Interests in Other Entities – Clarification of the scope of the Standard. The amendment clarifies the scope of application of IFRS 12 by specifying that the information required by the standard, with the exception of that provided for in paragraphs B10-B16, applies to all the shares that are classified as held for sale, held for distribution to shareholders or discontinued operations in accordance with IFRS 5. This change was applied as of January 1, 2018 without generating any effects on the Company's financial statements.
- On December 8, 2016 the IASB issued the amendment to **IAS 40** "***Transfers of Investment***

Property". These changes clarify the conditions which are necessary to transfer a property to, or from, a real estate investment. In particular, an entity must only reclassify a real estate property under, or from, real estate investments when there is evidence that a change in use of the property has occurred. This change must be ascribable to a specific event that has already occurred and must therefore not be limited to a change in intentions on the part of the Management of an entity. This amendment is effective for annual periods beginning on or after January 1, 2018. The adoption of these amendments had no impact on the Company's Financial Statements.

- On December 8, 2016 the IASB issued the interpretation "***Foreign Currency Transactions and Advance Consideration (IFRIC Interpretation 22)***". The purpose of the interpretation is to provide guidelines for transactions executed in foreign currencies if non-monetary advances are recorded in the financial statements (with an offsetting item in cash received/paid) prior to the booking of the relative asset, cost or revenue. This document provides specifications on how an entity must determine the date of a transaction and, consequently, the spot exchange rate to be used when foreign currency transactions occur in which the payment is made or received in advance.

  The interpretation clarifies that the transaction date is the earlier one between:

  - ✓ the date in which the advance payment is recorded in the entity's financial statements; and
  - ✓ the date in which the asset, cost or revenue (or part of the latter) is recorded in the financial statements (with consequent reversal of the advance payment).

- If there are numerous payments or cash inflows in advance, a specific transaction date must be identified for each of them. IFRIC 22 is effective for annual periods beginning on or after January 1, 2018. The adoption of this interpretation had no impact on the Company's Financial Statements.

Accounting standards, amendments and IFRS and IFRIC interpretations endorsed by the European Union, not yet mandatory and for which the Company has not opted for early adoption at December 31, 2018

- **IFRS 16 – Leases** (issued on January 13, 2016) will replace the following standards and interpretations: 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 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. Furthermore, IFRS 16 does not require an entity to recognize assets and liabilities for leases of low-value assets and leases with a term of 12 months or less. On the contrary, this standard does not introduce any significant changes for lessors.

  The standard is effective for annual periods beginning on or after January 1, 2019. An entity can choose to apply IFRS 16 before that date only if it also applies IFRS 15 – Revenue from Contracts with Customers. The Company's assessment of the application of this standard and any relevant impact is currently underway.

  During 2018, the Company performed an in-depth assessment on the impacts of IFRS 16. The effects expected from the application of the new standard are detailed below:

Effect on assets (increase/(decrease) as of December 31, 2018:	
(amounts in thousands of Euro) *Assets*	**2018**
Asset usage right	9,712
Total assets	**9,712**
Lease Liability (long term)	8,562
Lease Liability (short term)	1,141
Deferred Liability (closing of a deferral/accrual)	(9)
Total liabilities	**(9,712)**

Other standards or amendments that have not yet been endorsed by the European Union

The following table provides an overview of other standards or amendments that have not yet been endorsed by the European Union:

Description	Endorsed at the date of preparing these financial statements	Scheduled effective date
Amendments to IAS 28: Long-term Interests in Associates and Joint Ventures	SI	1/1/2019
Amendments to IAS 19: Plant Amendment, Curtailment or Settlement	NO	
Amendments to IFRS 1 and IAS 8: Definition of Material)	NO	
IFRS – 17 Insurance Contracts	NO	1/1/2021
Annual Improvements to IFRS Standards 2014-2016 Cycle (issued in December 2016)	SI	
IFRS 3 Business Combinations e IFRS 11 Joint Arrangements	NO	1/1/2019
IAS 12 Income Taxes	NO	1/1/2019
IAS 23 Borrowing costs:	NO	1/1/2019

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 business 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, 2018 are shown in the table below:

(amounts in Euro thousand)	Balance at December 31, 2017	Purchases	Reclassifications	Disposals	Depreciation and write downs	Balance at December 31, 2018
Gross book value						
Plant and machinery	1.800	28	7	(11)		1.824
Industrial and commercial equipment	9.368	1.033	399	(155)		10.645
Leasehold improvements	9.880	180	35			10.094
Other tangible assets	1.911	128		(17)		2.022
Ass. under construction and payments on account (Plant Bresso)	43	33	(42)			34
Ass. under construction and payments on account (equipment and other assets)	515	224	(399)			340
Ass. under construction and payments on account (Leasehold improvements Bresso)	17	4				21
Total gross book value	**23.535**	**1.629**	**-**	**(183)**	**-**	**24.982**
Accumulated depreciation						
Plant and machinery	(477)			11	(164)	(630)
Industrial and commercial equipment	(4.517)			116	(909)	(5.310)
Leasehold improvements	(5.435)			-	(501)	(5.936)
Other tangible assets	(1.247)			17	(176)	(1.406)
Total accumulated depreciation	**(11.676)**	**-**	**-**	**144**	**(1.750)**	**(13.282)**
Net book value						
Plant and machinery	1.323	28	7	-	(164)	1.195
Industrial and commercial equipment	4.851	1.033	399	(39)	(909)	5.335
Leasehold improvements	4.446	180	35	-	(501)	4.160
Other tangible assets	665	128	-	-	(176)	617
Ass. under construction and payments on account (Plant Bresso)	43	33	(42)	-	-	34
Ass. under construction and payments on account (equipment and other assets)	515	224	(399)	-	-	340
Ass. under construction and payments on account (Leasehold improvements Bresso)	17	4	-	-	-	21
Total net book value	**11.860**	**1.629**	**-**	**(39)**	**(1.750)**	**11.701**

** 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 specific plant and machinery used to develop the Company’s products and to provide services.

“Industrial and commercial equipment” includes tangible assets used in laboratories to develop the Company’s products and to provide services.

“Leasehold improvements” include the cost of renovating the premises used by the Company, in particular its pharmaceutical laboratories and offices. The aforementioned costs refer to building works as well as the adjustment of plants and are depreciated over the duration of the lease - 12 years, starting from January 2015.The costs accounted for and invoiced to the property owner, in accordance with the relevant agreements, concerned building work, and work planning services carried out by the “General Contractor”. 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 4,000 thousand Euro, will be borne by the property’s owner. As provided for under the agreement, the Company transferred the costs incurred for extraordinary maintenance work to the owner up to the previously-mentioned amount.

The item “Other tangible assets” includes furniture, fittings and electronic office equipment.

Tangible assets increased from Euro 11,860 thousand at December 31, 2017 to Euro 11,701 thousand at December 31, 2018.

Investments of Euro 1,629 thousand were made in tangible assets in 2018. The most significant changes in the period are shown below:

- increase in industrial and commercial equipment to the tune of Euro 1,432 thousand. This change is due to the amount invested in 2018 (Euro 1,033 thousand), and to the reclassification of Euro 399 thousand from assets under construction when the assets involved became fully operational;

- increase in leasehold improvements to the tune of Euro 215 thousand. This change is due to the amount invested in 2018 (Euro 180 thousand), and to the reclassification of Euro 35 thousand from assets under construction when the assets involved became fully operational.

