

# Annual Financial Report at December 31, 2015 Approved by the shareholders' meeting of April 18, 2016

English translation for convenience

**FROM GENES TO THERAPY** 

MOLMED S.p.A. Via Olgettina, 58 - 20132 Milan, Italy Phone +39 02 21277.1 - Fax +39 02 21277.325 info@molmed.com - <u>www.molmed.com</u> Share Capital Euro 19,841,682.30 fully paid - Office of Milan Company Registry number 1506630 – Tax ID number 11887610159



From gene...

Our mission: concentrate commitment and resources on the development of new cures for cancer, by combining scientific and research excellence with a high effectiveness of business management, focused on a clear industrial project.

...to therapy



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# General corporate information

Registered office:	Via Olgettina, 58 – 20132 MILANO (Italy)
Tax Number:	11887610159
VAT Number:	IT 11887610159
Milan Company Register:	n.11887610159
REA:	1506630
Share capital:	Euro € 19,841,682.30 fully paid
Ticker <i>Borsa italiana</i> :	MLM
ISIN:	IT0001080248
Ticker Reuters:	MLMD.MI
Ticker Bloomberg:	MLM IM
Outstanding shares: (100% ordinary shares with no par value)	421,450,672

#### DISCLAIMER

This financial report may contain certain forward-looking statements. Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, 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 responsibility to update forward-looking statements or adapt them to future events or developments. This document does not constitute an offer or invitation to subscribe or purchase any securities of MolMed S.p.A.



### Corporate bodies

#### Board of Directors

Chairman Chief Executive Officer Directors Claudio Bordignon Riccardo Palmisano

Alberto Luigi Carletti Gianluigi Fiorendi Sabina Grossi Khalid Islam Mario Masciocchi (Lead Independent Director) Monica Masolo (independent) Alfredo Messina Raffaella Ruggiero (independent) Didier Trono (independent)

The Board of Directors was appointed by the Shareholders' General Meeting of 22 April 2013, holdingd office until the Shareholders' Meeting called to approve the Financial Statements at 31 December 2015.

On 8 September 2014, following resignation of Directors Romolo Bardin and Maurizio Carfagna, the Shareholders' Meeting reduced the number of members of the Board of Directors from 13 to 12 and appointed Khalid Islam as non-executive director.

On 19 March 2015, Riccardo Cortese, a non-executive independent director and member of the Remuneration Committee, announced his resignation effective from 1 April 2015.

On 22 October 2015, Marina Del Bue, Germano Carganico and Lorenzo Salieri resigned from their offices within the Board. On the same date, the Board appointed by co-optation Riccardo Palmisano and Didier Trono as non-executive Directors.

On 9 November 2015, the Board of Directors appointed by co-optation Monica Masolo as non-executive Director.

On 11 December 2015, the Shareholders' Meeting confirmed the appointment as Director of Monica Masolo (independent), Riccardo Palmisano and Didier Trono (independent).

On the same date, the Board of Directors, implementing an amendment of its governance settings, appointed Dr Riccardo Palmisano as Chief Executive Officer, transferring to him the operational powers held so far by Professor Claudio Bordignon, who maintained the position of Chairman and will keep supporting the Company - also as Chairman of the Scientific Advisory Board - in the scientific research and development activities, as well as in drawing strategic plans.

Riccardo Palmisano also serves as "Director in charge of the internal control and risk management system".

On 29 January 2016, the Board of Directors approved the establishment of a Nomination Committee, unified with the Remuneration Committee and thus renamed Remuneration and Nomination Committee.

#### Board of Statutory Auditors

Chairman Auditors

**Deputy Auditors** 

Fabio Scoyni Flavia Daunia Minutillo Enrico Scio Alberto Gallo Francesca Meneghel

The Board of Statutory Auditors was appointed by the Shareholders' General Meeting of 22 April 2013, holding office until the Shareholders' Meeting called to approve the Financial Statements at 31 December 2015.

#### Committee for Control and Risks

Chairman Members Mario Masciocchi (independent, Lead Indipendent Director) Raffaella Ruggiero (independent) Gianluigi Fiorendi

By Board resolution of 11 November 2010, the Committee for Control and Risks also carries out the function of Committee for Transactions with Related Parties.



#### ANNUAL FINANCIAL REPORT AT DECEMBER 31, 2015

#### Remuneration and Nomination Committee

Chairman Members Raffaella Ruggiero (independent) Sabina Grossi Mario Masciocchi (independent)

External Auditing Firm

Deloitte & Touche S.p.A.



#### Scientific Advisory Board

MolMed's Scientific Advisory Board (SAB), chaired by Professor Claudio Bordignon, is an independent advisory body - characteristic of companies in which the quality of projects is determined by the value of their scientific content - which plays an important role in guiding the research and development of new therapeutic strategies, and in the external objective assessment of the results obtained.

MolMed's Scientific Advisory Board offers a unique combination of knowledge and experience, provided by leading international scientists. Its membership includes:

- Claudio Bordignon, Chairman Founding member of the Scientific Council of the European Research Council, and full Professor of haematology at the University *Vita-Salute San Raffaele* in Milan (Italy)
- Carl-Henrik Heldin Branch Director of the Ludwig Institute for Cancer Research in Uppsala (Sweden), and Professor of Molecular and Cell Biology at Uppsala University
- Robert Kerbel Senior Scientist in the Molecular and Cellular Biology Research Program at the Sunnybrook Health Sciences Centre in Toronto (Canada), Professor in the Departments of Medical Biophysics and of Laboratory Medicine & Pathobiology at the University of Toronto, and Canada Research Chair in Tumour Biology, Angiogenesis and Antiangiogenic Therapy
- Jean-Paul Prieels Advisor at GSK Vaccines and Chairman of the Board of Directors of ImmuneHealth, member of the Board of Directors or of the Scientific Advisory Board of several biotech companies and research institutions focused especially on immunotherapy and cell therapy
- Alberto Sobrero Head of the Medical Oncology Unit at the clinical centre Ospedale San Martino in Genova (Italy), and former member of the Protocol Review Committee of the European Organisation for Research and Treatment of Cancer (EORTC)

The professional profiles of the members of the Scientific Advisory Board are available on the Company's website (<u>www.molmed.com</u>).



# Letter to the Shareholders

#### Dear Shareholders,

2015 was an intense and challenging year, in which we consolidated our leadership position in the field of cell and gene therapy and made important choices for the future development of the Company. All this was possible also thanks to the trust you provided again to us by supporting the capital increase successfully closed in April: a result that witnesses the progress achieved by the Company, the value of the strategic choices we made and the potential of MolMed's therapies.

During 2015, the value of the choices made both for our research activities and for the development of industrial technological expertise led to major awards and achievements.

The strive for innovation that has always inspired our research and the excellence of our achievements in the biomedical field have been confirmed at international level by the assignment to MolMed of the Annual Most Innovative EU Biotech SME Award (in the category red biotech), the prestigious award sponsored by *EuropaBio*.

Our technological and know-how leadership in the field of development and GMP manufacturing of gene therapy treatments, as well as the excellent work performed by our Company in the development of innovative products, also in collaboration with multinational pharma and biotech companies, was confirmed by the satisfying results achieved in 2015. In fact, also in the past year the turnover of the activities for third parties showed a positive trend, recording a growth of 21.4% over the previous year. The Italian healthcare authority AIFA (Agenzia Italiana del Farmaco) granted to MolMed's currently operating facility located at the Biotechnology Department (DIBIT) of the San Raffaele Hospital the authorisation to manufacture medicines for marketing purposes, thereby confirming the technical and industrial excellence reached by MolMed in the field of gene and cell therapy, thanks to years of work carried out with seriousness and dedication in order to achieve the highest quality standards for the development and production of ex vivo gene therapy treatments, not only for investigational use. Finally, we expanded the strategic partnership with GlaxoSmithKline by closing a new multi-year agreement covering production of viral vectors and cell transduction in the context of gene therapy treatments for rare diseases.

*Further confirmations were collected during 2015, including with regard to our product pipeline. The results of the study* "Tracking genetically engineered lymphocytes long-term reveals the dynamics of T-cell immunological memory", *carried out by researchers of the San Raffaele Hospital on patients enrolled in MolMed's Phase I/II trial TK007 - which were presented at the ASH congress and published by the influential journal* Science Translational Medicine - *highlighted once again the long-term effectiveness of the TK therapy, confirming the validity of the choices made so far in our efforts to develop therapies based on the engineering of the immune system for the treatment of tumours.* 

The review of the Conditional Marketing Authorisation application (filed with the European Medicines Agency in March 2014) is ongoing, and the Company has promptly fulfilled every request for insights made by the committees called upon to deliver the final opinion on the filed application, which we hope will be expressed soon.

With regard to NGR-hTNF, data presented at the ASCO 2015 meeting supported the importance of efficacy results obtained in patients with a more aggressive form of mesothelioma and most in need of treatment options, and significantly confirm the therapeutic potential of the molecule already observed in other tumour indications investigated in Phase II trials. The identification of patients who benefit most from NGR-hTNF, their extended survival time and the robust reported efficacy represent three key results of the study and, more



importantly, offer the perspective of a relevant and appropriate treatment choice for patients with poorer prognosis.

2015 was also a year when we took key decisions and progressed in implementing activities necessary for the future growth of the Company.

By acquiring the CAR-CD44v6 project, we undertook an important expansion of our pipeline, entering one of the most promising fields of new anticancer strategies, i.e. the immuno-gene therapy of tumours. Indeed, this area – beyond being a very rapidly expanding market, as witnessed by numerous agreements involving major pharmaceutical companies in the last three years - represents a natural outlet for MolMed, which has technological leadership in the field of gene therapy as its main competitive advantage, and the treatment of cancer as its mission.

Work continued for completion of the new production facility at the Open Zone science park in Bresso (Milan), which will significantly increase our current production capacity and will allow us not only to support the treatment of patients with Zalmoxis<sup>®</sup>, but also - combined with the technological leadership of the Company in the field of therapies for rare genetic diseases and immune-gene therapy of tumours - to strengthen MolMed's position as strategic partner for major international pharmaceutical and biotech companies.

In 2015, important strategic decisions were made also as regards the Company's corporate governance and organisation structure, in order to enrich it with new skills and provide it with a more streamlined organisation, focused on the priorities that our company is getting ready to tackle: Dr Riccardo Palmisano, whose expertise in terms of market access and business development is well known, was appointed CEO, and the Company's organisation structure was renewed in order to achieve more responsive and faster internal decision-making processes, while at the same time enhancing the talents of our resources. This will allow us to make increasingly targeted decisions with a view to accelerating the integration process between science and market, while ensuring the continuity of the Company's excellence.

I am proud, and I hope that You share this feeling with me, of the efforts and commitment that led MolMed to be one of the leading players at international level in the promising field of gene and cell therapy, and a pioneer in the area of tumour immune gene therapy, thus also making MolMed an ideal partner for pharma and biotech companies in the field of haematopoietic stem cell transduction. These achievements represent the extent of our Company's most profound value. In recent years, research opened new scenarios in the treatment of cancer, and MolMed is ready to face the resulting challenges as a major player.

On behalf of the Company, let me assure You that we will continue to strive and devote our best efforts to the growth of MolMed, in the common interest of patients and investors.

I would like to thank You all again for the trust and support You have shown us this far.

[Signed by]

Claudio Bordignon, Chairman



# **1.** A history of excellence

MolMed is a medical biotechnology company established in 1996, focused on research, development and clinical validation of novel anti-cancer therapies.

Born as a spin-off of the San Raffaele Scientific Institute devoted to research in the field of gene and cell therapy - applied both to rare genetic diseases and to haematological malignancies - from year 2000 MolMed extended the scope of its activities from service to product company, with a primary focus on novel anticancer therapies. Today, MolMed is an established business, with the capability to cover all functions of a biotech product company, from basic research to manufacturing, up to clinical validation of its investigational therapeutics.

MolMed's approach to cancer therapy is characterised by an integrated strategy, aimed on one side at identification and development of bio-pharmaceuticals reducing the tumour mass and slowing down its growth, and on the other side at the development of highly selective therapies to eliminate residual tumour tissue. Its investigational therapies are new, completely original and first-in-class of new therapeutic classes.

MolMed's pipeline includes three anti-tumour therapeutics in clinical and preclinical development, with the first two in Phase III clinical trials: Zalmoxis<sup>®</sup> (TK), a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, currently in Phase III in high-risk acute leukaemia and under evaluation by EMA for a Conditional Marketing Authorisation; NGR-hTNF, a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the cancer and to the concentration of immune system cells into the tumour mass, currently investigated in a broad clinical programme, involving more than 1000 treated patients; CAR-CD44v6, an immuno-gene therapy project potentially effective for many haematological malignancies and several epithelial tumours, currently in preclinical development. MolMed also offers top-level expertise in cell and gene therapy to third parties to develop, conduct and validate projects from preclinical to Phase III trials, including scale-up and cGMP production of clinical-grade viral vectors, and manufacturing of patient-specific genetically engineered cells.

MolMed has the status of Pharmaceutical Company (*Officina farmaceutica*), granted by the Italian healthcare authority AIFA (*Agenzia Italiana del Farmaco*) for its GMP facility located at the biotechnology department of the San Raffaele hospital (DIBIT) and carries out all activities in compliance with the guidelines on best practices for the production of genetically modified patient-specific cells and of active pharmaceutical ingredients.

In 2013, MolMed started a major project at the Open Zone science park in Bresso (Milan), aimed at expanding its manufacturing capacity; upon its completion, MolMed will be endowed with a second GMP facility assuring the highest qualitative standards and technological expertise already recognised to the manufacturing site at the DIBIT.

Thanks to its consolidated leadership in cell and gene therapy, MolMed has entered into agreements with some of the major players in this field, including *Fondazione Telethon* and GlaxoSmithKline, for the provision of development, manufacturing and knowledge transfer services for the clinical application of gene therapies based on viral vector cell transduction. In addition, in 2003 the Company has entered into a strategic alliance with Takara Bio, an important Japanese biotechnology company listed on the Tokyo Stock Exchange, through co-development and out-licensing agreements for MolMed's cell-based therapies in major Asian markets

Since March 2008, MolMed is a public company listed on the main market (MTA) of the Milan Stock Exchange managed by *Borsa Italiana* (Ticker Reuters: MLMD.MI).



# 2. Our challenge: fighting cancer

MolMed's activities are focused on medical oncology, the therapeutic area devoted to cancer treatment. Cancer (i.e. tumour or neoplastic disease) is any type of malignant cell growth caused by abnormal and uncontrolled local cell proliferation that can have origin in different tissues, and its spread to other organs through the lymphatic system or the blood stream, giving origin to metastases.

In fact, cancer is actually a wide and heterogeneous group of diseases, made up of over 200 different types of tumour, commonly divided into two broad categories: solid tumours, and blood tumours (or haematological malignancies).