Such increases were primarily due to investments made to bring new production facilities online, following the acquisition of new customers, and to routine replacement of laboratory equipment, where necessary, to the purchase of new equipment used in the production process, as well as to maintenance and improvement work on the existing GMP facility.

Overall depreciation amounted to Euro 1,750 thousand. Its increase compared to the previous year (Euro 1,566 thousand) is due to the beginning of the depreciation period for the equipment purchased in 2017 and 2018 and held at the new facility in Bresso. 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.

It should also be noted that there is no collateral on tangible assets.

Note 2 – Intangible assets and goodwill

The breakdown and change in intangible assets at December 31, 2018 are shown in the table below:

(amounts in Euro thousand)	Balance at December 31, 2017	Purchases	Reclassifications	Disposals	Depreciation and write downs	Balance at December 31, 2018
Merger with Genera S.p.A.	77	-	-	-	(77)	-
Goodwill	**77**	-	-	-	(77)	-
Patents and intellectual property rights	225	12	-	-	(54)	183
Concessions, licenses and trademarks	347	65	-	-	(99)	313
Assets under construction	17	33	-	-	-	50
Intangible assets	**589**	**110**	-	-	**(153)**	**546**
Total	**666**	**110**	-	-	**(230)**	**546**

Goodwill, which was written down during the year, referred to the amount booked for this purpose following the incorporation of the company Genera S.p.A., which occurred in the 2002 financial year.

The increase of Euro 110 thousand in Intangible assets is primarily due to the purchase of software to manage laboratory equipment held at the new facility.

Overall amortization amounted to Euro 153 thousand.

It should be noted that there were no other intangible assets with an indefinite useful life.

As for the recoverability of intangible assets, reference should be made to the section “Use of estimates” in these Notes.

Note 3 – Financial assets

Non-current financial assets of Euro 210 thousand are in line with the prior-year figures and mainly consist of security deposits.

Note 4 – Tax receivables (non-current)

Non-current tax receivables of Euro 1,719 thousand refer to VAT credits accrued by the Company. As costs exceed revenues at this stage of business development, VAT credits are regularly recognized.

Note 5 – Other assets (non-current)

“Other non-current assets” refer to the long-term portion (Euro 500 thousand) of the amount paid as an advance on future rents to the owner of the property in the “Open Zone” scientific park in Bresso The rental contract provides that - as of 2018 and for the next two years - the amount paid in advance to the lessor of Euro 1,500 thousand will be returned to the lessee by reducing the annual fees by an amount of Euro 500 thousand. Given the above, an amount of 500 thousand Euro was reclassified under current assets and a corresponding amount was used to reduce the lease fee due for the 2018 financial year.

Note 6 – Inventory

Inventory at December 31, 2018 is broken down as follows:

(amounts in Euro thousand)	December 31, 2018	December 31, 2017
Processing materials	543	471
Reagents	1,095	1,152
General materials	80	131
Total inventories	**1,718**	**1,754**

Consisting of reagents and materials used in the Company's laboratories, inventory was mostly unchanged, with a slight decrease from Euro 1,754 thousand at December 31, 2017 to Euro 1,718 thousand at December 31, 2018.

Note 7 – Trade receivables and other commercial assets

The breakdown of trade receivables and other commercial assets at December 31, 2018 is as follows:

(amounts in Euro thousand)	December 31, 2018	December 31, 2017
Trade receivables	4,140	2,880
Prepayments	518	532
Invoices to be issued	812	1,480
Prepaid expenses concerning costs pertaining to future periods	-	4
Total trade receivables and other commercial assets	**5,470**	**4,896**

The Euro 1,260 thousand increase in trade receivables and other commercial assets reflects the billing and collection trends in relation to the services provided.

Receivables are recognized net of a bad debt provision of Euro 28 thousand, created in relation to the impairment of receivables due from Fondazione San Raffaele del Monte Tabor in liquidation.

Except for the above-mentioned bad debt, there are no significant amounts past due.

Note 8 – Tax receivables (current)

Tax receivables at December 31, 2018 are broken down as follows:

(amounts in Euro thousand)	December 31, 2018	December 31, 2017
VAT receivables	522	700
Tax crediti R&D costs	1,041	-
Withholding taxes	179	379
Total tax receivables	**1,742**	**1,079**

Current tax receivables, equal to Euro 1,742 thousand, reported an increase of Euro 663 thousand or 61.4% compared to Euro 1,079 thousand at the end of the previous year; they are mainly composed of receivables relative to the tax credit for R&D and VAT receivables.

The increase compared to the balance as of December 31, 2017 was due to the recognition of the tax credit for R&D activities pursuant to the Ministerial Decree of May 27, 2015, implementing law no. 190 of December

23, 2014 (2015 Stability Law) and its subsequent amendments and supplements, for an amount of Euro 1,041 thousand.

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, 2018 are broken down as follows:

(amounts in Euro thousand)	December 31, 2018	December 31, 2017
Accrued research and development grants	312	990
Prepayments relating to costs not pertaining to the period	310	334
Other receivables	-	2
Total other receivables and sundry asset	**622**	**1,326**

Other current receivables and sundry assets amounting to Euro 622 thousand at December 31, 2018 decreased by Euro 704 thousand (-53.1%) compared to Euro 1,326 thousand at December 31, 2017 and mainly consist of:

- accrued public sector research and development grants amounting to Euro 312 thousand;
- prepayments amounting to Euro 310 thousand and relating to:
  - ✓ operating costs incurred for contracts based on “work progress” and maintenance and assistance fees for information services and other minor amounts (Euro 296 thousand);
  - ✓ insurance premium costs (Euro 14 thousand).

The decrease compared to the closing date of the previous year of Euro 678 thousand is mainly due to the collection in November of the contribution relative to the European project EURE CAR-T in relation to costs incurred and reported from the beginning of the project until June 2018.

Note 10 – Other financial assets

The item in question, amounting to Euro 959 thousand as of December 31, 2018, and Euro 5,006 thousand as of December 31, 2017, reported a decrease of Euro 4,047 thousand due to the combined effect of the time deposit maturity date of January 2018 - classified as held to maturity, and equal to Euro 5,006 thousand– as well as a reinvestment for an amount equal to approximately 1,000 thousand Euro in corporate bonds.

Note 11 – Cash and cash equivalents

Cash and cash equivalents are broken down as follows:

(amounts in Euro thousand)	December 31, 2018	December 31, 2017
Bank and post office accounts	15,499	13,069
Bank and post office accounts - related parties	-	24
Cash and cash equivalents	8	12
Total cash and cash equivalents	**15,507**	**13,105**

At December 31, 2018 cash and cash equivalents amounted to Euro 15,507 thousand (Euro 13,105 thousand at December 31, 2017), including Euro 15,499 thousand of bank deposit accounts and Euro 8 thousand of cash on hand.

Note 12 – Shareholders' equity

Shareholders' equity at December 31, 2018 totaled Euro 23,595 thousand. Their breakdown is as follows:

(amounts in Euro thousand)	December 31, 2018	December 31, 2017
Share capital	21,819	21,514
Share premium reserve	61,754	58,976
Other reserves:		
Stock option plan reserve	-	396
Actuarial valuation reserve	(11)	(13)
Other	223	223
Retained earnings (accumulated losses)	(56,067)	(47,966)
Profit (loss) for the year	(4,123)	(8,497)
Total shareholders' equity	**23,595**	**24,633**

Following the agreement of SEF - Standby Equity Facility with Société Générale, signed on October 6, 2016, the fifth and final installment of the share capital increase was underwritten on May 25, 2018 with the exclusion of option rights. After the capital increase, a of 6,488,279 shares were issued for an overall amount of Euro 3,108 thousand, of which Euro 305 thousand credited to the capital account and Euro 2,803 thousand to the share premium account.

Capital

At December 31, 2018, the fully subscribed and paid-in capital amounted to 21,819 thousand Euro and consisted of 463,450,672 ordinary shares with no par value.

Shareholder	No. of shares (*)	%
Fininvest S.p.A.	107,173,138 *	23.13
Airain Ltd.	24,037,678 **	5.19
H-Invest S.p.A.	7,326,216 *	1.58
H-Equity S.r.l.	6,039,692 *	1.30
Market	318,873,948	68.80
Total	**463,450,672**	**100.00**

** based on the Company's figures at October 25, 2018*
*** based on the Company's figures at April 12, 2018*

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.

Share premium reserve

The share premium reserve totaled Euro 61,754 thousand. The increase in the share premium reserve, totaling Euro 2,778 thousand, reflects the increase connected to the share capital increase underwritten in relation to the agreement of SEF - Standby Equity Facility with Société Générale for Euro 2,803 thousand, described in the previous paragraph, and net of legal fees of Euro 25 thousand which were incurred in relation to the latter.

Other reserves

Other reserves are broken down as follows:

a) Stock option plan reserve

The reserve relative to stock option plans amounting to Euro 396 thousand as of December 31, 2017 was released at the end of the 2018 financial year. This reserve was set up on January 1, 2006 upon first-time adoption of IFRSs, in order to include the fair value of stock option plans. The reserve was calculated by determining the fair value of the rights granted at the granting dates. In later years, the stock option plan reserve has increased, and changes were recognized as part of personnel costs in the income statement. The Euro 396 thousand decrease in the reserve is attributable to the following factors:

- a decrease of Euro 222 thousand due to the expiration of type A options in the 2008 stock option plan, whose period of operation ended on March 5, 2018;
- a decrease of Euro 174 thousand due to the release of the portion of the reserve ascribable to the 2016-2021 stock option plan so that, as of today's date, it is highly probable that the conditions for exercising the options will not be met.

b) *Actuarial valuation reserve*

The Actuarial valuation reserve was negative to the tune of Euro 11 thousand at December 31, 2018, with a change amounting to Euro 2 thousand compared to the prior year.

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

Retained earnings (accumulated losses)

This item totaled Euro 56,067 thousand at December 31, 2018. The Euro 8,101 thousand change compared to the year ended December 31, 2017, is due to:

- a Euro 8,497 thousand increase relating to the loss for 2017 which was recognized under accumulated losses as per the Shareholders' Meeting resolution of April 12, 2018;
- a Euro 396 thousand decrease following the release of the Type A stock option reserve from the 2008 stock option plan and the 2016-2021 stock option plan, as explained in note a) Stock option plan reserve.

Main shareholders' equity items

(amounts in Euro thousand)	Balance at December 31, 2018	Purpose of use	Amount available
Reserves			
-Share premium reserve	61,754	A,B	61,754
-Stock option plan reserve	-	-	-
-Fair value reserve	-		-
-Other reserves			
- Shareholders' advance payment for share capital increase	(11)	-	-
- Actuarial valuation reserve	45	A,B	45
- Unexercised rights 2014 reserve	178	A,B	178
- Unexercised rights 2015 reserve	(56,067)	-	-
-Retained earnings (accumulated losses)	-		

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 143 thousand at December 31, 2018 (Euro 147 thousand at December 31, 2017).

Changes in the period are reported below:

(amounts in Euro thousand)	December 31, 2018	December 31, 2017
Opening balance	**147**	**146**
Uses	(6)	-
Other movements	-	-
Financial loss	0	1
Actuarial (gain)/loss	2	-
Total liabilities for pensions and employee severance indemnity (TFR)	**143**	**147**

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, 2018, the Iboxx Corporate AA discount rate was used with seven to ten year 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, 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: 1.13%
- Annual inflation rate: 1.50%
- TFR annual increase rate: 2.625%
- 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 %
143	142	144	144	141	140	145

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: 8.6

Note 14 – Trade payables (non-current)

Non-current trade payables amounted to Euro 200 thousand at December 31, 2018. They refer to the non-current portion of the deferred income relating to GSK's upfront payment arising from the agreement signed on March 19, 2015 (taken over by Orchard Therapeutics in 2018), and recognized in the income statement over the term of the relevant agreement.

Note 15 – Other liabilities (non-current)

Other non-current liabilities amounted to Euro 3,611 thousand at December 31, 2018. Their breakdown is as follows:

(amounts in Euro thousand)	**December 31, 2018**	**December 31, 2017**
Project pre-financing payments	964	964
Other debts	333	-
Deferred income relating to the Bresso	2,314	2,647
Total cash and cash equivalents	**3,611**	**3,611**

The item mainly consists of:

- Deferred income relating to the Bresso facility to the tune of Euro 2,314 thousand. This item mainly includes the deferred income relating to costs incurred for the new 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 million, shall be borne by the property's owner. As provided for by the agreement, the Company shall transfer 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. The Company continued recognizing Euro 333 thousand, representing the depreciation for the next 12 months, as current liabilities. For further details, reference should be made to **Note 17**.

The Euro 333 thousand decrease in the year 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, 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;

- an increase relative to the booking of the short-term portion of the payable due to Mr. Bordignon in connection with the recognition - during the third quarter of the year - of the lump sum payment totaling Euro 800 thousand, gross of the withholdings required by law and due to the former Chairman of the Board of Directors following the termination of the employment relationship with the Company on September 24, 2018 as well as the 24-month non-compete agreement provided for in the contract stipulated on January 26, 2017. Disbursement of the fee was paid in installments over 24 months, thereby generating, net of the amounts previously recognized during 2018, a non-current payable for an amount of Euro 333 thousand and a current payable for an amount of Euro 412 thousand.

Note 16 – Trade payables

Trade payables amounted to Euro 9,620 thousand at December 31, 2018, compared to Euro 9,766 thousand at December 31, 2017, and are broken down as follows:

(amounts in Euro thousand)	**December 31, 2018**	**December 31, 2017**
Trade payables	7,547	8,542
Deferred income concerning revenues pertaining to future periods	2,073	1,224
Total trade payables	**9,620**	**9,766**

At December 31, 2018, payables to suppliers included Euro 6,815 thousand due in Italy, Euro 497 thousand due in other European Union countries and Euro 235 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 the first months of 2019. The item, which increased by Euro 849 thousand compared to the amount booked at the end of the previous year, is essentially linked to:

- Euro 1,100 thousand for the booking of deferrals recorded in relation to the agreement signed with GSK, the latter replaced by Orchard Therapeutics during 2018. The agreement and its subsequent

amendments provide for the recognition of deferred income relating to the up-front payment and advances recorded in the income statement over the duration of the agreement and when the service is actually provided, respectively;

- Euro 973 thousand for the booking of deferred income booked in relation to invoices receivable from customers which were issued, as required by the contract, in advance with respect to the actual moment of service provision.