Conventional treatment options available for solid tumours are surgery, radiotherapy and pharmacotherapy (or chemotherapy). Early surgical removal is potentially curative for some tumour types. But, sometimes, surgical treatment proves not to be sufficient, and the surgical option is unavailable for patients with advanced and/or metastatic disease. In this case, available options are only radio- and pharmacotherapy, often used in sequential combination. In haematological malignancies settings (e.g. leukaemia and lymphomas), radio- and pharmacotherapy are often followed by transplants of haematopoietic stem cells.

Within pharmacotherapy, the most commonly used regimens are based on cytotoxic agents, known as chemotherapies and characterised by high toxicity, lack of specificity and loss of efficacy over time, leading patients to undergo a particular line of treatment until they become refractory or reach the maximum tolerated cumulative toxicity, and then having to switch to another line of treatment (when available).

Clinical benefits limited over time and high levels of toxicity of current standard treatments translate into a significant level of unmet medical need in oncology, making it an area of high intensity in terms of research and development investments, with high potential for new therapies based on a better understanding of the mechanisms implied in tumour genesis and growth, and thus able to provide increased selectivity, reduced toxicity, enhanced therapeutic efficacy and improved survival of patients.

According to a report published by IMS Health in 2014<sup>1</sup>, oncology currently represents the largest segment of the global pharmaceutical market, and the fifth fastest-growing. In Europe, the United States and Japan, cancer is the second most common cause of death, and recently an increase in incidence has been observed. This phenomenon is due to a combination of several factors, first of all to the ageing of the population worldwide, due to improved nutrition, living standards and treatment of many chronic diseases: this leads per se to an increased incidence of cancer, as the risk of all tumours increases with age. Moreover, as treatments for cancer become more effective in prolonging patient survival the number of affected people increases, and the fall of mortality leads to a general increase of prevalence, i.e. of the number patients living with the disease.

The very high level of unmet medical need in oncology has driven the emergence of the so-called innovative therapies, either biologics or anyway biotechnology-derived. Such innovative therapies have as a common trait the fact of being specific and/or targeted, i.e. directed at specific molecular targets involved in tumour genesis and/or tumour growth, and thanks to their targeted action they have a remarkably lower systemic toxicity as compared to conventional regimens.

The molecular targets of novel therapeutics may be tumour type-specific, or common to different tumour types, or specific to the blood vessels feeding the tumour mass or to the factors supporting their formation and growth:

<sup>&</sup>lt;sup>1</sup> IMS Health, *Top 20 Global Therapy Areas* 2014, IMS Health, 2014.



in the second and third case, they offer the potential for application of a therapy in several different oncology indications.

Finally, novel targeted therapies often can act both as single-agent alternatives, and as enhancers of or in synergy with existing treatments. The current focus in tumour therapy improvement is to use a combination of different classes of agents rather than a single therapeutic approach: the introduction of next-generation biotech-derived cancer therapies could enable further extension of patients' survival and improvement of their quality of life, eventually reducing tumours from rapidly progressing and life-threatening diseases to well-managed chronic pathologies.

The investigational therapeutics and/or therapeutic strategies developed by MolMed belong to the context of novel anti-tumour biologics.

# 3. MolMed's activities: research, development and production

#### 3.1 *R&D*: targeted therapies for the treatment of severe and high-risk tumours

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

On the one hand, MolMed is addressing tumours considered to be uncommon - although with ever-growing incidence because of exposure to environmental conditions that contribute to disease onset - that have no or very few therapeutic options available, such as high-risk leukaemia, malignant pleural mesothelioma, primary liver cancer, small-cell lung cancer (SCLC) and soft-tissue sarcomas.

On the other hand, 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 either intolerant (because reaching cumulative toxicity) or refractory (because of loss of disease control over time) to all possible treatment lines. For these heavily pre-treated patients with no effective treatment lines left, MolMed devotes its efforts to offer a new therapeutic option.

MolMed's product pipeline is characterised by two anticancer therapeutics in advanced clinical development, Zalmoxis® (TK) and NGR-hTNF, and by a cancer immuno-gene therapy project, CAR-CD44v6 in preclinical development.



			Preclinical	Phase I	Phase II	Phase III
ТК Н	igh Risk Leukaemia	TK007 TK008				Random
NGR-hTNF	Solid Tumours	NGR001 (low doses) NGR002 (low doses) NGR003 (+ doxorubicin) NGR013 (high doses)				
	Mesothelioma 2 <sup>nd</sup> line (Orphan Drug) 2 <sup>nd</sup> line 1° line maintenace	NGR015 (+ B.I.C.) NGR010 (monotherapy) NGR019 (monotherapy)			Random	Random
	NSCLC 1 <sup>st</sup> line ≥ 2 <sup>nd</sup> line	NGR014 (+ cisplatin) NGR004 (+ cisplatin)			Random	
	Ovarian Cancer ≥ 2 <sup>nd</sup> line ≥ 2 <sup>nd</sup> line	NGR012 (+ doxorubicin) NGR018 (+ doxorubicin)			Random	
5	oft Tissue Sarcoma ≥ 1 <sup>st</sup> line Colorectal Cancer	NGR016 (+ doxorubicin)		I	Random	
	≥ 3 <sup>rd</sup> line ≥ 2 <sup>nd</sup> line Liver Cancer	NGR006 (monotherapy) NGR005 (+ Xelox)		[		
	$(Orphan Drug) \ge 2^{nd} line$ SCLC $\ge 2^{nd} line$	NGR008 (monotherapy) NGR007 (+ doxorubicin)		[		
CAR CD44v6 Solid		Preclinical	-			

Figure 1. MolMed pipeline at 31 December 2015

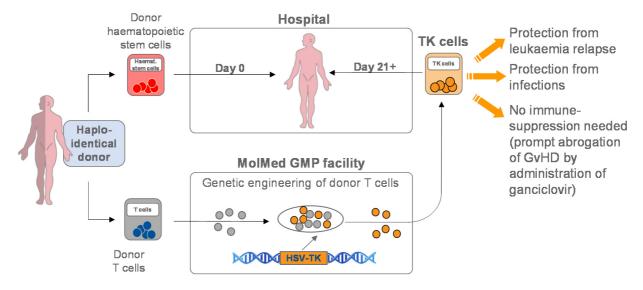
#### 3.2 TK - A cell-based therapy for the treatment of leukaemia

Zalmoxis<sup>®</sup> (TK) is an investigational cell therapy product based on genetically engineered cells, allowing more safe and effective transplant of haematopoietic stem cells (HSCT) even from a partially compatible donor, thus opening to all patients the door of this practice, which is the only potentially curative treatment available, especially for high-risk leukaemia.

HSCT allows regenerating the haematopoietic and immune system of patients affected by leukaemia, which is severely compromised by the disease and by the radiotherapy and pharmacotherapy endured before the transplant; but it needs time - several months - in order to give origin to the mature cells characterising a fully functional immune system. In the meantime, the patient lacks any defence against both infections and possible disease relapse, so it is in absolute need of a vicarious protection: when the donor is fully compatible, this can be provided by donor T cells, thanks to their ability to fight infections and to detect and eliminate residual leukaemia cells. But, at present, donor T cells cannot be used as vicarious protection when the donor is only partially compatible with the patient, because in this case they become a double-edged sword: on one hand, they provide an effective immunotherapeutic benefit against infections and leukaemia relapse, but on the other hand they carry a very high risk of eliciting an attack to the normal tissues of the patient, known as graft-versushost disease (GvHD), that can produce very serious damage. This risk has so far prevented the use of donor



T cells as add-backs to HSCT in all cases of partial incompatibility between donor and recipient, thus making the transplant option unavailable for approximately the half of leukaemia patients.



#### Figure 2. Overview of TK therapy application in HSC transplant from a partially compatible donor

Zalmoxis<sup>®</sup> (TK therapy) was designed in order to allow keeping the protective action of donor T cells, which is vital for the transplant to be really successful, even in the case of partial incompatibility between donor and recipient. Zalmoxis<sup>®</sup> consists of genetically engineering donor T cells, in order to endow them with a selective elimination system acting only on the cells actively involved in a GvHD reaction. To this end, donor T cells are transduced with the TK gene, making them sensitive to the common antiviral drug ganciclovir. In the case of GvHD onset, T cells involved in the aggression can be promptly eliminated by administering the drug at the very first symptoms without any radical and prolonged immune-suppression. Thus, Zalmoxis<sup>®</sup> (TK) allows to take advantage of the vicarious protection of a fully functional immune system provided by donor T cells, while the new immune system entirely reconstitutes from the transplanted haematopoietic stem cells, and therefore it opens the door of HSCT to all patients, since a partially compatible family donor is available for nearly every candidate to the transplant.

Zalmoxis<sup>®</sup> was granted Orphan Drug designation both in the European Union and in the United States.

The outcome of a Phase II trial of Zalmoxis<sup>®</sup>, i.e. trial TK007, published by *The Lancet Oncology*<sup>2</sup>, demonstrated that Zalmoxis<sup>®</sup> add-backs after haplo-HSCT allow to achieve a rapid and efficient immunereconstitution in adult patients affected by high-risk leukaemia, substantially reducing transplant-related mortality and leading to long-term disease-free survival. Data from the long-term follow-up on the clinical benefit following treatment with Zalmoxis<sup>®</sup> show that patients treated (including patients enrolled in the ongoing Phase III trial) show a rapid post-transplant restoration of a fully functional immune system due to TK cells.

Published cumulative data<sup>3</sup> were collected on over 130 patients treated with the TK technology in different academic studies, in Phase II trial TK007 and in the ongoing pivotal Phase III trial. This analysis has shown that this therapeutic approach can offer to patients with high-risk leukaemia the abolition of post transplantation immunosuppression, a rapid immune-reconstitution and an effective control of GvHD in the context of haplo-identical transplantation. Moreover, data on the anti-leukaemia activity of TK cells were presented for the first

<sup>&</sup>lt;sup>2</sup> Ciceri, Bonini et al, Lancet Oncology 2009;10:489-500

<sup>&</sup>lt;sup>3</sup> Front Pharm 2015, 6;95 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4419602)



time. Overall, these effects led to a relevant increase in survival rates in treated patients compared to historical data. Also, preliminary efficacy data of the ongoing Phase III trial (TK008) showed a further increase in survival rates and an inverse correlation between the dose of administered cells and the probability of leukaemia relapse.<sup>4,5</sup>

The analysis of data on the first 24 patients enrolled in the Zalmoxis<sup>®</sup> arm of this randomised Phase III trial showed a 1-year disease free survival (DSF, the primary endpoint of the trial) rate of 74%, which largely exceeds the target DSF rate for the Zalmoxis<sup>®</sup> arm (52%), versus a rate of 30% expected in the control arm.

Notably, with regard to the secondary endpoint of the trial, i.e. overall survival, 85% of patients recruited in the Zalmoxis<sup>®</sup> arm were alive at one year (100% in the case of patients who achieved immune reconstitution), rising to 86% as to 1-year DSF.

The therapeutic effect of TK cells was further confirmed by a very low rate of 1-year leukaemia relapse (16%, falling to 0% for patients receiving higher TK cell doses) and of non-relapse related mortality (10%, falling to 0%% in the case of patients who achieved immune reconstitution).

The Phase III trial TK008 involves adult patients affected by high-risk leukaemia and undergoing haplo-HSCT. The trial is aimed at assessing efficacy and safety of Zalmoxis<sup>®</sup>, and compares the outcome of haplo-HSCT with or without add-backs of Zalmoxis<sup>®</sup>, with a randomisation ratio of 3:1 in favour of Zalmoxis<sup>®</sup> add-backs. The primary end-point of the trial is disease-free survival evaluated on a study population of 170 patients; secondary end-points include overall survival, reduction of transplant-related mortality associated with the haplo-HSCT procedure, safety profile and patients' quality of life. (Trial identifier in clinicaltrials.gov: NCT00914628)

In order to provide additional clinical benefit to patients, in 2012 the Company made two important changes in the design of the Phase III trial protocol. The first change consists in widening the indication to patients in leukaemia relapse, in addition to those in disease remission; the second change provides for the introduction in the control arm of a further treatment option, based on un-manipulated marrow transplant followed by post-transplant administration of cyclophosphamide. According to the Company's estimates, these changes could considerably increase the number of patients eligible for recruitment in each centre and the potential number of participating centres.

The review process is ongoing for a Conditional Marketing Authorisation (CMA) filed with the European authority (EMA), based on Phase II clinical data; if granted, it will allow the commercialisation of Zalmoxis<sup>®</sup>. Filing a CMA (which represents a special early authorisation procedure) was possible thanks to the rarity of the indication (Zalmoxis<sup>®</sup> was granted Orphan Drug designation), the favourable risk/benefit rate and the demonstration of safety and clinical efficacy. Clinical efficacy data, and particularly long-term survival data of patients treated with Zalmoxis<sup>®</sup>, will be used during the analysis and discussion of the dossier filed with the EMA and currently under review.

Key publications on Zalmoxis® are available on MolMed's website (www.molmed.com).

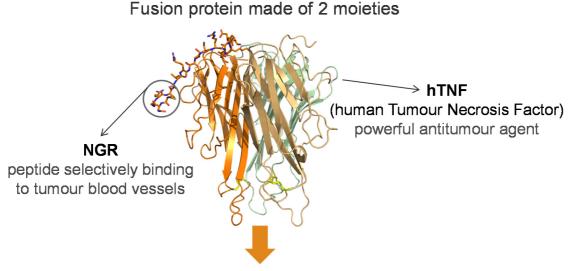
<sup>&</sup>lt;sup>4</sup> ASH Meeting 2014, Abstract 2535

<sup>&</sup>lt;sup>5</sup> EBMT Meeting 2015, Abstract 35

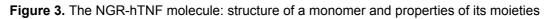


# 3.3 NGR-hTNF - A biological drug targeting tumour blood vessels for the treatment of solid tumours

NGR-hTNF is a selective vascular targeting agent characterised by a unique mode of action, and is first-inclass in the class of peptide-cytokine complexes targeting tumour blood vessels. It is a homo-trimeric protein, where each of the three subunits is formed by combining the powerful anticancer human cytokine Tumour Necrosis Factor (hTNF) with a tumour homing peptide (NGR) targeting a particular receptor complex including CD13, present only on the surface of endothelial cells forming the walls of blood vessels feeding the tumour.



#### Protein with unique biological properties



NGR-hTNF acts specifically on blood vessels feeding the tumour mass, exerting an anti-vascular activity that allows, *inter alia*, an improved penetration into the tumour tissue of other anticancer drugs administered in combination, thereby enhancing their therapeutic efficacy. Therefore, NGR-hTNF can be used both as new single-agent therapeutic option, and in combinations with most cytotoxic-based chemotherapeutic regimens currently available. In addition, studies on animal models have shown the ability of NGR-TNF to enhance the anti-tumour activity of the immune system by promoting the migration of lymphocytes in the primary tumour site and in metastatic lesions.

Unlike all other drugs commonly classified as vascular disrupting agents, NGR-hTNF appears to exert its antivascular and anti-tumour activity without inducing harmful counter-regulatory mechanisms: in particular, it does not increase bone marrow-derived cell infiltrates at the tumour site nor circulating growth factors, i.e. two phenomena that stimulate angiogenesis, post-therapy tumour re-growth and formation of metastases.

The clinical development of NGR-hTNF includes clinical trials both as monotherapy and in combination with different chemotherapeutic regimens, in a total of seven indications: colorectal, liver, small-cell lung, non-small-cell lung and ovarian carcinomas, malignant pleural mesothelioma and soft tissue sarcomas. For mesothelioma and liver cancer, NGR-hTNF has received Orphan Drug designation both in the U.S. and in the European Union. Clinical data obtained by MolMed so far demonstrate the clinical efficacy of NGR-hTNF in six different types of solid tumours; these include two orphan indications as well as more widespread diseases, which altogether account for more than 1.4 million new cases each year in Europe, North America and Japan.



With regard to malignant pleural mesothelioma, a Phase III trial (NGR015) was completed, involving more than 40 clinical centres across 12 countries in Europe, North America and Egypt. NGR015 was a randomised, double-blind, placebo-controlled trial, involving patients affected by malignant pleural mesothelioma resistant or refractory to the standard pemetrexed-based chemotherapy. The primary endpoint of the trial was overall survival; secondary endpoints included progression-free survival, disease control rate, tolerability profile and patients' quality of life. The trial investigated the weekly administration of either NGR-hTNF or placebo in addition to the "best investigator's choice", consisting of supportive care either alone or combined with one chemotherapeutic agent selected among doxorubicin, gemcitabine or vinorelbine. (Trial identifier in clinicaltrials.gov: NCT01098266).

Although the primary endpoint of the trial – i.e. overall survival - was not met for the entire patient population, its results showed a statistically significant improvement of 45% (p=0.02 in stratified analysis, p=0.01 in non-stratified analysis) observed in both overall survival and progression-free survival in patients with a poorer prognosis, i.e. those progressing either during or immediately after first-line treatment. These patients, representing 50% of the study population, were identified by means of a protocol pre-specified analysis based on the treatment-free interval after completion of the first-line chemotherapy.

In addition, an increased impact of NGR-hTNF on survival was observed in parallel with treatment duration, particularly marked in patients treated for at least 3 months who showed a median survival almost doubled compared to patients in the control arm : 16.5 *versus* 9.8 months.

These data, obtained mainly in combination with gemcitabine or vinorelbine in a disease form particularly aggressive and resistant to standard chemotherapy, are of particular significance as they confirm the efficacy previously shown by the combination of NGR-hTNF and gemcitabine in a first-line Phase II trial for patients affected by squamous lung cancer, who have a poorer prognosis with respect to those affected by non-squamous lung cancer.

With regard to soft tissue sarcomas, a four-arm, randomised Phase II trial (NGR016) showed a statistically significant doubled survival time observed for the treatment based on low-dose NGR-hTNF in combination with doxorubicin as compared with the other schedules investigated, including high-dose NGR-hTNF in combination with doxorubicin or NGR-hTNF as monotherapy, at either low or high dose. The 3- year survival rate with this schedule exceeded 40% and, notably, similar results were reported for both chemo-naïve and pre-treated patients, thus confirming the high efficacy of NGR-hTNF in more aggressive and chemo-resistant disease forms.

In a randomised Phase II trial in patients with resistant/refractory ovarian cancer (NGR018), NGR-hTNF in combination with anthracycline improved overall survival in patients with normal or high baseline lymphocyte counts, as compared to patients receiving anthracycline alone.

Furthermore, NGR-hTNF confirmed in these broad patient populations its very favourable tolerability profile, also in combination with the different chemotherapeutic agents administered in the trials.

Taken together, these clinical evidences are consistent with the drug mechanism of action, based both on promoting an increased intra-tumour chemotherapy uptake and on interacting with the patient's immune system. Results obtained so far in randomised Phase II trials for the treatment of different solid tumours are supportive of the therapeutic potential of the investigational drug, which may find application in a wide range of oncological indications.

he Company plans to continue in its search for an industrial partner in order to out-license the product and, in parallel, to start the process for submitting to the EMA a Conditional Marketing Authorisation application for



NGR-hTNF as second line treatment of pleural mesothelioma in patients with poorer prognosis, once the industrial development of the product will been completed.

The key publications on NGR-hTNF – both presentations at congresses and full-text open-source articles - are available on MolMed's website (www.molmed.com).

In terms of manufacturing, scale-up and formulation, NGR-hTNF is a fusion protein suited for industrial development; it is produced by recombinant DNA technology in the host bacterium *Escherichia coli* through a fermentation and purification process. Manufacturing of the molecule - representing the active pharmaceutical ingredient of the investigational drug - and of the drug product in its final formulation are outsourced to external specialised CMOs.

#### 3.4 CAR-T

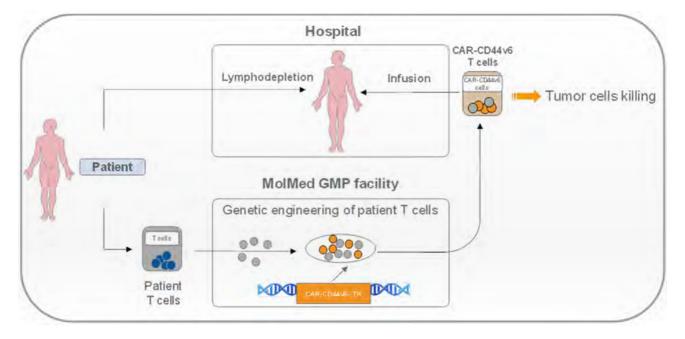
In April 2015, MolMed exercised its option right for the purchase from the San Raffaele Hospital of the cancer immune-gene therapy project CAR-CD44v6, belonging to the CAR-T family, i.e. T-cells armed with chimeric receptors that have demonstrated high anti-tumour potential.

In the field of adoptive cell immunotherapy, engineering T cells with receptors directed against tumour antigens is an effective strategy to quickly generate a high number of tumour-specific T cells. In particular, the use of chimeric antigen receptors (CAR), generated by the fusion of an antigen recognition domain (derived from monoclonal antibodies) with domains derived from co-stimulatory molecules promoting T cell proliferation, represents to date an innovative therapeutic strategy, already clinically validated as in terms of safety and efficacy. Most of the clinical trials conducted so far have used CARs specific for antigen CD19, expressed exclusively by B cells and by tumours derived therefrom.

The CAR-CD44v6 project has high therapeutic potential, as it specifically recognises the version 6 (v6) of the antigen CD44 (CD44v6), expressed by many haematological malignancies, including acute myeloid leukaemia and multiple myeloma, as well as by several epithelial tumours (including breast, lung, colon, pancreatic and head-and-neck carcinomas). Moreover, this CAR displays a peculiar spacing structure between the external and internal parts of the protein, i.e. between the antigen-targeting portion and the intracellular signal-activating portion, which is covered by a patent application.

The CAR-CD44v6 project will benefit from MolMed's extensive experience and know-how in the field of gene and cell therapy and from the conjugation with the suicide gene HSV-TK Mut2. The therapy using CAR-CD44v6, already successfully tested in appropriate murine models, implies the isolation of T cells derived from a patient affected by a tumour expressing the antigen CD44v6 and their modification *in vitro* using a retroviral or lentiviral vector in order to make them express the CAR-CD44v6 and the suicide gene HSV-TK Mut2 (see Figure 4). The presence of CAR-CD44v6 allows T cells to recognise and kill cancer cells, while HSV-TK will enable the removal of CAR-CD44v6-expressing cells should adverse reactions occur during the treatment. After their genetic engineering, the CAR-expressing T cells are expanded *in vitro* until obtaining the therapeutic dose, and then are infused into the patient. Before the infusion, the patient undergoes T cell-depleting chemotherapy, i.e. a treatment with drugs which, by eliminating some of the patient's T cells, create the space needed for the engraftment and persistence in the patient's circulation of the CAR-CD44v6-expressing T cells.





#### Figure 4. Synthesis of the CAR-CD44v6 treatment algorithm

The T cells infused in the patient will be guided *in vivo* by the CAR-CD44v6 to the tumour site, where they can exert their cytotoxic function destroying cancer cells. In the case of adverse reactions arising, e.g. the targeting of normal tissues of the patient, the presence of the suicide gene HSV-TK Mut2 will allow to kill T cells through the administration of ganciclovir. This proprietary technology allows to reduce the risks typically associated with this approach of cancer immuno-gene therapy. Firstly, MolMed plans to conduct a Phase I/IIa trial in patients affected by acute myelogenous leukaemia and multiple myeloma. Once proof-of- concept for safety and efficacy of CAR-CD44v6 is obtained, the plan is to extend this therapy to the treatment of solid tumours.

#### 3.5 Development and GMP production activities for third parties

Over the years, MolMed has developed a specific expertise in the field of gene and cell therapy, including the use of stem cells and T cells for the treatment of different pathologies and tissues, positioning the Company among the leading players at international level.

In this field, MolMed performs tailor-made activities for third parties, offering top-level competencies and expertise to develop, conduct and validate investigational therapies, from preclinical to Phase III trials, as well as devising innovative testing procedures addressing the unique test specifications required for novel cell-based therapeutics. In particular, MolMed holds leading expertise in clinical-grade manufacturing of viral vectors and patient-specific genetically engineered cells according to current good manufacturing practices (cGMP).

#### Development

Development activities, conducted by staff with high experience in the fields of cell biology, virology and molecular biology, involve design and optimisation of processes and analytical methods in order to transfer methods from the lab to GMP production. In this context, MolMed works constantly on a dual perspective: on one hand, implementing a technology platform for the large-scale, semi-stable and stable production of lentiviral vectors; on the other hand, automating cell transduction and quality control processes. Such process



improvements allow both to enhance manufacturing capacity and improve the process output, and to increase the Company's competitive advantage and differentiation allowing to broaden its partner portfolio and keep its role of co-developer.

#### GMP production

MolMed has since 2003 the status of Pharmaceutical Company (*Officina farmaceutica*), granted by the Italian healthcare authority AIFA (*Agenzia Italiana del Farmaco*), and runs an in-house GMP facility authorised for the production of cell-based medicinal products for use in clinical trials, qualified to support all stages of drug development of cell-based therapies, including pivotal clinical trials. In December 2015, AIFA granted to this facility the authorisation to manufacture medicinal products for the market; the authorisation covers specifically a stem cell-based gene therapy and a cell therapy based on the engineering of the immune system, once these therapies will be approved by the EMA.

The facility - which includes six aseptic rooms, five production rooms, one quality control room, separate areas dedicated to fermentation and purification processes, and to research laboratories, having a total surface area of approximately 1,400 m<sup>2</sup> - satisfies EMA and FDA requirements for the production of clinical-grade sterile investigational medicines.

Besides manufacturing Zalmoxis<sup>®</sup> (TK) for its own Phase III trial, MolMed's GMP facility also provides to third parties production services in gene and cell therapy. Provision of such services often includes also the relevant regulatory support activities. These service activities allow MolMed to optimise its manufacturing capacity and to build and maintain strategic collaborations.



# 4. A key element: intellectual property

The Company aims to obtain market exclusivity and freedom to operate in the major pharmaceutical markets as well as in emerging markets worldwide. MolMed holds rights to a patent portfolio covering its products and technologies and including proprietary or in-licensed patents and patent applications, and it constantly carries out activities aimed to the growth and consolidation of its patent portfolio. In particular, the Company directly follows the entire process leading to the granting of a patent in the countries of interest, starting from the filing stage of a patent application for a new invention, throughout the examination procedure of patentability requirements where expected, until the grant phase and subsequent patent maintenance. The rights to new inventions may arise both from internal research activity, as in the case of the recently granted patents on the packaging cell line for the production of lentiviral vectors, as well as from the purchase of new research projects that can enrich the pipeline, such as the CAR-CD44v6 project.

At December 31, 2015, MolMed holds rights – as owner or licensee - to 22 patent families, for a total of 483 granted patents or pending applications, namely 424 granted patents (of which 291 European National Patents) and 54 patent applications filed. MolMed's patent portfolio includes:

- Six patent families (97 granted patents and 2 pending applications), either owned or in-licensed from third parties, covering the key elements of Zalmoxis<sup>®</sup>, including the viral vectors encoding the TK gene to be used in the therapeutic procedure, safe and effective variants of the TK gene (TK-Mut2) and the relevant production processes
- Six patent families (194 granted patents and 20 pending applications) either owned or in-licensed from third parties, covering the NGR-TNF molecule, its use at low doses either alone or in combination with other drugs, its therapeutic use for mesothelioma, as well as the rDNA construct for its production
- One new patent family covering chimeric antigen receptors (CARs) containing new spacer molecules between the antigen-targeting portion and the intracellular signal-activating portion
- Eight patent families (123 granted patents and 31 pending applications), either owned or in-licensed from third parties, covering gene therapy-related technologies and including, *inter alia*, stable and semi-stable packaging cell lines for the production of retroviral and lentiviral vectors, production methods based on their use and a new system for their purification
- One patent family (including 10 granted patents) covering molecules targeting tumour blood vessels

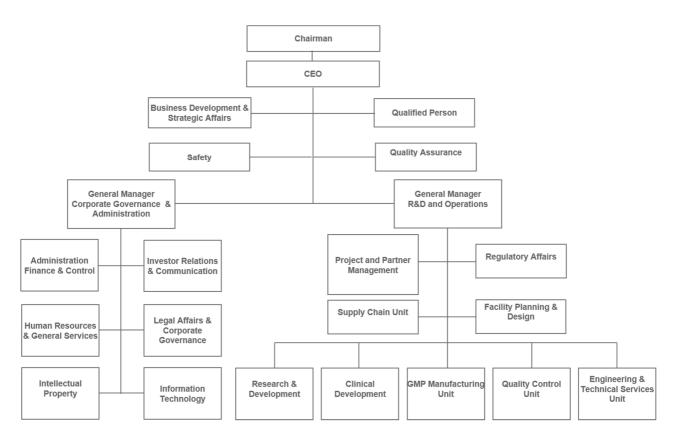
### 5. A basic factor for success: our people

MolMed's highly qualified and skilled staff is indeed of key importance in order to successfully attain the Company's strategic goals. Respect, fairness, career development, team work and continuous training are therefore basic points for the Company.

MolMed's staff can be distinguished by a high level of education and training: more than 80% hold a university degree and over 40% a post-graduate degree. MolMed's management team consists of a hand-selected group of professionals, who provide the company with a wealth of scientific, clinical, business and management expertise.