Note 17 – Other liabilities

This item is broken down as follows:

(amounts in Euro thousand)	December 31, 2018	December 31, 2017
Amounts due to employees for holidays and bonuses	1,474	1,667
Amounts due to social security institutions	551	702
Tax payables	360	344
Other payables	762	776
Deferred income (Bresso)	378	438
Total other liabilities	**3,525**	**3,927**

Amounts due to employees for holiday and bonus pay decreased by Euro 193 thousand, from Euro 1,667 thousand at December 31, 2017 to Euro 1,474 thousand at December 31, 2018.

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 2018, paid to the authorities the following month.

The Company recorded tax losses in the two periods considered; it has no taxable income for IRAP purposes.

The item Other payables was mostly unchanged, with a slight change of Euro 14 thousand.

Accruals and Deferred income mainly relates to the current portion (Euro 333 thousand) of depreciation for the next 12 months of an amount equal to Euro 4 million, recorded as tangible assets and charged to the owner of the property in the “Open Zone” park in Bresso. For further details, reference should be made to **Note 15**.

5. Notes to the income statement

Note 18 – Revenues from customers

(amounts Euro thousand)	**Year 2018**	**Year 2017**
Revenues from development and manufacturing activities	24,224	20,500
Revenues from Zalmoxis®	4,223	2,500
Total operating revenues	**28,447**	**23,000**

Sales revenues amounted to Euro 28,447 thousand in 2018, compared to Euro 23,000 thousand in 2017, broken down as follows:

- Euro 24,224 thousand revenues arising from development and production activities on behalf of third parties (including Euro 1,016 thousand for milestones) and increasing by Euro 3,724 thousand compared to the prior year (+18.2%);

- revenues from the Zalmoxis® product equal to Euro 4,223 thousand, consisting of (i) the milestones deriving from the Zalmoxis® license and distribution agreement signed on July 26, 2017 with Dompé for Euro 4,000 thousand, including Euro 3,000 thousand following the agreement for the consensual termination of the contract and (ii) the sale of the product under the Aifa fund regime for Euro 223 thousand.

Revenues from sales are distributed as a percentage of 19.1% in Italy, 71.5% within the European Community and 9.4% outside the European Community.

Note 19 – Other income

This item, amounting to Euro 1,433 thousand, mainly consists of public sector research and development grants and is broken down as follows:

(amounts in Euro thousand)	**Year 2018**	**Year 2017**
Other revenues	1,433	987
Total other income	**1,433**	**987**

At December 31, 2018, other income, recognized as part of operating revenues and amounting to Euro 1,433 thousand (compared to Euro 987 thousand in 2017), mainly consists of:

- tax receivables pursuant to “Decree dated May 27, 2015 implementing tax credit for research and development” amounting to Euro 1,041 thousand;
- Euro 372 thousand income relating to research and development grants the Company received based on its participation in public-sector subsidized projects;

Note 20 – Purchases of raw materials and consumables

This item is broken down as follows:

(amounts in Euro thousand)	Year 2018	Year 2017
Processing materials	2,011	1,518
Reagents	3,011	3,141
General laboratory materials	665	639
Maintenance materials	180	77
Total purchases of raw materials and consumables	**5,867**	**5,375**

The costs for raw materials and consumables, which largely consist of materials and reagents used in production and development activities, rose from Euro 5,393 thousand at the end of 2017 to Euro 5,867 thousand at the end of 2018. The Euro 474 thousand increase (+16.3%) is mainly due to growing activities concerning the products in the pipeline.

Note 21 – Costs for services

The breakdown of this item at December 31, 2018 and December 31, 2017 is as follows:

(amounts in Euro thousand)	Year 2018	Year 2017
Outsourced development costs	3,956	2,348
Consultancy and technical fees	692	619
License and patents consultancy fees	490	1,004
Maintenance	1,128	898
Transport and storage of laboratory materials	535	581
Utilities	1,139	1,172
Directors and statutory auditors' fees	391	374
Audit	77	74
Legal, administrative and managerial fees	669	550
Listing consultancy fees and other listing costs	149	68
Supervisory board fees	96	112
Communications agency fees	261	904
IT assistance and other IT costs	435	338
Other general and administrative costs	995	916
Ttravel, staff training and othe personnel costs	704	849
Total costs for services	**11,717**	**10,807**

Costs for services slightly increased from Euro 10,807 thousand at December 31, 2017 to Euro 11,717 thousand at December 31, 2018. The Euro 910 thousand increase in the period is mainly attributable to the following combined effects:

- higher outsourced development costs, increasing from Euro 2,348 thousand in 2017 to Euro 3,956 thousand in 2018 (+68.5%) due to an extended pipeline;

- maintenance costs, increasing from Euro 898 thousand in 2017 (+25.6%) to Euro 1,128 thousand in 2018, after revamping of both facilities;
- the reduction in license fees and patent costs from Euro 1,004 thousand in 2017 to Euro 490 thousand in 2018 (-51.2%). 2017 figures included the recognition of the second milestone tranche amounting to USD 500 thousand (Euro 422 thousand) concerning the development of Zalmoxis®, after the Conditional Marketing Authorization (CMA) was granted;
- market access costs, decreasing from Euro 904 thousand in 2017 to Euro 261 thousand in 2018, mainly due to pricing and reimbursement advisory services in relation to Zalmoxis® ended in 2017;
- an increase of Euro 119 thousand from Euro 550 thousand in 2017 to Euro 669 thousand in 2018 due to legal and notary fees. The increase is mainly ascribable to legal consulting fees for the finalization of the consensual agreement undersigned with Dompé on November 12, 2018;
- a decrease of Euro 145 thousand - from Euro 849 thousand in 2017 to Euro 704 thousand in the year 2018 - in costs related to training, travel expenses and other personnel costs. The decrease is linked to 2017 costs related to organizational HR consultancy fees.

Note 22 – Costs for use of third-party assets

(amounts in Euro thousand)	**Year 2018**	**Year 2017**
Rental of premises	1,322	1,300
Other rentals	185	172
Total costs for use of third-party assets	**1,507**	**1,472**

Costs for use of third-party assets of Euro 1,507 thousand in 2018 are broadly in line with the prior year (Euro 1,472 thousand).

Note 23 – Personnel costs

These costs are broken down as follows:

(amounts in Euro thousand)	Year 2018	Year 2017
Wages and salaries	10,199	9,317
Social security contributions	2,446	2,545
Defined contribution plans	227	875
Stock option costs	-	151
Other personnel costs	30	40
Total personnel costs	**12,902**	**12,928**

Personnel costs are in line with the previous year (+5.0%), slightly decreasing from Euro 12,928 thousand in 2017 to Euro 12,902 thousand in 2018. The change in these costs is mainly due to the saving arising from the cancellation of the roles of General Manager and Head of Strategic Affairs in 2017, offset by the recognition in 3Q of a one-off gross compensation of Euro 800 thousand in favor of Mr. Bordignon who resigned from his office as Chairman of the Board of Directors on September 24, 2018 (for further details, reference should be made to Note 35 in this report).