At December 31, 2015, MolMed's total personnel counts 152 employees and 10 project contractors. the Company's organisation chart at December 31, 2015 is shown in the following page.





# 6. MolMed and the environment and health & safety issues in the workplace

Both the Company's facilities and operations must comply with stringent environmental and work safety regulations. These regulations set provisions for, *inter alia*, air polluting emissions, release of harmful substances into water, soil or subsoil, 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 81/08 and Italian Legislative Decree 206/01 on the handling of genetically modified microorganisms (GMMOs). Concerned staff members are provided with specific training and operate following procedures aimed at minimising the risk of biological contamination.

In compliance with the provisions of Article 37 of Italian Legislative Decree 81/08 and pursuant to the procedures indicated by the State-Region Agreement of December 21, 2011, training courses on safety issues are implemented for all staff members, including general and specific training.

Operations require the Company to use chemical and biological agents for which a specific risk assessment is performed pursuant to Italian Legislative Decree 81/08. Staff uses personal protective equipment in line with regulatory requirements.

Special waste is disposed in compliance with current regulations (Italian Legislative Decree 152/06) and following specific procedures, with the support of a specialised and authorised firm. The Company also adopted the waste tracking system SISTRI, an information system set up by the Italian Ministry of Environment to monitor both hazardous and non-hazardous waste.

The Company believes that it carries out its activities in full compliance with regulations on environmental



issues, and has obtained all the authorisations 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 management systems.

### 7. Corporate governance

MolMed complies with the conduct code for listed companies issued by the Corporate Governance Committee promoted by *Borsa Italiana* in March 2006 and subsequent amendments. In compliance with regulations, MolMed prepares an annual report on corporate governance, providing information on ownership, compliance with the conduct code and relevant commitments, and focusing on the Company's actual application of corporate governance principles. The report, to which reference should be made, is available on MolMed's website (www.molmed.com) and in the authorised storage system 1Info-Storage in terms and ways complying with applicable provisions.

#### 7.1 Direction and coordination activities

The Company is not subject to direction and coordination activities pursuant to art. 2497 of the Italian Civil Code.

Please note that:

- Information required by Article 123-bis, paragraph 1, letter i) of the Italian consolidated law on finance (TUF), "agreements between the company and the directors which provide for compensation in case of resignation or dismissal without just cause or if their employment is terminated due to a tender offer purchase" is included in the remuneration report published pursuant to art. 123-ter of the TUF.
- Information required by article 123-bis, paragraph 1, letter I) of the TUF, "rules governing the replacement of directors and the amendment of the corporate bylaws, if different from supplemen\tary applicable laws and regulations" is reported within the chapter devoted to the board of directors of the report on corporate governance (Chapter 4.1).

# 7.2 Model of organisation, management and control (pursuant to Italian Legislative Decree 231/2001)

As set forth by the Italian Legislative Decree n° 231 issued on 8 June 2001 (231/2001), legal entities are subject to administrative liability in relation to offences committed by directors, officers or employees to the benefit or advantage of the entity, unless the entity proves, *inter alia*, the adoption and effective implementing of a model of organisation, management and control (the "Model") suitable to prevent such offences from being committed.

In order to comply with provisions in force, in 2007 the Company approved the adoption of a Model aimed at preventing the commission of offences, and established a supervisory body complying with the necessary requirements of autonomy, independence and professionalism, vested with inspection and control powers as well as with the functions and powers provided for by the Model itself. In 2014, the Company also prepared an anti-corruption code following the introduction of bribery offences within the private sector among the predicate offences included in Italian Legislative Decree 231/2001.



Both the public version of the Model<sup>6</sup> and the anti-corruption code (the latter in Italian) are available on the Company's website (<u>www.molmed.com</u>) within the section "Investors/Corporate Governance/Documents".

#### 7.3 Transactions with related parties

MolMed adopted specific procedures for transactions with related parties (TRP Procedures). In addition, MolMed's board of directors entrusted on a permanent basis the duties of Committee for transactions with related parties (CTRP) – pursuant to the TRP Procedures and to Article 7 of the Consob<sup>7</sup> Regulation on the matter – to the Committee for control & risks, composed by three non-executive directors in majority independent and identified as the appropriate body to perform the functions of COPC because of its composition, skills and nature.

The updated version of the TRP procedures is available (in Italian) on the Company's website (www.molmed.com) within the section "Investors/Corporate Governance/Documents".

Information on transactions with related parties is provided in **Note 32** within the Notes to the Financial Statements, to which reference should be made.

<sup>&</sup>lt;sup>6</sup> Last update now available: 1<sup>st</sup> January 2016

<sup>&</sup>lt;sup>7</sup> Consob is the supervisory authority on the Italian stock exchange



1. *Report on operations* 

#### 1.1 Main achievements in 2015

#### Clinical development of Zalmoxis® (TK)

 In March 2015, presentation at the annual congresses of the European Society for Blood and Marrow Transplantation (EBMT), of cumulative data on patients treated with Zalmoxis<sup>®</sup> in different academic trials and in MolMed's completed and ongoing trials (TK007 and TK008).

These data show the ability of the treatment with Zalmoxis<sup>®</sup> to offer to patients with high-risk leukaemia a rapid immune reconstitution along with protection against leukaemia relapse and effective control of GvHD in the context of transplantation from a haplo-identical donor, with abolition of post-transplantation immune-suppression. Overall, these effects show a significant increase in survival in treated patients compared with historical data.

In December 2015, publication in the influential scientific journal Science Translational Medicine of results of the study "Tracking genetically engineered lymphocytes long-term reveals the dynamics of T-cell immunological memory", conducted by researchers of the San Raffaele Hospital on patients enrolled in MolMed's Phase I/II trial TK007. The outcomes were also presented during the American Society of Hematology (ASH) Annual Congress, held in Orlando between on December 5-8, 2015.

The study analysed the immune cells of patients with acute high-risk leukaemia who underwent haploidentical haematopoietic stem cell transplantation (haplo-HSCT) and infusion of donor memory T cells transduced to express the TK suicide gene (Zalmoxis<sup>®</sup>) between 1995 and 2012, within trial TK007. Ten adult patients were studied; in three of them, the suicide gene TK was activated in order to abrogate the graft versus host disease (GvHD) which set in early after the haplo-HSCT. After a follow-up period ranging from 2 to 14 years, all patients were in complete remission, free of GvHD and displaying a normal immune system. Furthermore, TK cells were detected in all patients, armed with a still functioning suicide gene. Analysis of the patients' immune system and of the single engineered TK cells allowed scientists to unravel which T cell subtypes are the most capable of expansion and long term-persistence, i.e. memory stem T cells.

Results published in the prestigious journal *Science Translational Medicine* represent an important finding and will support the future development of more effective and lasting therapies against leukaemia. In addition, long-term efficacy of Zalmoxis<sup>®</sup>, highlighted once again by this study, confirms the success of the strategy followed thus far by MolMed in developing innovative treatments against cancer.

#### Clinical development of NGR-hTNF

In June 2015 at ASCO, MolMed presented data from the pivotal randomised Phase III trial as second-line treatment for malignant pleural mesothelioma (NGR015) related to the patient sub-population with poorer prognosis and showing that, although the primary endpoint (overall survival) was not met for the entire patient population, for the first time in this indication a highly significant clinical benefit was obtained in the patient population with poorer prognosis, clearly identified on the basis of objective and acknowledged parameters. In particular, the full results presented show:

 a statistically significant increase of 45% in both overall survival and progression-free survival in 50% of patients, characterised by a poorer prognosis and identified by a pre-specified analysis based on the treatment-free interval after the first-line chemotherapy;



- an impact of NGR-hTNF on survival that correlates with treatment duration, particularly marked in the case of patients treated for at least 3 months, for whom median survival duration was almost doubled compared to patients in the control arm;
- a favourable tolerability profile, also in combination with the three chemotherapeutic agents administered in the trial (gemcitabine, vinorelbine and doxorubicin).

These data, obtained mainly in combination with gemcitabine or vinorelbine in a particularly aggressive and chemo-resistant disease, are of considerable importance as they confirm the effectiveness previously shown by the combination of NGR-hTNF with gemcitabine in a first-line Phase II trial in patients affected by squamous non-small cell lung cancer (NSCLC), who have a poorer prognosis than non-squamous NSCLC.

In addition, the planned target recruitment of 100 patients was reached for the ongoing randomised Phase II trial in mesothelioma as first line maintenance treatment (NGR019), which was extended also to Russia, where the unmet medical need could get higher in the next years.

Follow-up was continued for patients enrolled in randomised Phase II and Phase III trials in soft tissue sarcoma (NGR016), ovarian cancer (NGR018) and mesothelioma (NGR015).

Results obtained so far in randomised Phase II studies for the treatment of different solid tumours support the therapeutic potential of NGR-hTNF, which might find application in a wide range of oncology indications.

#### *Research in gene therapy*

On April 13, 2015 MolMed exercised its option right for the purchase from the San Raffaele Hospital (OSR) of an immune-gene therapy project against cancer, developed using the chimeric antigen receptor CD44v6 (CAR-CD44v6) with potential application in several haematological tumours and carcinomas. The acquisition of this project allows the Company to significantly expand its product pipeline and enter one of today's most promising fields of new anti-tumour strategies, i.e. the immune-gene therapy of cancer.

The CAR-CD44v6 project has been acquired for 3.2 million Euro on the basis of the agreement signed in 2001 between MolMed and OSR, with which the Company holds an option right for the exploitation of intellectual property generated by OSR research projects in the fields of gene and molecular therapy for oncology and AIDS.

In 2015 MolMed started research and development activities on the CAR CD44v6 project, aimed at the characterisation of the anti-tumour activity of CAR CD44v6-expressing T cells in animal models of human and murine tumours, as well as at the development of production systems for viral vectors encoding CAR CD44v6 in association with the suicide gene HSV-TK. Such activities will be carried on and strengthened in 2016.

#### Development and GMP production

In 2015, work continued under four major agreements signed in 2011, 2013 and 2015 with GlaxoSmithKline and Fondazione Telethon for the development and production of highly innovative gene therapy treatments for patients affected by highly severe inherited diseases.

In December 2015, MolMed was granted by the Italian healthcare authority AIFA (*Agenzia Italiana del Farmaco*) authorisation to manufacture medicinal products for the market in its currently operating facility located in Milan at the San Raffaele Biotechnology Department (DIBIT). The authorisation is valid for manufacturing of medicinal products used in a specific gene therapy based on genetically modified stem cells and in a specific cell therapy based on genetic engineering of the immune system, and could become



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operational following the outcome of the marketing authorisation applications filed with the EMA (European Medicines Agency) for such therapies.

Moreover, work continued for the completion of the new production facility at the "Open Zone" science park in Bresso (Milan, Italy). The Bresso site is a further production facility of about 3,300 m<sup>2</sup> which will add to the currently operating one of about 1,400 m<sup>2</sup> located in Milan at the DIBIT, thus considerably increasing the current production capacity.

This expansion, necessary to support the treatment of patients with Zalmoxis<sup>®</sup>, coupled with the technological leadership of the Company in developing therapies in the fields of rare genetic diseases and immune-gene therapy of tumours, will also allow MolMed to position itself as an ideal strategic partner for biotech and big pharma companies.

Finally, in line with its plans, work continued for the industrialisation of Zalmoxis<sup>®</sup> manufacturing process, focused mainly on the development of an automated production and quality control system.

#### Business development activities

In 2015, the business development area focused its activities both on exploring collaboration agreement opportunities for MolMed's pipeline and on broadening partnerships in development and production for third parties.

As to the first aspect, contacts continued with major pharma and biotech companies that showed their interest in possible collaborations for development and marketing of MolMed's most advanced investigational products.

With regard to strengthening partnerships for development and production for third parties, the major event was indeed the subscription on March 19, 2015, of a new strategic agreement with GlaxoSmithKline (GSK), under which MolMed will supply development, manufacturing and technology transfer services aimed at the clinical application of gene therapies based on viral vector-mediated cell transduction. As part of the agreement, MolMed will provide its expertise in process development and its manufacturing competencies and capacity for the production of viral vectors and cell transduction. Under the terms of the agreement, MolMed will be eligible for a minimum of  $\in$  34 million in the form of upfront, milestones, services and supply over the next five years.

Still during 2015, MolMed entered into two new industrial collaborations, the first one with a multi-national biotech corporation and the second one with an Italian biotech start-up company, paving the way for further strengthening of activities for third parties. These new customers come in addition to MolMed's historical partners GSK and Fondazione Telethon.

#### Intellectual property protection activities

In 2015, MolMed carried on for activities aimed at consolidating the intellectual property covering its two more advanced investigational products Zalmoxis<sup>®</sup> (TK) and NGR-hTNF. In addition, further activities have been performed in order to broaden the patent portfolio owned by the Company, both with new cancer therapeutics and with protection of technologies for manufacturing and purification of vectors for gene therapy.

Regarding Zalmoxis<sup>®</sup>, as the key-patent on a non-splicing variant of the TK gene forming the basis of the investigational product has been granted in all territories where the application was filed, in 2015 activities were focused on maintenance of these patents as well as of other patents covering market exclusivity on the



product and its manufacturing.

Regarding NGR-hTNF, in 2015 activities were focused on maintenance of the granted patents covering the product and its use at low dose alone or in combination with other drugs. In addition, the patent covering the use of NGR-TNF for the treatment of mesothelioma was granted also in the US, thus further extending the market exclusivity already obtained in the past years in Australia, Europe, Canada, China, Japan and Russia.

In 2015, MolMed acquired the rights on a new priority patent application covering chimeric antigen receptor technology (CAR), and particularly CARs containing new spacer molecules between the antigen-targeting portion and the intracellular signal-activating portion. In this respect, activities were focused on priority extension.

Finally, regarding the protection of technologies for the manufacturing of viral vectors, in 2015 MolMed continued the activities of maintenance of granted patents and of pending applications covering a stable packaging cell line for the production of viral vectors for gene therapy, its semi-stable intermediary and the related production processes, as well as the viral vector purification process. In particular, a patent protecting the semi-stable intermediary was granted in the US and by the European patent office. The European patent was then validated in 19 countries belonging to the European patent treaty, thus further strengthening protection of this production technology, which is covered by patents expiring in 2031.

#### Organisation and human resources

In 2015, staff training activities were focused both on briefing new staff members on the Italian Legislative Decree 231/01 and on updating the management team on the changes to Act 186/14 regarding self-money laundering, and to article 2635 of the Italian Civil Code brought by Act 190/12 (i.e. the so-called "Anti-Bribery Act").

As usual, update and development of staff's skills continued through the participation in workshops, congresses and other events, according to the staff professional category or organisation area. In addition, the compulsory training programme on safety (pursuant to Italian Legislative Decree 81/08).was also carried on.

#### *Environment and safety in the workplace*

In 2015, the Company carried on the periodical review and implementation of safety procedures in its Milan site at the DIBIT, and introduced the safety procedures in the new Bresso site, pursuant to the Italian Legislative Decree 81/08 and to the Italian Legislative Decree 206/01 on the handling of genetically modified microorganisms (GMMOs).

In 2015, the Bresso laboratory area was notified to the Ministry of Health (notification of new facility, with authorisation issued on May 5, 2015); for each new GMMO introduced and used, in both Milan and Bresso laboratories, a specific authorisation to the Ministry of Health (notification of use) was requested.

In compliance with the provisions of Article 37 of Italian Legislative Decree 81/08 and pursuant to the procedures indicated by the State-Region Agreement of December 21, 2011, training courses on safety issues were implemented in 2015 as well for all staff members in Milan and Bresso, including general and specific training.

Special waste is disposed in compliance with current regulations (Italian Legislative Decree 152/06) and following specific procedures, with the support of a specialised and authorised firm. In 2015, the waste procedure and waste management were adapted to the new European agreement concerning the international



carriage of dangerous goods by road (ADR).

At December 31, 2015, there were no specific environmental issues that may affect the use of existing fixed assets by the Company.

The Company also adopted the waste tracking system SISTRI, an information system set up by the Italian Ministry of Environment to monitor both hazardous and non-hazardous waste.

#### Communication and investor relations activities

Communication and relations with the financial community are becoming more and more of strategic importance for MolMed: in fact, they are a key tool for bringing the financial community closer to the Company's business, which is intrinsically technical and specialised, and to build a trustworthy relationship with its stakeholders.

In 2015, the financial communication was aimed not only at strengthening dialogue and relations with major stakeholders, but also at providing prompt and transparent information, especially about the rationale underlying the share capital increase successfully completed in March 2015, the strategic choices behind the acquisition of the CAR project, the intrinsical potential of the strategic agreement with GSK, as well as the evolution of the Company's corporate governance and organisation structure. During the year, the Company organised several meetings in some of the major European markets in order to update its shareholders about the Company's operations, and top management also held company presentations at various international conferences, both financial and scientific. Moreover, the Company participated in the European Biotech Week with an "open doors" day on October 13, when it was possible for anyone interested to visit the laboratories of the new production facility located at the Open Zone area in Bresso. MolMed's top management also held company presentations at various international company presentations at various international company presentations at various international conferences, both financial and scientific.

Also for 2016 MolMed is committed to maintaining an ongoing dialogue with analysts and investors (both institutional and individual), promoting an equal, transparent, timely and accurate communication. The Company will also keep attending and promoting meetings with financial analysts and major investors, even in order to achieve a greater internationalisation of its shareholders' base.

# *Implementing the model of organisation, management and control (pursuant to the Italian Legislative Decree 231/01)*

In 2015, all the heads of corporate function provided the Company with a statement of knowledge and application of the code of ethics (i.e. annex 1 to the special part of MolMed's model of organisation, management and control [the "Model"]), including the commitment, *inter alia*, to:

- observe with the utmost care all the obligations and provisions laid down in the code;
- monitor its observance and implementation by their collaborators;
- inform the supervisory body, in the terms and way prescribed by the Model, in case he or she should become aware of any violation of its provisions.

During the year, with the assistance of external consultants, the Company implemented the Model following the introduction of a series of new offences within those encompassed by the Italian Legislative Decree 231/01, and in particular the introduction of the crime of "self-money laundering" as provided for in article 648-ter of the Italian Penal Code by Act 186/14, as well as the increase of the so-called "environmental crimes" with stiffer penalties, provided for by Act 68/15.



Following approval by the Company's board of directors of the new organisation structure – which occurred after the end of 2015, but is already operating at the date of this financial report - the Company will consistently update the Model, with particular reference to the map of sensitive areas and to the operating procedures (forming annexes 5 and 6 of the special part of the Model).

#### Supervisory body activities

As in previous years, the supervisory body – which is particularly careful of staff compulsory training – audited again each corporate function, and also met the newly appointed executives in a "cognitive meeting", while waiting for the update and/or integration by the Company of the operating procedures pursuant to Legislative Decree 231/01. In 2015, the supervisory body also organised training seminars (i) for newly hired employees in order to raise awareness on the Model in general, and (ii) for the heads of corporate functions about the changes to Act 186/14 regarding self-money laundering, and to article 2635 of the Italian Civil Code brought by Act 190/12 (i.e. the so-called "Anti-Bribery Act").

#### Transactions with related parties

In 2015, the Company carried out a transaction with a related party – i.e. the acquisition from the San Raffaele Hospital of the CAR-CD44v6 project - considered of major importance both from a quantitative point of view because of the amount of its turnover, and from a qualitative point of view because of the strategic value of the project for the enrichment of the Company's pipeline. The transaction was approved by the board of directors on April 9, 2015, following a favourable opinion by the Committee for transactions with related parties issued on the same date and available within the information document on the transaction, available in the authorised storage system 1INFO-STORAGE and on MolMed's website in the section "Investors/Corporate Governance/Documents"; reference to the information document should be made for detailed information on the transaction.

Information on transactions with related parties are presented in the Notes, to which reference should be made.

#### 1.2 Other events occurred in 2015

#### Share capital increase completed in April 2015

On March 3, 2014, the extraordinary shareholders' meeting resolved to give the board of directors, pursuant to article 2443 of the Italian Civil Code, the power to increase the share capital against payment for an aggregate maximum amount of Euro 50 million, including the relevant share premium, to be executed – also in more tranches – by December 31, 2016, through the issuance of ordinary shares with no par value and with the same characteristics and granting the same rights of the outstanding shares, to be offered with pre-emptive rights to the shareholders of the company pursuant to Article 2441, paragraph 1 of the Italian Civil Code. Following this resolution, the board of directors executed said power on February 23, 2015, resolving to increase the share capital for a maximum amount of Euro 50 million, even in more tranches. On March 4, 2015 the board of directors resolved upon the final terms of the share capital increase, to be executed through the issuance of a maximum of 187,311,408 new ordinary shares with no par value, having the same characteristics of the outstanding MolMed ordinary shares at the relevant issuance date and with regular entitlement, to be offered on a pre-emptive basis to the shareholders of the Company, at an option ratio of 4 new shares for every 5 ordinary shares held, at an issue price equal to Euro 0.2660 per share (of which Euro 0.0471 attributed to share capital and the remaining amount to share premium) for an aggregate value equal to maximum Euro 49,824,834.53.



During the offering period from 9 to 30 March 2015, 184,693,240 option rights were exercised for the subscription of 147,754,592 new shares, corresponding to 99.24% of the total new shares offered, for an aggregate value equal to Euro 39,302,721.48, net of Euro 10,144,774.00 anticipated as an advance payment on future share capital increase by shareholders Fininvest S.p.A., Airain Ltd., H-Equity S.r.I. and H-Invest S.p.A.

The rights remained unexercised were offered to the Milan stock exchange (offer to the market) and were sold out during the second trading session of the offer to the market. Thereinafter, all the 1,418,576 new shares from the exercise of the unexercised rights were subscribed, for a total value of Euro 377,341.22.

The new share capital, following the share capital increase described above, amounts to Euro 19,841,682.30, represented by No. 421,450,672 ordinary shares with no par value.

#### Grant of the Annual Most Innovative EU Biotech SME Award

On June 23, 2015, MolMed received from Carlos Moedas, the European Commissioner for research, science and innovation, the Annual Most Innovative EU Biotech SME Award (red biotech category), a prestigious award promoted by EuropaBio.

#### Corporate governance strengthening

On October 22, 2015, Marina Del Bue, Germano Carganico Lorenzo Salieri resigned from their offices as members of the board of directors. On the same date, The board appointed by co-optation Riccardo Palmisano and Didier Trono as new board members, while Monica Masolo was appointed as board member by co-optation during the subsequent board meeting on November 9, 2015.

On December 11, the shareholders' meeting - having examined the above-mentioned candidates' *curricula vitae*, together with their nomination acceptance declaration, and the compliance with applicable legislation and independence requirements – confirmed the appointment as board members of Monica Masolo, Didier Trono (both independent according to the code of conduct and according to article 148-ter of the TUF) and Riccardo Palmisano (independent according to the code of conduct).

After the closure of the shareholders' meeting the board of directors, amending its governance settings, appointed Dr Riccardo Palmisano as Chief Executive Officer, transferring to him the operational powers held thus far by Professor Claudio Bordignon, who maintains the position of Chairman and, also as President of the Scientific Advisory Board, will keep supporting the Company in the scientific research and development activities, as well as in drawing strategic plans.

#### *1.3 Other information*

#### Grants and other financial support

In its particular area of activity, MolMed takes advantage of the benefits resulting from European, national or regional subsidised loans intended to support and encourage innovation.

MolMed is a strategic partner in two projects co-financed by the European Union under the scope of the Seventh Research & Development Framework Programme, working as a team with various international research organisations. In the projects, named "SUPERSIST" and "CELL-PID", MolMed is involved in different development and production activities for testing highly innovative therapies, as well as various activities involving the exchange and training of highly specialised personnel.



As of the date of this document, "SUPERSIST" is the most significant project under the scope of the subsidies of the Seventh Framework Programme. The project, officially launched in May 2013, has a duration of 42 months and, in addition to MolMed, involves four national and international partners. The total amount of the grant awarded by the European Community to the project is approximately Euro 6 million and corresponds to 75% of the total expected cost of the project. The contribution to which MolMed is entitled, equal to approximately 50% of the total, therefore stands at approximately Euro 3 million. The activities relating to the above-mentioned projects will continue in successive periods. The anticipated subsidies comprise a contribution to expenses of between 50% and 75% of the costs that will be incurred by the Company over the time span of the projects.

#### Treasury shares

The Company does not – either directly or indirectly - own treasury shares, nor were purchases or sales of such shares made - either directly or indirectly - during 2015.

#### Protection of sensitive data and information

Because of the activities carried out by the Company, the protection of personal data and information collected and stored – both electronically and using traditional methods – is of great importance. For this reason, the Company has adopted a personal data protection system that meets the requirements of applicable regulations provided for by the personal data protection code (i.e. the Italian Legislative Decree 196/03).

In particular, in 2015 the Company updated the documents available on its intranet, in order to provide employees with access to its entire privacy protection system, as amended and supplemented from time to time, by means of this useful means of internal communication.

Furthermore, with the assistance of its consultants, the Company continued reviewing a number of corporate processes handling potentially sensitive information and the relevant data flows.

It should be noted that in 2015 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 Consob Issuers' Regulations, MolMed specifies that, based on information received at December 31, 2015, 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 w hich stake is held	Shares held at December 31, 2014	Shares purchased	Shares sold	Shares held at December 31, 2015
Alfredo Messina	Director	MolMed S.p.A.	746,387	597,108	-	1,343,495



### 1.4 Economic and financial data

#### Income results

(amounts in Euro thousands )	Year 2015	Year 2014	Change	% change
Revenues	13,576	11,181	2,395	21.4%
Other revenue	3,188	1,241	1,947	156.9%
Total operating revenues	16,764	12,422	4,342	35.0%
Purchases of raw materials and consumables	4,063	2,966	1,097	37.0%
Costs for services	19,590	11,165	8,425	75.5%
Costs for use of third-party assets	1,414	1,236	178	14.4%
Personnel costs	11,472	9,145	2,327	25.4%
Other operating costs	137	127	10	7.9%
Amortization and depreciation	626	411	215	52.3%
Total operating costs	37,302	25,050	12,252	48.9%
Operating result	(20,538)	(12,628)	(7,910)	62.6%
Financial income	160	70	90	128.6%
Financial charges	(406)	(445)	39	(8.8%)
Net financial income (charges)	(246)	(375)	129	34.4%
Pre-tax result	(20,784)	(13,003)	(7,781)	(59.8%)
Income taxes	-	-		
Profit (loss) for the year	(20,784)	(13,003)	(7,781)	(59.8%)

#### **Operating revenues**

Operating revenues amounted to Euro 16,764 thousand in 2015, recording an increase (+35.0%) compared to 2014 (Euro 12,422 thousand), primarily thanks to activities related to the aforementioned agreements concluded with GSK and Fondazione Telethon, both regarding the development and GMP production of new gene therapy treatments for rare genetic diseases. In particular, in 2015 revenues benefitted from the impact of the agreement signed on March 19, 2015 with GSK described in section *1.1 Summary of activities during 2015*.

Development and production activities for new gene and cell therapy treatments carried out on behalf of third parties are consolidating the technological leadership of the Company in such area and resulted in an increase of 21.4% in revenues for activities on behalf of third parties in 2015 (Euro 13,576 thousand) compared to the previous year Euro (Euro 11,181 thousand).

Other income, amounting to Euro 3,188 thousand, resulted mainly from:

- Tax receivables pursuant to "Decree dated May 27, 2015 implementing tax credit for research and development" amounting to Euro 2,397 thousand;
- Activities performed within the scope of projects with low-interest financing, which amounted to Euro 719 thousand, decreasing compared to 2014 (-36.3%).



#### **Operating costs**

Operating costs amounted to Euro 37,302 thousand in 2015, increasing by Euro 12,252 thousand with respect to 2014 (Euro 25,050 thousand). The aforementioned change, equal to +48.9%, is essentially attributable to the purchase of the CAR-CD44v6 project and to the costs related to the continuation of the industrial development of one of the products in the pipeline.

The costs for services rose from Euro 11,165 thousand at December 31, 2014 to Euro 19,590 thousand at December 31, 2015. The increase recorded during the period, of Euro 8,425 thousand (+75.5%) is attributable to the increase in external development costs and utilities costs partially offset by lower costs for "License fees" and patent expenses. In 2015, external development costs increased by 130.9% (Euro 6,834 thousand) compared to the previous year, substantially as a result of (i) the acquisition of the CAR-CD44v6 research project on April 13, 2015 from Ospedale San Raffaele, which amounted to 3.2 million Euro, through the exercise of the aforementioned option right (section *3. Activities: research, development and production of this Report*) and due to (ii) the continuation of the industrial development of one of the products in the pipeline. The increase in utility costs from Euro 507 thousand in 2014 to Euro 1,083 thousand in 2015 (+113.6%), is linked to the expansion of the surface area occupied by MolMed at the Open Zone in Bresso. Costs for "License fees" and patent expenses decreased by Euro 502 thousand (-54.8%) due to the recognition in the previous year of a milestone relating to the regulatory procedure of a product in the pipeline.

Following the intensification of development and GMP production activities, the increased treatment of Zalmoxis® (TK) patients enrolled in the clinical study and the industrial development of such product, costs for raw materials and consumable increased by Euro 1,097 thousand (+37.0%), going from Euro 2,966 thousand at December 31, 2014 to Euro 4,063 thousand at December 31, 2015.