In 2018 the average number of employees was 199 (185 in 2017). The number of employees at December 31, 2018 was 206, broken down by position as follows:

	Year 2018	Year 2017
Executives	9	9
Middle management	33	32
Clerical staff	160	141
Technicians	4	4
Total	**206**	**186**

Note 24– Other operating costs

The item “Other operating costs” of Euro 105 thousand at December 31, 2018 is broken down below and compared with figures at December 31, 2017.

(amounts in Euro thousand)	Year 2018	Year 2017
Printed and promotional materials	2	3
Stationery	13	18
Entertainment costs	18	27
Membership fees	50	59
Books and magazines	8	17
Other costs	14	62
Total other operating costs	**105**	**186**

Note 25 – Amortization, depreciation and impairment

Amortization, depreciation and impairment totaled Euro 1,647 thousand in 2018. They increased by Euro 298 thousand compared to the previous year (Euro 1,349 thousand) following the beginning of the amortization/depreciation period for the assets relating to the new facility in Bresso. Investments in the year of Euro 1,739 thousand mainly concerned the need to bring new production facilities online following the acquisition of new customers, and to routine replacement of laboratory equipment, where necessary, to the purchase of new equipment used in the production process, as well as to maintenance and improvement work on the existing GMP facility.

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 15**.

(amounts in Euro thousand)	**Year 2018**	**Year 2017**
Amortization of intangible assets	153	116
Depreciation of intangible assets	77	-
Amortization of tangible assets	1,750	1,566
Pro-quota ammortization Bresso	(333)	(333)
Total amortization, depreciation & write-downs	**1,647**	**1,349**

Note 26 – Financial income and charges

This item is broken down as follows:

(amounts in Euro thousand)	**Year 2018**	**Year 2017**
FINANCIAL INCOME:		
Interest and other financial income	32	20
Exchange gains	16	184
Total financial income	**48**	**204**
FINANCIAL CHARGES:		
Exchange losses	(14)	(24)
Other charges	(292)	(529)
Total financial charges	**(306)**	**(553)**
Total financial income (charges)	**(258)**	**(349)**

The Company's financial activities generated a negative result of Euro 258 thousand, a decrease of Euro 91 thousand compared to 2016.

Financial income decreased by Euro 156 thousand from Euro 204 thousand at December 31, 2017 to Euro 48 thousand at December 31, 2018. Such decrease is mainly attributable to foreign exchange gains.

Financial charges amounted to Euro 306 thousand in 2018, a decrease (-44.7%) compared to 2017. The decrease is mainly due to the decrease in other financial charges on commissions incurred in 2017 and resulting from the underwriting of three installments in relation to the one installment underwritten in 2018 within the SEF “Standby Equity Facility” agreement signed with Société Générale.

Note 27 – Income taxes

No current or deferred taxes were recorded at the date of this Report.

As in the previous reporting periods, 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, 2018 the tax losses to be carried forward totaled Euro 208,572 thousand and the theoretical deferred tax assets totaled Euro 50,057 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, 2018 and 2017:

(amount in Euro thousand)	December 31, 2018			December 31, 2017		
	Temporary differences amount	Rate	Tax effect	Temporary differences amount	Rate	Tax effect
Directors' fees	-	24.00%	-	-	24.00%	-
Manteinance in exceeds	1,004	24.00%	241	583	24.00%	140
Other temporary differences	131	24.00%	31	27	24.00%	6
Bad Debt provision	29	24.00%	7	29	24.00%	7
Start up losses	1,552	24.00%	372	1,552	24.00%	372
Tax losses carrid forword	205,856	24.00%	49,405	201,365	24.00%	48,328
Total deferred tax assets	**208,572**		**50,057**	**203,556**		**48,853**
Other temporary differences	-	24.00%	-	138	24.00%	33
Total deferred tax liabilities	**-**		**-**	**138**		**33**

Note 28 – Basic and diluted earnings (loss) per share

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

(amounts in Euro)	FY 2018	FY 2017
Basic earnings/(loss) per share	(0.0089)	(0.0194)

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 recorded in 2018 and 2017 – Euro 4,123 thousand and Euro 8,497 thousand, respectively – and on the weighted average number of ordinary shares outstanding in the relevant periods – 463,450,672 and 437,236,661, respectively.

6. Other notes

Note 29 – Net financial position

The net financial position, based on the format provided for by Consob Communication 6064293 of July 28, 2006, is provided below:

(amounts Euro thousand)	December 31, 2018	December 31, 2017
Cash on hand	8	12
Other cash	15,499	13,093
Cash equivalents	-	-
A. Total cash and cash equivalents	**15,507**	**13,105**
B. Current financial receivables and other financial assets	**959**	**5,006**
Finance lease payables	-	-
Current financial Debts	-	-
C. Current financial debt	-	-
D. Net current financial position (A+B+C)	**16,466**	**18,111**
Finance lease payables	-	-
Non current financial Debts	-	-
E. Non-current financial debt	-	-
F. Net financial position (D+E)	**16,466**	**18,111**

Net financial position was positive to the tune of Euro 16,466 thousand at December 31, 2018. It only consists of cash and cash equivalents and current financial receivables (corporate bonds), since no financial debt is recognized.

Note 30 – Contingent liabilities, commitments, and guarantees

Contingent liabilities

With specific reference to the Zalmoxis® product - based on current contracts in force, and upon the occurrence of specific events - the Company could be exposed to the payment of a contingent liability for a total maximum amount of USD 1,950 thousand. The conditions that could determine the payment of this contingent liability are the following:

- at time of occurrence of the first of the following three events, the payment of USD 800 thousand is envisaged as milestones:
  - ✓ conditional marketing authorization still in force within the European Community or in one of the primary markets as of August, 2021;
  - ✓ attainment of a non-conditional marketing authorization and therefore a full approval by the European Commission or by one of the main markets;
  - ✓ attainment of sales of USD 50,000 thousand.
- following attainment of a non-conditional marketing authorization and therefore a full approval by the European Commission, a milestone of USD 1,150 thousand is provided for;

With reference to CAR-CD44v6, the payment to a third party of a percentage equal to 2% on any sales of the product - and a percentage of 20% on proceeds deriving from the granting of the product license to a third party - is contractually envisaged.

Based on the co-development contract of the CAR pipeline, the Company will be required - if certain results are achieved on purchases and target IP licenses – to disburse a milestone payment for a maximum total of approximately Euro 580 thousand.

Finally, the contract for the development of the CAR-CD44v6 project with NK cells provides for the payment of milestones up to a maximum of Euro 11,700 thousand in the case of occurrence of certain events such as the beginning and end of the clinical trial, attainment of the first approval for a product and the extension of the approval itself. Royalties are also provided for on any sales for a percentage equal to 5% in countries covered by patents and 2.5% in countries not covered by patents. At the date of preparation of these financial statements, the aforementioned conditions did not occur.