The expansion of the production site of the Company at the secondary site in Bresso, starting from May 2014, resulted in an increase in the cost of utilization of third-party assets, from Euro 1,236 thousand in 2014 to Euro 1,414 thousand in 2015 (+14.4%).

The increase in personnel costs (+25.4%) compared to the previous year, Euro 11,472 thousand in 2015 and Euro 9,145 thousand in 2014, was related to both an increase in the number of employees with operational roles and the termination of the employment relationship with Ms. Marina Del Bue resulting from the aforementioned renewal process of the organizational structure which began in December 2015. Investments of Euro 6,152 thousand in the period were mainly due to the secondary site in Bresso, while the rest to routine replacement of laboratory equipment and the purchase of new machinery to be used in the Zalmoxis® (TK) manufacturing process, as well as to maintenance and improvement work on the already existing GMP facility.

#### **Operating result**

Despite the increase shown in operating revenues (Euro 4,342 thousand), the operating result of 2015, a loss of Euro 20,538 thousand, was lower by a percentage of 62.6% compared to that recorded in 2014, a loss of Euro 12,628 thousand, due to the aforementioned increases in costs of services amounting to Euro 8,425 thousand, costs for raw material and consumables amounting to Euro 1,097 thousand and personnel costs amounting to Euro 2,327 thousand.

MolMed's financials are peculiar to the business model of biotech companies developing new therapeutic products and having no product on the market. At this stage significant costs must be borne, in relation to the testing and development of investigational new drugs, and return is expected in forthcoming years.

Based on the Company's operations and the characteristics of the trials performed, research and development costs are fully expensed as incurred.



#### Net financial income (charges)

The Company's financial activities were negative to the tune of Euro 246 thousand, showing a positive change of Euro 129 thousand on the year 2014.

Financial income of Euro 160 thousand (Euro 70 thousand at December 31, 2014) mainly arose from the management of the Company's cash resources through temporary low-risk investments.

Financial charges amounted to Euro 406 thousand in 2015, a decrease (-8.8%) compared to 2014. The decrease recorded during the year was mainly attributable to commissions without recourse recoded in the first half of the previous year relating to the transfer of VAT receivables, collected by the end of 2014.

#### Profit (loss) for the year

The result for 2015 was a loss of Euro 20,784 thousand, compared to a loss of Euro 13,003 thousand recorded in 2014.

#### 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 thousands )	December 31, 2015	December 31, 2014
Non-current assets		
Fixed assets and other non-current assets	15,688	10,476
Total non-current assets	15,688	10,476
Net working capital		
Inventories	794	774
Trade receivables and other commercial assets	5,632	4,364
Tax receivables	3,257	845
Other receivables and current assets	1,576	1,734
Trade payables	(13,559)	(9,852)
Other liabilities	(5,287)	(2,124)
Total net working capital	(7,587)	(4,259)
Non-current liabilities		
Other non-current liabilities	(6,110)	(5,525)
Total non-current liabilities	(6,110)	(5,525)
TOTAL USES	1,991	692
Shareholders' equity	31,929	12,082
Net financial position	29,938	11,390
TOTAL SOURCES	1,991	692
	1,001	052

Non-current assets



(amounts Euro thousands )	nts Euro thousands ) December 31, I 2015			% change
Tangible assets	11,138	5,996	5,142	85.8%
Goodwill	77	77	-	0.0%
Intangible assets	304	253	51	20.4%
Financial assets	212	7	205	3024.2%
Tax receivables	2,457	2,557	(100)	(3.9%)
Other assets	1,500	1,586	(86)	(5.4%)
Total non-current assets	15,688	10,475	5,213	49.8%

Non-current assets at December 31, 2015 and December 31, 2014 are detailed in the table below:

Non-current assets amounted to Euro 15,688 thousand at December 31, 2015.

The increase in tangible assets is mainly due to the investments made in 2015, essentially relating to renovation work at the new Bresso facility (as better explained in the Notes) and, to a lower extent, to routine replacement of laboratory equipment and the purchase of new machinery to be used in the production process, as well as to maintenance and improvement work on the GMP facility.

The increase in "Intangible assets" for a gross amount of Euro 105 thousand was mainly due to the validation in 19 countries of the European Patent which had been granted for a cell line for the semi-stable production of lentiviral vectors (Euro 21 thousand) and to the purchase of software to manage laboratory equipment in the new facility which is not yet operational (Euro 82 thousand).

Tax receivables consisted mainly of VAT receivables and remained almost unchanged compared to the closing date of the previous year.

Other non-current assets include an advance on future rents of Euro 1,500 thousand to the owners of the property located in the "Open Zone" scientific park in Bresso (Milan) that belongs to the Zambon chemical-pharmaceutical group. Further details are provided in the Notes.

Investments made in 2015 amounted to Euro 6,152 thousand.

#### Net working capital

Net working capital at December 31, 2015 and December 31, 2014 is broken down as follows:

(amounts Euro thousands )	December 31, 2015	December 31, 2014	Change	% change
Inventories	794	774	20	2.6%
Trade receivables and other commercial assets	5,632	4,364	1,268	29.1%
Tax receivables	3,257	845	2,412	285.6%
Other receivables and current assets	1,576	1,734	(158)	(9.1%)
Trade payables	(13,559)	(9,852)	(3,707)	(37.6%)
Other liabilities	(5,287)	(2,124)	(3,163)	(149.0%)
Total net working capital	(7,587)	(4,258)	(3,328)	78.2%



Net working capital at December 31, 2015 was negative to the tune of Euro 7,587 thousand, down by Euro 3,328 thousand compared to December 31, 2014 (negative to the tune of Euro 4,258 thousand).

The increase in trade receivables, for Euro 5,632 thousand (+29.1%), from Euro 4,364 thousand at the end of the previous year to Euro 5,632 thousand at the end of the year under review, was a result of normal commercial invoicing dynamics.

The increase in current tax receivables, amounting to Euro 2,412 thousand (+285.6%) is attributable, for Euro 2,397 thousand, to the recognition of tax credits for research and development pursuant to Ministerial Decree dated May 27, 2015 implementing Law No. 190 dated December 23, 2014 (2015 Stability Law).

The change in trade payables was mainly related to the increase in deferred income by Euro 3,707 thousand, from Euro 9,852 thousand at December 31, 2014 to Euro 13,559 thousand at December 31, 2015. This increase was related to the impacts of the agreement signed with GSK on March 19, 2015, which resulted in the recognition of deferred income, against the up-front payments and advances recognized in the income statement throughout the duration of the agreement and at the time the service is actually provided respectively.

As already pointed out, pursuant to the aforementioned agreement, Company's revenues are expected to reach a minimum amount of Euro 34 million over the next 5 years. For more information in this regard, please refer to section *1.1 Main achievements in 2015* 

The increase in the item Other liabilities by Euro 3,163 thousand from Euro 2,124 thousand at December 31, 2014 to Euro 5,287 thousand at December 31 2015, was due to the reclassification of Euro 1,961 thousand for advances on projects financed from the item "other non-current liabilities" as these shall be completed within the next 12 months, as well as the termination of the employment relationship with Ms. Marina Del Bue resulting from the aforementioned renewal process of the organizational structure which began in December 2015.

#### Non-current liabilities

The table below describes the items included under non-current liabilities:

(amounts Euro thousands )	December 31, 2015	December 31, 2014	Change	% change
Liabilities for pensions and employee severance indemnity				
(TFR)	197	208	(11)	(5.4%)
Trade payables	2,600	-	2,600	100.0%
Other liabilities	3,313	5,317	(2,004)	(37.7%)
Total non-current liabilities	6,110	5,525	585	10.6%

"Non-current liabilities" increased by Euro 585 thousand, going from Euro 5,525 thousand at December 31 2014 to Euro 6,110 thousand at 31 December, 2015, mainly due to:

- An increase of Euro 2,600 thousand in the item Non-current trade payables, in relation to the deferred income of the upfront payments made by GSK on the basis of the agreement signed on March 19, 2015.
- A decrease of Euro 2,004 thousand in the item Other liabilities, mainly arising from the reclassification from "Other non-current liabilities" to "Other current liabilities" of Euro 1,961 thousand in relation to advances on projects financed by the European Community CELL-PID and SUPERSIST, the completion of which is expected within the next 12 months.



#### Shareholders' equity and capital transactions

Details about changes in shareholders' equity from January 1, 2015 to December 31, 2015 are provided in the table below:

(amounts in Euro thousands)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Fair value valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2015	11,019	5,635	8,638	644	(19)	-	(832)	(13,003)	12,082
Allocation of prior year result	-	-	-	-	-	-	(13,003)	13,003	-
Shareholders' advance payment for share capital increase	-	-	1,552	-	-	-	-	-	1,552
Use of Shareholders' advance payment for share capital increase	-	-	(10,145)	-	-	-	-	-	(10,145)
Capital increase	8,823	41,002	-	-	-	-	-	-	49,825
Capital increase expenses capitalized	-	(873)	-	-	-	-	-	-	(873)
Unsubscribed rights for share capital increase	-	-	178	-	-	-	-	-	178
Personnel costs for stock options 2012	-	-	-	87	-	-	-	-	87
Other variations - stock options, Plan 2012	-	-	-	(315)	-	-	315	-	-
Profit (loss) for the year	-	-	-	-	7	-	-	(20,784)	(20,777)
Balance at December, 31 2015	19,842	45,764	223	416	(12)	-	(13,520)	(20,784)	31,929

It should be noted that the increase in Shareholders' equity reflects the impacts generated by the extraordinary capital increase for a total of Euro 50 million completed in April 2015. Further details about changes in shareholders' equity are provided in the Notes.

#### Net financial position

(amounts Euro thousand )	December 31, 2015	December 31, 2014
Cash on hand	14	10
Other cash	11,756	
Cash equivalents	-	_
A. Total cash and cash equivalents	11,770	11,384
B. Current financial receivables and other financial assets	18,168	6
Finance lease payables	-	-
Current financial Debts	-	-
C. Current financial debt	-	-
D. Net current financial position (A+B+C)	29,938	11,390
Finance lease payables	-	-
Non current financial Debts	-	-
E. Non-current financial debt	-	-
F. Net financial position (D+E)	29,938	11,390

Net financial position was positive to the tune of Euro 29,938 thousand at December 31, 2015, almost fully consisting of cash and cash equivalents and current financial receivables consisting of bonds and time deposits, with no financial debt. Net financial position was positive to the tune of Euro 11,390 thousand at December 31, 2014 and the change in 2015 (Euro 18,548 thousand) was mainly due to (i) income of Euro 39,858 thousand from the capital increase, (ii) Euro 1,552 thousand received in February 2015 from shareholders parties to the shareholders' agreement as a capital contribution on account of future issues of shares (offset with the 2015 capital increase), (iii) income from the aforementioned agreement entered into with GSK on March 19, 2015 and (iv) the purchase of the CAR-CD44v6 research project for Euro 3,904 thousand, including VAT.



# 2. Main risks and uncertainties to which MolMed is exposed

#### 2.1 Risks associated with external factors

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

The Company has still not completed the development of its experimental products that are currently at the clinical trial stage, in particular TK and NGR-hTNF. In regard to the experimental products TK and NGR-hTNF, which have the highest revenue prospects, no guarantee can be provided that the Company will successfully complete Phase III trial. The experimental products which are being developed by the Company 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 obtain such approvals promptly enough to sell the products. In addition, it might happen that the non-randomized Phase II trials, which were successfully completed, do not provide the same positive results in subsequent stages of development. Moreover, clinical trials may be suspended at any time by the Company, or by the competent authorities in the interest of the patients' health. Even after approval by the competent authorities, a product might prove to be unsafe or not to have the expected effects (for example, side effects might emerge after the product is sold on the market or the product's real effectiveness may be lower than that emerging in the experimental stages), or, in any case, it might not be accepted by the market (which might prefer rival products) or, generally, for other reasons which are beyond the Company's control, thus preventing the product's use on a wide scale or forcing the Company to withdraw it from the market. Should the Company not be able to timely complete the development programs and clinical trials for its products, its business and financial position, results of operations, and cash flows could be negatively affected.

#### Risks associated with strong competition

The biotechnology and pharmaceutical product markets are characterized by significant competition. This is especially true in the field of oncology. 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 the development and the product sales stage, the Company also faces competition from current and potential competitors benefitting from higher financial resources, investment budget and better capacity to acquire (in-license) new products and technologies.

Moreover, the Company is in competition with companies of similar size and operations to sign out-licensing agreements or partnerships with other biopharmaceutical companies. In the future, these competitors might be able to develop safer, more effective or cheaper products than those developed by 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 the Company's competitive position and a drop in expected revenue and profit.

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

#### **Risks associated with sector 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, 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, but it may need to be further tested, thus involving the use of other significant resources. In addition, the subsequent identification of previously unknown problems or failure to comply with applicable regulations, might lead to restrictions on the sale of the products, the withdrawal of the authorization or the withdrawal of the products from the market, as well as the application of sanctions. Furthermore, regulatory changes may delay the production and/or trial process, with a consequent increase in the costs incurred by the Company.

Should these circumstances occur in the future, the Company's business and its financial position, result 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 undertakes research, preclinical and clinical trials on its products as well as production activities both directly and through third parties on the basis of cooperation agreements (with entities, institutions and companies operating in the medical biotechnology industry). The Company's strategy involves maintaining the current cooperation and possibly signing other agreements to develop these products with third parties, to perform a number of clinical trials and any subsequent drug production.

In addition, despite there are numerous companies specializing in the sector and the Company is not contractually bound, it may happen that third parties appointed to carry out research, preclinical and clinical trials, and production activities on behalf of the Company do not fulfill their obligations in whole or in part or in an appropriate manner or do not meet the deadlines required or do not comply with the quality standards requested by the Company. Should such circumstances occur, the preclinical and clinical trials could be delayed or it may become necessary to replace the third party that had been appointed.

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 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 becomes 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.



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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, limits or a ban on the use of the products involved in the dispute and/or lead to the payment of milestones and royalties.

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 (including biotechnology and pharmaceutical companies, universities and research institutes) to acquire rights over a range of technologies, patents and manufacturing and supply processes for the development and future 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 and, especially, on the Chairman, on Mr. Claudio Bordignon, on and Chief Executive Officer Mr. Riccardo Palmisano, on the Director and General Manager, Mr. G. Paolo Rizzardi and on the Director and Business Development & Strategic Affairs Manager, Mr. Germano Carganico who have been actively contributing 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 (for example in commercial development and marketing) will make it necessary to recruit managerial and technical 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 operations and production capacity of the GMP manufacturing facility and the laboratories

MolMed owns a 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 facility MolMed provides cell therapy services to selected customers or 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 the authorizations being revoked, new regulatory measures or environmental regulations, including the risk that the facility be 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 facility is adequate for its current production needs and the business plans provide for an increase in the production capacity aimed at both supporting patients being treated with the TK cell therapy so that the Phase III trial can continue and the product will be able to be sold in the future, and at intensifying the development and production activities for new gene and cell therapy treatments on behalf of third parties. However, should the Company increase the number of products under development in the future or should it be necessary to produce greater quantities of existing products, the 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 expanding its facilities and production capacity in the new Bresso premises – additional to the current 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

The Company has never been involved in legal action for its trial 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 the 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, result of operations and cash flows could be negatively affected.

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

In its research and development activities, the Company uses dangerous materials and chemical and biological substances requiring special disposal systems which must be set up in compliance with specific 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, result of operations and cash flows could be negatively affected.

#### 2.3 Financial risks

#### Risks associated with funding for research and development activities

The financial risk that the Company could be subject to is the failure to obtain adequate financial resources necessary for its operations.

As is common knowledge, the Company's business model, typical of biotech companies developing new therapeutic products and having no product on the market, 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 is also 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 effectively achieve, and the relevant methods and timings.

Based on the accounting policies adopted, requiring full recognition of research and development costs in the Income Statement of the year they are incurred, the Company has always reported a loss since its incorporation. Consequently, the loss for 2015 was Euro 20,784 thousand, up Euro 7,781 thousand from the Euro 13,003 thousand loss recorded in the previous year. This trend is attributable to higher research and development costs in accordance with the provisions of the business plan.

The new business plan 2016-2018, updated on the basis of 2015 results and approved by Board of Directors during December 2015, assuming it becomes fully operational, provides for the following to be achieved in the 2016-2018 period:

- continuing the clinical and industrial development of the main experimental products;
- pursuing operations and investments aimed at boosting production capacity.

The Company has met its liquidity requirements from its incorporation up to the date of these Financial Statements through contributions from its shareholders. In particular, the capital increase, which was completed on April 9, 2015, generated gross income of Euro 49,825 thousand (including Euro 10,145 thousand received from the main shareholders as future share capital increase).



Finally, as described in more detail in the 2014 Annual Report, the existing SEF agreement (expiring July 31, 2016) aims at making the Company's financial structure more flexible, diversifying the funding sources required to meet the Molmed's cash requirements.

Based on the above and on the analysis of future cash flows projected by the 2016-2018 business plan, the Company deems that the financial means and equity available can guarantee enough resources 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.

Although the financial position as at the date of this Report can guarantee enough resources for the Company to continue its operations in the foreseeable future, it cannot be ruled out that in the future the Company, even before it completes the clinical development of its products, may require additional financial resources, to be collected through venture capital or debt financing, or by entering into further cooperation agreements, sponsored research, or other means.

In fact, it should be noted that it is impossible to guarantee that further funds will be available or, if found, will be provided at satisfactory conditions for the Company. In particular, the loan agreements could include obligations such as financial and non-financial covenants that could result in restrictions to the Company's operational flexibility. Should sufficient funds not be available, the Company's activity could be negatively influenced and it could be compelled to delay, reorganize or cancel research and development programs, to enter into loan agreements, licensing or cooperation agreements under unfavorable terms or waive rights on certain products that it would not otherwise waive.

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.

#### Currency and interest rate risk

At December 31, 2015, the Company did not have significant exposure to currency fluctuations, because there were no significant receivables or payables in a currency other than the Euro, nor were there any financial instruments subject to currency risk.

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

Further information on risk management is provided in the Notes to which reference should be made.

# *3. Main events occurred after the end of 2015*

#### Organisation structure optimisation and further corporate governance strengthening

On January 29, 2016, the board of directors - advancing in the corporate governance changing process started in December 2015 with the appointment of Riccardo Palmisano as Chief Executive Officer - approved the establishment of a nomination Committee and the renewal of the Company's organisation structure.

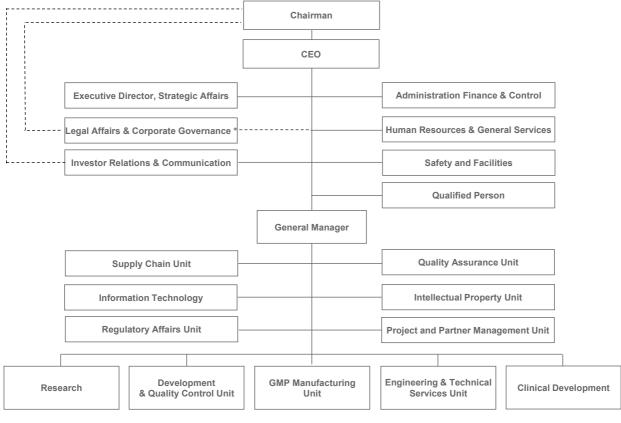
With regard to corporate governance, being the board of directors' term close to expiry, it was considered appropriate to establish a nomination Committee (composed by Raffaella Ruggiero, Sabina Grossi and Didier Trono), unified with the remuneration Committee and consisting mainly of



independent members, with an advisory and consulting role to the board of directors regarding the optimal composition of the board itself, identifying and indicating the professional profiles that can facilitate its effective functioning.

With regard to the renewal of the organisation structure, it provided for the establishment of a single General Manager office, held by G. Paolo Rizzardi, and thus for the removal of the General Manager office for Corporate Governance & Administration, whose main functions now directly report to the CEO.

Here below is the chart of MolMed's organisation effective after the board meeting of January 29, 2016.



\* outsourced

Following this renewal of the organisation structure, the employment relationship with Marina Del Bue ended on February 16, 2016, with a settlement of Euro one million. For more information, please refer to chapter 1.4 (Financial data) of this report.

#### Application for a conditional marketing authorisation (CMA) for Zalmoxis®

The evaluation of the application for a conditional marketing authorisation - filed with the European Medicines Agency (EMA) in March 2014 - is ongoing, according to the procedure laid down for such authorisation



processes: the Company has in fact recently processed a second list of outstanding issues (LoOi) on details requested by the committees called upon to provide the final opinion on the application filed.

## 4. Business outlook

During 2016, the Company plans to continue clinical and industrial development of the main investigational products, as well as activities and investments aimed at significantly increasing the production capacity dedicated to the development and production of both proprietary cell and gene therapy and for third parties.

In particular, with regard to proprietary products, the interaction with the European authorities in order to obtain the Conditional Marketing Authorisation (CMA) for Zalmoxis® will continue and, in parallel, activities preparatory to market access (both directly and through distributors/dealers) will be intensified.

As for NGR-hTNF, based on clinical data obtained so far, on evolutionary trends in the specific clinical area at an international level, and taking into account potential industrial partners' feedback, in 2016 activities will proceed as follows: the opportunity to begin the submission process of a CMA request with the EMA (European Medicines Agency) and an Accelerated Approval with the FDA (Food and Drug Administration) for the treatment of pleural mesothelioma in second-line in patients with poor prognosis will be evaluated; at the same time, once the place in therapy of the product has been reviewed and potential industrial partners' feedback has been analysed, the search for an industrial partner for product development will continue and therapeutic indications considered more promising on the basis of results already obtained from randomized Phase II clinical trials, and of specific unmet therapeutic needs, as indicated by clinicians and the market, will be considered first; in parallel, the industrial development of the product aimed at the validation of the production process will continue.

Finally, taking advantage of its established development expertise, the Company intends to invest on research and pre-clinical development of the CAR project, acquired in 2015, in order to enhance enhancing its distinctive specificity. With regard to development and contract manufacturing activities, supported by 2015 results, efforts to identify new industrial partners and signing of new service contracts will continue.

In this perspective, completion of commissioning and validation of the new facility in Bresso and request for manufacturing authorization from AIFA is scheduled in 2016, this will lead to a significant increase in production capacity for the Company.

## 5. Loss allocation proposal for the year

The 2015 Company's Financial Statements, as also described by this Report and the Notes, recognized a loss of Euro 20,784 thousand, which is proposed to be carried forward.



# Financial Statement at 31 December 2015

# 1. Statement of financial position

		December 31, D	ecember 31,
(amounts in Euro thousands )		2015	2014
ASSETS			
Tangible assets	1	11,138	5,996
Goodwill	2	77	77
Intangible assets	2	304	253
Financial assets	3	212	7
Tax receivables	4	2,457	2,557
Other assets	5	1,500	1,586
TOTAL NON-CURRENT ASSETS		15,688	10,476
Inventories	6	794	774
Trade receivables and other commercial assets	7	5,632	4,364
Tax receivables	8	3,257	845
Other receivables and sundry assets	9	1,576	1,734
Other financial assets	10	18,168	6
Cash and cash equivalents	11	11,770	11,384
TOTAL CURRENT ASSETS		41,197	19,107
TOTAL ASSETS		56,885	29,583
LIABILITIES AND SHAREHOLDERS' EQUITY			
Capital		19,842	11,019
Share premium reserve		45,764	5,635
Other reserves		627	9,263
Retained earnings (accumulated losses)		(13,520)	(832)
Profit (loss) for the year		(20,784)	(13,003)
TOTAL SHAREHOLDERS' EQUITY	12	31,929	12,082
Liabilities for pensions and employee severance indemnity (TFR)	13	197	208
Trade payables	14	2,600	-
Other liabilities	15	3,313	5,317
TOTAL NON-CURRENT LIABILITIES		6,110	5,525
Trade payables	16	13,559	9,852
Other liabilities	17	5,287	2,124
TOTAL CURRENT LIABILITIES		18,846	11,976
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY		56,885	29,583



# 2. Income Statement

(amounts in Euro thousands )	Note	Year 2015	Year 2014
Revenues	18	13,576	11,181
Other revenue	19	3,188	1,241
Total operating revenues		16,764	12,422
Purchases of raw materials and consumables	20	4,063	2,966
Costs for services	21	19,590	11,165
Costs for use of third-party assets	22	1,414	1,236
Personnel costs	23	11,472	9,145
Other operating costs	24	137	127
Amortization and depreciation	25	626	411
Total operating costs		37,302	25,050
Operating result		(20,538)	(12,628)
Financial income		160	70
Financial charges		(406)	(445)
Net financial income (charges)	26	(246)	(375)
Pre-tax result		(20,784)	(13,003)
Income taxes	27	-	-
Profit (loss) for the year		(20,784)	(13,003)
(amounts in Euro)		Year 2015	Year 2014
Basic earnings/(loss) per share		(0.0553)	(0.0566)
Diliuted earnings/(loss) per share		-	-



# 3. Statement of comprehensive income

(amounts in Euro thousands )	Year 2015	Year 2014
Profit (loss) for the year	(20,784)	(13,003)
Other comprehensive income (not subsequently reclassified to the income statement)		
Profit (loss) actuarial	7	(16)
Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)	7	(16)
Other comprehensive income (subsequently reclassified to the income statement)		
Net change in fair value of assets available for sale	-	-
Other comprehensive income, net of taxes (subsequently reclassified to the income		
statement)	-	-
Total comprehensive income (loss) for the year	(20,777)	(13,019)



# 4. Statement of cash flow

(amounts in Euro thousands )		December 31, 2015	December 31, 2014
Cash and cash equivalents		11,384	8,562
Opening cash and cash equivalents	A	11,384	8,562
Cash flow from operating activities:		-	-
Profit (loss) for the year		(20,784)	(13,003)
Amortization/Depreciation of intangible/tangible assets		626	411
Change in liabilities for pensions and employee severance indemnity		(12)	8
Non-cash costs for stock options		87	161
Decrease in other non current assets due to option rights		86	516
Decrease in other current assets due to option rights	(*)	430	0
Reversal of financial income and charges		246	375
Cash flow from operating activities before changes in working capital		(19,320)	(11,532)
Changes in current assets and liabilities:		-	-
(Increase) decrease in inventories		(20)	(98)
(Increase) decrease in trade and other receivables	(*)	(4,050)	1,213
Increase (decrease) in trade and other payables	(*)	3,708	372
Increase (decrease) in other liabilities		3,164	(28)
Total changes in current assets and liabilities		2,802	1,459
(Increase) decrease in non-current tax receivables		100	1,443
Increase (decrease) in other liabilities		2,600	0
Increase (decrease) in other financial assets		(1,678)	2,794
Increase (decrease) in other activities		(205)	(5)
Interest paid		(145)	(391)
Total cash flow generated (absorbed) by operating activities	В	(15,846)	(6,232)
Cash flow from investing activities:			-
Net (investment) divestment in tangible assets		(6,047)	(4,627)
Net (investment) divestment in intangible assets		(105)	(107)
Net (investment) in other financial assets		-	1
(investment) in other financial assets		(18,162)	-
Interest received		10	15
Total cash flow generated (absorbed) by investing activities	С	(24,305)	(4,718)
Cash flow from financing activities:		-	-
Increases in capital and share premium reserve		39,858	6,475
Shareholders' advance payment for share capital increase		1,552	8,638
Other Equity movemenets (share increase cost)		(873)	(306)
Financial Debts variation		0	(1,032)
Change in finance lease payables		0	(3)
Total cash flow generated (absorbed) by financing activities	D	40,537	13,772
Cash flow generated (absorbed) during the year	E=B+C+D	386	2,822
Closing cash and cash equivalents	A+E	11,770	11,384
(*) of which with related parties (as required by Consob Resolution no.15519 of .	July 27, 2006)		
(amounts in thousands of Euro)		December 31,	-
(Increase) decrease in trade and other receivables		<b>2015</b> 86	(21)
(Increase) decrease in thate and other receivables		430	(21)
(Increase) decrease in other financial assets		430	510
		-	(250)
Increase (decrease) in trade and other payables		5	(259)



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# 5. Statement of changes in equity

(amounts in Euro thousands)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Fair value valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at December 31, 2012 (published data)	43,609	-	-	1,081	-	15	585	(22,001)	23,289
Effects of IAS 19 emendment					(62)		54	8	
Balance at January 1, 2013	43,609	-	-	1,081	(62)	15	639	(21,993)	23,289
Allocation of prior year result	-	-	-	-	-	-	(3,388)	3,388	-
Capital reduction ex art 2446 CC	(18,028)	-	-	-	-	-	(577)	18,605	-
Capital increase	1,490	3,499	3	-	-	-	-	-	4,993
Capital increase expences capitalized	-	(121)	-	-	-	-	-	-	(121)
Decadence of stock options, Plan 2008 B	-	-	-	(329)	-	-	329	-	-
Decadence of stock options	-	-	-	(422)	-	-	422	-	-
Personnel costs for stock options 2012	-	-	-	160	-	-	-	-	160
Profit (loss) for the year	-	-	-	-	(3)	(15)	-	(18,169)	(18,187)
Balance at December 31, 2013	27,071	3,378	3	490	(65)	-	(2,575)	(18,169)	10,133