Commitments and guarantees

Commitments and guarantees are broken down as follows:

(amounts in Euro thousand)	**December 31, 2018**	**December 31, 2017**
Guarantees	439	1,718
Total guarantees and commitments	**439**	**1,718**

Euro 363 thousand refer to the guarantees issued for the payment of real estate leases, Euro 75 thousand refer to the guarantees issued in favor of Università Vita Salute San Raffaele for commitments undertaken by the Company in relation to the funding of research scholarships.

Note 31 – Share-based payments

2008 stock option plan

Pursuant to the Shareholders' Meeting resolution dated October 29, 2007 on a capital increase with consideration, the Board of Directors, pursuant to the powers granted to it, approved the rules of a share-based incentive scheme, as amended on October 11, 2010, under which the Company's executive directors, consultants, and employees may receive two different types of options, in one or more tranches:

- type A options: vesting at the end of the third year from the date on which the Company's shares start to be traded on the MTA; these may be exercised in a single tranche, starting from the vesting date and up to a deadline of seven years from the vesting date;
- type B options: vesting is subject to achievement of specific business objectives, identified by the Board of Directors upon granting and, in any case, no earlier than the end of the third year from the grant date. The options may be exercised in one or more tranches, starting from the vesting date and up to a deadline of seven years from the vesting date.

At the meetings on May 9, 2011 and June 24, 2013, the Board of Directors acknowledged that the vesting condition for the first and second tranches of type B options was not met; therefore, all type B options have expired.

Following the approximately Euro 57.9 and 50 million capital increases made in 2010 and 2015 respectively, the Board of Directors approved the amendments to the rules of the mentioned stock option plan to maintain the substantial value of the options by adjusting the strike price of those not yet exercised, as required by said rules.

It should be noted that the exercise period of the type A options for the 2008 stock option plan ended on March 5, 2018; for this reason, these options are to be considered expired.

2016-2021 stock option plan

On November 7, 2016, the Shareholders' Meeting of the Company approved the 2016-2021 stock option plan pursuant to Article 114-bis of the Consolidated Law on Finance and vested the Board of Directors with the power of implementing the plan in compliance with the terms and conditions provided for by the Regulations.

The 2016-2021 stock option plan is reserved for the Company's executive directors, executives with strategic responsibilities, employees, and consultants, and involves granting free-of-charge options to subscribe for ordinary shares resulting from the dedicated capital increase with consideration, including in installments, and excluding pre-emption rights, up to Euro 595,250.46 (i.e. 12,643,520 ordinary shares), approved by the Shareholders' Meeting of November 7, 2016.

Therefore, on November 7, 2016, the Board of Directors granted 11,442,386 options to subscribe for an equivalent number of shares in the Company, whose vesting is conditional on the achievement of specific performance targets. The strike price of the options granted was set at Euro 0.3878.

It should be noted that – as of the closing date of the 2018 financial statements - the reserve relative to the 2016-2021 stock option plan was released given that it is highly probable that the conditions for exercising the options will not be met.

For more information on the 2016-2021 stock option plan, see the relevant disclosure on the Company's website.

Note 32 – Transactions with related parties

As of December 31, 2018, the Company has no relations with related parties.

Note 33 – Significant non-recurring events and transactions

Pursuant to Consob Communication of July 28, 2006, it should be noted that during 2018 the Company carried out a capital increase, which qualify as significant non-recurring transaction:

(importi in migliaia di Euro)	Patrimonio netto		Risultato dell'esercizio		Flussi finanziari	
	Valore	%	Valore	%	Valore	%
Valore	**23.595**	**%**	**(4.123)**	**%**	**2.402**	**%**
Effetto aumento di capitale SEF 2016	(3.108)	(13%)	-	0%	(3.108)	(129%)
Costi relativi all'aumento di capitale SEF 2016	25	0%	155	0%	180	8%
Valore figurativo lordo	**20.512**		**(3.968)**		**(526)**	

Note 34 – Transactions resulting from atypical and/or unusual events

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

Note 35 – Fees due to Directors and Statutory Auditors

Pursuant to Article 78 of Consob Regulation no. 11971 of May 14, 1999, as subsequently amended, concerning the adoption of regulations implementing Legislative Decree no. 58 of February 24, 1998 (*Testo Unico Draghi*) on the provisions governing issuers, the following disclosure is provided in relation to the fees paid to the Directors and Statutory Auditors.

(importi in Euro migliaia)

Name Surname	Carica ricoperta	Periodo per cui è stata ricoperta la carica	Scadenza della carica	Compensi fissi	Compensi fissi CdA	Gettoni presenza CdA	Compensi fissi Comitati	Gettoni presenza Comitati	Compensi variabili non equity		Benefici non monetari	Altri compensi	Totale	Fair value dei compensi equity	Indennità fine carica o cessaz. rapporto di lavoro
									Bonus, altri incentivi	Partecip. a utili					
AMMINISTRATORI - Consiglio di Amministrazione in carica dal 18 aprile 2016															
Claudio Bordignon	Presidente	01.01.2018-24.09.2018		293							71				800
Carlo Incerti*	Presidente	01,01.2018-31.12.2018	Approv. bilancio es. 2018	67	9	9									
Riccardo Palmisano	Amministratore Delegato	01.01.2018-31.12.2018	Approv. bilancio es. 2018	450					123		14				
Allberto Carletti	Consigliere	01.01.2018-31.12.2018	Approv. bilancio es. 2018		12	11									
Laura Iris Ferro	Consigliere	01.01.2018-31.12.2018	Approv. bilancio es. 2018		12	10	5	3							
Sabina Grossi	Consigliere	01.01.2018-31.12.2018	Approv. bilancio es. 2018		12	11	15	8							
Mario Masciocchi	Consigliere	01.01.2018-31.12.2018	Approv. bilancio es. 2018		12	10	23	8							
Alfredo Messina	Consigliere	01.01.2018-31.12.2018	Approv. bilancio es. 2018		12	10									
Elisabeth Robinson	Consigliere	01.01.2018-31.12.2018	Approv. bilancio es. 2018		12	10	15	8							
Raffaella Ruggiero	Consigliere	01.01.2018-31.12.2018	Approv. bilancio es. 2018		12	11	8	3							
Didier Trono	Consigliere	01.01.2018-31.12.2018	Approv. bilancio es. 2018		12	10	5	2							
				810	**105**	**92**	**70**	**32**	**123**	**-**	**85**	**-**	**-**	**-**	**800**
SINDACI - Collegio Sindacale in carica in carica dal 18 aprile 2016															
Riccardo Perotta	Presidente Coll.sindacale	01.01.2018-31.12.2018	Approv. bilancio es. 2018	30											
Enrico Scio	Sindaco effettivo	01.01.2018-31.12.2018	Approv. bilancio es. 2018	20											
Flavia Daunia Minutillo	Sindaco effettivo	01.01.2018-31.12.2018	Approv. bilancio es. 2018	20											
				70	-	-	-	-	-	-	-	-	-	-	
DIRIGENTI CON RESP. STRATEGICHE - non ci sono dirigenti con responsabilità strategiche															
				-	-	-	-	-	-	-	-	-	-		

* i compensi fissi si riferiscono al periodo 24/09/2018 al 31/12/2018 a seguito della nomina a Presidente del Consiglio

On April 18, 2016, the Board of Directors resolved to pay the Company's Chairman Claudio Bordignon a gross fixed remuneration of Euro 400 thousand per year to carry out its duties. The Board of Directors also resolved to pay Mr. Bordignon Euro 800 thousand, gross of taxes, as compensation for the 24-month non-competition obligation after the end of his term of office for whatever reason. Such amount is to be paid in a lump sum at the end of his term of office and should it not be renewed. A penalty shall apply if the obligation is not fulfilled. In this regard, it should be noted that, following the resignation of Mr. Claudio Bordignon from the office of Chairman and Director on September 24, 2018, the Company and the latter undersigned an agreement modifying the non-competition agreement, which provides that payment of the amount of Euro 800 thousand must be divided into 24 equal installments, paid monthly for the entire duration of the non-competition agreement.

Following the resignation of Mr. Bordignon from the office of Chairman, the Board of Directors appointed - on the same date of September 24 - the director Carlo Incerti as the new Chairman and, given the short period between the time of appointment and the natural expiration date of the mandate, deliberated in favor of the following:

(i) that the remuneration in his favor be exclusively composed of a fixed component of Euro 250 thousand gross per year to be paid pro rata temporis (including the attendance fee provided for only non-executive directors), while excluding any form of variable compensation (MBO, LTI and lump sum payments);

(ii) a professional and non-occupational accident policy similar to that stipulated for the managing director, as well as the reimbursement of expenses incurred as a result of his office.

On April 18, 2016, the Board of Directors resolved to pay the Company's CEO Riccardo Palmisano a gross fixed remuneration of Euro 450 thousand per year. The Board of Directors also resolved to pay Mr. Palmisano Euro 225 thousand, gross of taxes, as compensation for the 24-month non-competition obligation required by the Company after the end of his term of office for whatever reason. Furthermore, the Board resolved that compensation equal to the CEO's overall annual remuneration of Euro 450 thousand will be paid if his appointment as CEO is revoked without fair reason before the end of current Board's term of office, or before the date of approval of the Financial Statements at December 31, 2018.

No agreements have been signed by other Directors, and no compensation was paid to Directors resigning from their office in the period.

Note 36 – 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 2018 and 2017 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.

(importi in migliaia di Euro)	**Soggetto che ha erogato il servizio**	**Corrispettivi esercizio 2018**	**Corrispettivi esercizio 2017**
Revisione contabile	EY S.p.A.	77 (1)	74 (1)
Servizi di attestazione	EY S.p.A.	-	-
Totale		**77**	**74**

(1) Revisione contabile del bilancio d'esercizio, revisione contabile limitata della relazione finanziaria Semestrale, verifica della regolare tenuta della contabilità e della corretta rilevazione dei fatti di gestione nelle scritture.

Note 37 – 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 financial 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 instruments.

Interest rate risk

The Company has no financial payables or receivables. Cash and cash equivalents were invested in current account deposits and bonds. Their yield depends on the trend in short-term interest rates. In order to limit the risk of counterparties' default in performing their obligations, investments were made at top-flight banks and financial institutions with high credit ratings, in order to diversify the counterparty risk.

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, 2018 and 2017, 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.

(importi in migliaia di Euro)	**Esercizio 2018 effetto sui proventi finanziari**		**Esercizio 2018 effetto sulla riserva *fair value***	
Shift rispetto a zero-coupon	**+1%**	**-1%**	**+1%**	**-1%**
Effetto	155	(155)	-	-

Currency risk

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

Credit risk

This is the risk that a client or counterparty causes a loss by defaulting on an obligation and it is primarily related to financial transactions. Given the nature of the Company's business, and the relevant asset structure, the Company is subject to limited credit risk. The maximum credit risk relating to the Company's current assets, including cash and cash equivalents, other financial assets, tax receivables, trade receivables and other assets, is equal to the value of these assets in the event that the counterparty becomes insolvent. There are

no significant amounts past due. It should also be noted that all the main counterparties consist of leading financial institutions and widely recognized companies.

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, 2018, and the amount recognized in the relevant reserve.

(amounts in Euro thousand)	Measurement criteria for financial instruments in the Statutory Financial Statements					
Class of financial instruments	Financial instruments at fair value through		Financial instruments at amortized cost	Book value at December 31, 2018	Fair value at December 31, 2018	of which fair value reserve
	profit or loss	equity				
	(1)	(2)	(3)			
Assets						
Cash and cash equivalents	-	-	15,507	15,507	15,507	-
Financial assets	-	-	959	-	-	-
Trade receivables	-	-	5,470	5,470	5,470	-
Liabilities						
Trade payables	-	-	9,820	9,820	9,820	-
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, 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 Company has no indebtedness and, at December 31, 2018, it recorded a positive net financial position of Euro 16,466 thousand, consisting of cash and cash equivalents and financial receivables. 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 the financial flows generated by the Company's operations and of the net financial position, so that any necessary actions can be taken forthwith;
- monitoring of prospective liquidity conditions related to corporate planning.

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 38 – Pubblic Payments - Information pursuant to Article 1, paragraphs 125-129 of Law n.124 / 2017

With reference to the fulfillment of the obligations of transparency and public disclosure, governed by Article 1, paragraphs 125-129 of Law no. 124/2017 and subsequently supplemented by the 'security' decree law (n. 113/2018) and by the 'simplification' law decree (n. 135/2018), which introduced, starting from the financial statements for the 2018 financial year, a series of obligations of publicity and transparency for the subjects that have economic relations with the Public Administration and in the light of the interpretation made by Assonime with the Circular n. 5 of 22 February 2019, it is considered that the legislation does not apply in cases of:

- ✓ subsidy, grants, contributions and economic advantages of any kind, the advantages of which are accessible to all companies that meet certain conditions on the basis of predetermined general criteria (for example, measures envisaged by ministerial decrees aimed at specific industrial sectors and aimed at finalizing project-related activities research and development);
- ✓ general measures that can be used by all companies and that fall within the general structure of the reference system defined by the State (for example the mechanism aimed at favoring the reinvestment of profits envisaged by the ACE);
- ✓ public resources from European / foreign sources;
- ✓ interprofessional funds for the financing of training courses, considering that the funds are financed by the contributions of the beneficiary companies themselves and are required to comply with specific management criteria based on transparency (for example training courses funded by Fondimpresa).

Considering the above, the company has analyzed its own situation and considered that it does not fall into any case involving the disclosure of Information pursuant to Article 1, paragraphs 125-129 of Law n.124 / 2017.

Note 39 – 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, 2012, based on the amendments to Articles 70 and 71 of the Issuers' Regulations introduced by Consob Resolution no. 18214 dated May 9, 2012, the Company resolved to depart from the disclosure requirement as described in paragraph 6 and paragraph 1, respectively, disclosing 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, 1999 and subsequent amendments and additions

The undersigned, Mr. Carlo Incerti, Chairman of the Board of Directors, 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, 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, 2018;
- measurement of the adequacy of the administrative and accounting procedures used for the preparation of the Financial Statements for the year ended December 31, 2018 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, 2018:

  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, 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 18, 2019

[Signed by]
Carlo Incerti
Chair of the Board of Directors

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

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

Dear Shareholders,

this Report illustrates the activities carried out by the Board of Statutory Auditors during the year 2018 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, 2018, 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 2018, the Board of Statutory Auditors acquired the necessary information to perform its general supervisory duties, by participating in the meetings of the Board of Directors and the board committees (i.e. the Control and Risk Management 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 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. The Board of Directors collectively provides prior approval of significant or material transactions with related parties, with the Board of Statutory Auditors' members being present. 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.

   MolMed is a medical biotechnology company, focused on the research, development and clinical validation of innovative therapies for the treatment of malignant tumors with high medical need. MolMed has developed an innovative and diversified product portfolio and specific expertise in the gene and cell therapy sector, including the use of stem cells for various diseases or tissues, ranking the Company among the key players at an international level. Furthermore, MolMed carries out customized activities on behalf of third parties for projects in this field, offering high-level expertise to develop, produce and validate experimental therapies, from the pre-clinical stage to Phase III clinical trials and, eventually, to the market,

in addition to the development of innovative control procedures that meet the requirements of the new advanced cell-based therapies.

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.

Obtaining the financial resources necessary to support the Company's development plan

It should be noted that, on October 6, 2016, the Company's Board of Directors agreed to sign a "SEF - Stand-by Equity Facility" agreement with Société Générale ("SG").

On May 24, 2018 the Company sent SG a request to underwrite a second tranche of the share capital increase reserved to it, which took place on May 25, 2018 with the issue of 6,488,279 ordinary shares corresponding to 1.42% of MolMed's share capital, for a total value of Euro 3,107,237.

At the date of the Report, the new composition of the share capital – fully underwritten and paid-up – was Euro 21,819,020.83 divided into 463,450,672 shares.

The Board of Statutory Auditors confirmed that the above-mentioned transactions comply with the law, the company by-laws and the principles of good management, having ascertained that they were not manifestly imprudent or risky, with a potential conflict of interest, that they did not conflict with the resolutions of the Shareholders' Meeting or negatively affect the Company's assets. Transactions with related parties were subject to procedures aimed at ensuring their transparency, as provided for by the relevant provisions.

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 2018 or after the reporting period. The Board of Statutory Auditors point out that the company does not hold own shares.

3. On the date hereof, 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, 2018 comply with the policies used for their preparation, they have 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, 2018. Finally, the External Auditors 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. During 2018, MolMed S.p.A. did not assign any tasks other than the financial statement audit to the External Auditors EY S.p.A., nor did it assign any tasks to entities connected to EY on the basis of continuing relations and/or to companies belonging to EY's 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.

5. During the 2018 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 audit plan.

6. During the year 2018, the Company’s Board of Directors held 11 meetings, which were all attended by the Board of Statutory Auditors.

   The Control and Risk Management Committee met 8 times. The Remuneration and Nomination Committee met 3 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 10 meetings. The Board of Statutory Auditors also took part in the Shareholders’ Meeting held on April 12, 2018.

7. 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. For the purposes of these activities the Board of Statutory Auditors relied, when necessary, on the services provided 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. In particular, the Board of Statutory Auditors monitored the organizational changes introduced in 2018, The Board of Statutory Auditors' opinion on the organizational structure, as currently modified, is positive: it appears adequate to cover the functions necessary to achieve corporate targets and suitable with respect to the size of the Company, the activities to be performed and the coordination to be implemented.

   During 2018, 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.

8. The Board of Statutory Auditors also acquired due information on organizational and procedural activities which were undertaken pursuant to Legislative Decree no. 231/2001, sharing information with the Supervisory Board on the respective checks and controls undertaken. 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.

9. 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.

   The Board of Statutory Auditors acknowledged the statements issued by the Chief Executive Office 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 2018 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.

10. The Board of Statutory Auditors ascertained, through direct assessments and based on information received from the External Auditors EY and the Management, that the Financial Statements and the Directors' Report were drafted in compliance with IASs/IFRSs (as well as with relevant rules and regulations). In particular, Directors detailed in the Directors' Report the financial risks to which the Company is exposed and, in the Notes, the activities carried out to cover financial needs.

11. 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 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 six 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.

12. 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.

13. 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, 2018.

14. 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, 2018 and has no objections to raise regarding the resolution proposals submitted by the Board of Directors about carrying forward the loss for 2018.

15. 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.

Thanking for the trust placed in it, the Board of Statutory Auditors reminds the Shareholders' Meeting that, with the approval of these financial statements, the mandate given to them expires and, therefore, invites them to decide on the matter.

Milan, April 8, 2019

The Board of Statutory Auditors

Riccardo Perotta (Chairman) [Signature]

Flavia Daunia Minutillo (Statutory Auditor) [Signature]

Enrico Scio (Statutory Auditor) [Signature]

Independent Auditors' Report

Building a better working world

MolMed S.p.A.

Financial statements as at December 31, 2018

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

EY S.p.A.
Via Meravigli, 12
20123 Milano

Tel: +39 02 722121
Fax: +39 02 722122037
ey.com

Building a better working world

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 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 2018, and the income statement, statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and the 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 2018, 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.

EY S.p.A.
Sede Legale: Via Po, 32 - 00198 Roma
Capitale Sociale Euro 2.525.000,00 i.v.
Iscritta alla S.O. del Registro delle Imprese presso la C.C.I.A.A. di Roma
Codice fiscale e numero di iscrizione 00434000584 - numero R.E.A. 250904
P.IVA 00891231003
Iscritta al Registro Revisori Legali al n. 70945 Pubblicato sulla G.U. Suppl. 13 - IV Serie Speciale del 17/2/1998
Iscritta all'Albo Speciale delle società di revisione
Consob al progressivo n. 2 delibera n.10831 del 16/7/1997

A member firm of Ernst & Young Global Limited

Building a better working world

We identified the following key audit matters:

Key Audit Matter	Audit Response
Going concern	
The Company's business model, typical of biotech companies developing new therapeutic products and not having yet reached a stable income and financial position, foresees negative cash flows, mainly related to the financing of research and development costs for products, whose return is uncertain and expected in the forthcoming years. The assumptions underlying the 2019-2021 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 the uncertainties which are typically embedded in such forecast analysis; in particular, the Company is subject to the uncertainties related to the sector in which it operates and the current stage of development of its products, regarding the results that it may achieve, as well as the related methodologies and timing. Considering the estimates and assumptions made by the Directors underlying the forecasted future results, 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. Financial statements disclosure related to the going concern assessment are reported in the notes to the financial statements at paragraph "Going concern" and in the report on the operations at paragraph "Risk associated with funding research and development activities".	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 2019 - 2021 business plan approved by the Board of Directors in February 2019 and the assessment of the events occurred after the balance sheet date. Lastly, we assessed the disclosure included in the notes to the financial statements as at 31 December 2018.

Building a better working world

Recognition of revenues from contracts with customers	
The contracts with customers signed by the Company in the development and production activities on behalf of third parties and development of new biopharmaceuticals products may include upfront payments, milestone payments (related to the achievement of specific targets or the occurrence of events contractually agreed) and royalties. The recognition of revenues from such contracts requires the Directors to identify the various elements included within the terms of the contracts, as well as the timing for their recognition. Considering the judgment required by management to perform such assessment, we deemed that this matter represents a key audit matter. 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 2018.	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 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 2018.

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, 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.

Building a better working world

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.

Building a better working world

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 18 April 2016, engaged us to perform the audits 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 2018, 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 2018 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 31 December 2018 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, 8 April 2019

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

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