(amounts in Euro thousands)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Fair value valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2014	27,071	3,378	3	490	(65)	-	(2,575)	(18,169)	10,133
Allocation of prior year result		-		-	-	-	(839)	839	-
Capital reduction ex art 2446 CC	(16,586)	(3,378)	(3)	-	62	-	2,575	17,330	-
Capital increase	389	4,580	-	-	-	-	-	-	4,969
Capital increase dedicated to SG	145	1,361	-	-	-	-	-	-	1,506
Capital increase expences capitalized	-	(306)	-	-	-	-	-	-	(306)
Unsubscribed rights for share capital increase	-	-	45	-	-	-	-	-	45
Shareholders' advance payment for share capital increase	-	-	8,593	-	-	-	-	-	8,593
Personnel costs for stock options 2012	-	-	-	161	-	-	-	-	161
Other variations - stock options, Plan 2012	-	-	-	(7)	-	-	7	-	-
Profit (loss) for the year	-	-	-	-	(16)	-	-	(13,003)	(13,019)
Balance at December, 31 2014	11,019	5,635	8,638	644	(19)	-	(832)	(13,003)	12,082

(amounts in Euro thousands)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Fair value valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2015	11,019	5,635	8,638	644	(19)	-	(832)	(13,003)	12,082
Allocation of prior year result	-	-	-	-	-	-	(13,003)	13,003	-
Shareholders' advance payment for share capital increase	-	-	1,552	-	-	-	-	-	1,552
Use of Shareholders' advance payment for share capital increase	-	-	(10,145)	-	-	-	-	-	(10,145)
Capital increase	8,823	41,002	-	-	-	-	-	-	49,825
Capital increase expenses capitalized	-	(873)	-	-	-	-	-	-	(873)
Unsubscribed rights for share capital increase	-	-	178	-	-	-	-	-	178
Personnel costs for stock options 2012	-	-	-	87	-	-	-	-	87
Other variations - stock options, Plan 2012	-	-	-	(315)	-	-	315	-	-
Profit (loss) for the year	-	-	-	-	7	-	-	(20,784)	(20,777)
Balance at December, 31 2015	19,842	45,764	223	416	(12)	-	(13,520)	(20,784)	31,929



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

(amounts in Euro thousand)	Notes	December 31, 2015	December 31, 2014	
ASSETS				
Tangible assets	1	11,138	5,996	
Goodwill	2	77	77	
Intangible assets	2	304	253	
Financial assets	3	212	7	
Tax receivables	4	2,457	2,557	
Other assets	5	1,500	1,586	
of which with related parties	32	-	86	
TOTAL NON-CURRENT ASSETS		15,688	10,476	
Inventories	6	794	774	
Trade receivables and other commercial assets	7	5,632	4,364	
of which with related parties	32	110	115	
Tax receivables	8	3,257	845	
Other receivables and sundry assets	9	1,576	1,734	
of which with related parties	32	86	516	
Other financial assets	10	18,168	6	
Cash and cash equivalents	32	11,770	11,384	
of which with related parties	11	3,465	3,459	
TOTAL CURRENT ASSETS		41,197	19,107	
TOTAL ASSETS		56,885	29,583	
LIABILITIES AND SHAREHOLDERS' EQUITY				
Capital		19,842	11,019	
Share premium reserve		45,764	5,635	
Other reserves		627	9,263	
Retained earnings (accumulated losses)		(13,520)	(832)	
Profit (loss) for the year		(20,784)	(13,003)	
TOTAL SHAREHOLDERS' EQUITY	12	31,929	12,082	
Liabilities for pensions and employee severance indemnity (TFR)	13	197	208	
Trade payables	14	2,600	-	
Other liabilities	15	3,313	5,317	
TOTAL NON-CURRENT LIABILITIES		6,110	5,525	
Trade payables	16	13,559	9,852	
of which with related parties	32	156	151	
Other liabilities	17	5,287	2,124	
TOTAL CURRENT LIABILITIES		18,846	11,976	
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY		56,885	29,583	



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

(amounts in Euro thousands )	Notes	Year 2015	Year 2014
	10	10.570	
Revenues	18	13,576	11,181
of which with related parties	32	-	111
Other income	19	3,188	1,241
Total operating revenues		16,764	12,422
Purchases of raw materials and consumables	20	4,063	2,966
Costs for services	21	19,590	11,165
of which with related parties	32	4,261	837
Costs for use of third-party assets	22	1,414	1,236
of which with related parties	32	665	842
Personnel costs	23	11,472	9,145
Other operating costs	24	137	127
Amortization, depreciation and write-downs	25	626	411
Total operating costs		37,302	25,050
Operating result		(20,538)	(12,628)
Financial income		160	70
of which with related parties	32	8	17
, Financial charges		(406)	(445)
of which with related parties	32	-	-
Net financial income (charges)	26	(246)	(375)
Pre-tax result		(20,784)	(13,003)
Income taxes	27	-	-
Profit (loss) for the year		(20,784)	(13,003)



### *Notes*

### 1. General information

MolMed's Financial Statements have been prepared in accordance with the International Accounting Standards ("IFRS") issued by the International Accounting Standards Board ("IASB") and approved by the European Union, as well as the provisions issued pursuant to art. 9 of Legislative Decree 38/2005. "IFRS" is also intended as including the International Accounting Standards (IAS) currently in force, as well as all the interpretations issued by the International Financial Reporting Interpretations Committee ("IFRIC"), previously known as the Standing Interpretations Committee ("SIC").

The Financial Statements formats have been prepared on the basis of the revised version of IAS 1 - Presentation of Financial Statements, as approved by Regulation no. 1274/2008 issued by the European Commission on 17 December 2008 and effective as from January 1, 2009.

The financial statement formats adopted are consistent with those indicated in IAS 1. In particular, the Statement of Financial Position has been prepared by classifying assets and liabilities into current and noncurrent; the Income Statement has been prepared by classifying operating expenses by nature of expense, since this form of presentation is considered more appropriate and representative of the Company's specific business. This type of presentation is considered representative of the Company's business.

The Statement of Cash Flows has been prepared showing the financial flows using the "indirect method", as indicated by IAS 7. In the Statement of Cash Flows, in order to provide a better representation of cash flows, some reclassifications have been made to the comparative figures.

In compliance with the requirements of Consob Resolution no. 15519 of July 27, 2006 as to the format of the Financial Statements, specific supplementary formats have been provided for related party transactions so as not to compromise an overall reading of the statements.

The Financial statements are in thousands of Euro, unless otherwise indicated. The Euro is the Company's functional currency.

### 2. Accounting standards and measurement criteria

#### General policies

The Company's Financial Statements have been prepared on a historical cost basis, adjusted for measurement of some financial instruments, and on a going concern basis.

#### Going concern

The Company's business model is typical of biotech companies developing new therapeutic products and having no product on the market. Negative cash flows 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 expected in forthcoming years.

The Company is also subject to some uncertainties associated with the sector in which it operates (notably the



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current product trial stage) regarding both the results that it may effectively achieve, and the relevant methods and timings.

Based on the accounting policies adopted, requiring full recognition of research and development costs in the Income Statement of the year they are incurred, the Company has always reported a loss since its incorporation. Consequently, the loss for 2015 was Euro 20,784 thousand, up Euro 7,781 thousand from the Euro 13.003 thousand loss recorded in the previous year.

The new business plan 2016-2018, updated on the basis of 2015 results and approved by Board of Directors during December 2015, assuming it becomes fully operational, provides for the following to be achieved in the 2016-2018 period:

- continuing the clinical and industrial development of the main experimental products;
- pursuing operations and investments aimed at boosting production capacity;

The Company has met its liquidity requirements from its incorporation up to the date of these Financial Statements through contributions from its shareholders. In particular, the capital increase, which was completed on April 9, 2015, generated gross proceeds of Euro 49,825 thousand (including Euro 10,145 thousand received from the main shareholders as future share capital increase).

Finally, as described in more detail in the 2014 Annual Report, the existing SEF agreement (expiring July 31, 2016) aims at making the Company's financial structure more flexible, diversifying the funding sources required to meet the Molmed's cash requirements.

Based on the above and on the analysis of future cash flows projected by the 2016-2018 business plan, the Company deems that the financial means and equity available can guarantee enough resources 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.

#### **Business combinations**

Acquisitions of subsidiary companies are accounted for under the acquisition method. The acquisition cost is determined based on the sum of fair values, at the transaction date, of the assets acquired, the liabilities assumed and the financial instruments issued by the Company in exchange for control, plus any costs directly attributable to the combination.

The acquiree's identifiable assets, liabilities and contingent liabilities complying with the recognition criteria of IFRS 3 are recorded at their fair value at the acquisition date, except for non-current assets (or groups of assets subject to disposal) which are recognized and measured at the lower of carrying amount and fair value net of costs to sell.

Therefore, the cost of a business combination is allocated by recognizing, at the acquisition date, the fair value of assets, liabilities and contingent liabilities which can be identified upon acquisition. The positive difference between the acquisition cost and the fair value of identifiable assets, liabilities and contingent liabilities is recorded under assets as goodwill. Should the difference be negative, it is directly recognized in profit or loss. Goodwill arising from acquisition is initially measured at cost and subsequently impaired, if necessary.

In accordance with IAS 36 (Impairment of assets), goodwill is tested for impairment annually, or more frequently, if specific events or changes in circumstances indicate that it may be impaired. However, impairment losses are not reversed when indications for impairment no longer exist. For further details, please refer to the "Impairment" paragraph below.

Upon IFRS first-time adoption, MolMed opted to retrospectively apply IFRS 3 to business combinations taking place before January 1, 2004, as provided for by IFRS 1. Consequently, goodwill generated from acquisitions



prior to that date was measured (without prejudice to any effects arising from the application of new standards) at the value determined according to the Italian accounting standards, after verification of recoverability. This kind of measurement applied to the acquisition of 100% shareholding of the research company Genera S.p.A. in December 2001, followed by its merger into MolMed S.p.A. effective from May 2, 2002.

#### Impairment

Intangible assets with an indefinite useful life (goodwill) are tested annually or when there has been some indication that an impairment has occurred.

Tangible and intangible assets are tested when any indication of impairment exists. If any indication of impairment exists, the recoverable amount of these assets is estimated to determine the amount of the writedown. When it is not possible to estimate the recoverable amount of an individual asset, the Company estimates the recoverable amount of the cash-generating unit to which the asset belongs.

The recoverable amount of an asset is the higher of the fair value, less costs to sell, and its value in use. In assessing the value in use, the estimated future cash flows are discounted to their present value, using a pretax discount rate that reflects current assessments of market, time value of money and risks specific to the asset.

An impairment loss is recognized in profit or loss when the recoverable amount of an asset or of a cashgenerating unit is lower than the carrying amount.

When indications of impairment loss for assets other than goodwill cease to exist, the carrying amount of the asset or the cash-generating unit is increased to the revised estimate of its recoverable amount, but it shall never exceed the carrying amount that would have been recorded had no impairment loss been recognized. A reversal of an impairment loss is recognized in profit or loss.

For the purpose of preparing the Financial Statements at December 31, 2015, and specifically testing tangible and intangible assets for impairment, the recoverable value is calculated on the basis of expected cash flows and under the following assumptions:

- use of post-tax cash flows deducted from the plans drawn up by the management;
- use of a discount rate equivalent to the Weighted Average Cost of Capital (WACC) at 13.22% and determined by considering a 1.70% free risk rate, 6.00% market risk premium and a 1.253 Beta coefficient. This rate was prudentially increased by 4 percentage points to account for the risks inherent in the Company's business;
- assessment of the probability of success during Phase III studies of products in the pipeline, based on studies in the sector and doctrine.

In determining the period over which management projected cash flows, account was taken of MolMed's business model, which is typical of biotech companies that are engaged in the development of new biopharmaceutical products and do not yet have any products out on the market. During this phase, massive costs are incurred, primarily due to testing and product development activities, with return expected in future years. Therefore, a period of 10 years was selected, in order to take into account the positive financial effects of the launch and distribution of the Company's products on the market, until they become mature, based on the penetration curves in their sector. It should also be noted that no terminal

For the purposes of the impairment test, the Company used the 2016-2018 business plan.approved by Board of Directors on December 11, 2015, based on the most recent available information following the end of the capital increase. Management projected the relevant flows using its best estimates to account for the effects of the launch of products currently in development under various assumptions.

The sensitivity of the results was also analyzed, based on scenarios that take into consideration reductions in



the probability of success for Phase II and III trials of products in the pipeline, considered to be a key parameter in estimating the fair value, and, in all cases, values in use proved to be higher than the relevant carrying amounts, even assuming a +/- 10% decrease in these probabilities.

Measurements made for the medium/long term take account of the sector in which the Company operates and of its research and development activities. In addition, forecast figures for the Company's activities and its expected results are based on business assessments regarding future and uncertain events: their occurrence could lead to significant differences from the forecasts made.

These events include, among other things, the Company's ability to find adequate financial resources to meet the investment planned in order to continue with its research and development activities, since the financial sustainability of the approved plans involves, as noted above, the acquisition of these resources.

At December 31, 2015, the carrying amount of tangible and intangible assets, and of shareholders' equity, was considerably lower than the Company's market capitalization.

#### **Tangible assets**

Tangible assets, net of accumulated depreciation and of any impairment losses, are recognized at purchase cost, including directly attributable ancillary costs. Costs subsequently incurred for improvements and transformations of tangible assets are capitalized only if they increase the reliably measurable future economic benefits. Maintenance or repair costs that did not significantly increase 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 by estimating the type of use and relevant life of the assets based on the residual useful life method. The depreciation rates indicated below (unchanged from 2014) 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 under the item to which they refer and are depreciated over their estimated useful life or, if shorter, over the remaining period of the lease agreement.

#### Leased assets

Lease agreements are classified as finance leases when the terms of the agreement substantially transfer all of the risks and benefits of ownership to the lessee. All other leases are considered operating leases. Assets held under finance leases are recognized as tangible assets at their fair value at the date of 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 useful life of the asset.

Since there is no reasonable certainty as to the acquisition of ownership of the asset at the end of lease period, assets held under finance leases are depreciated over the shorter of the lease term and their useful lives.

Leases where the lessor substantially retains all the risks and rewards of ownership of the assets are classified



as operating leases. Operating lease fees are recognized in profit or loss on a straight-line basis over the lease term.

#### Intangible assets

A purchased or internally-generated intangible asset is recognized under assets in accordance with IAS 38 – Intangible Assets, if it is identifiable and separable, it can be controlled, it is probable that future economic benefits are generated and its cost can be reliably measured.

Intangible assets may be classified as assets with a finite useful life and assets with an indefinite useful life.

The former are recognized at purchase or production cost, net of amortization and of any accumulated impairment losses. Amortization is calculated over their estimated useful lives, beginning from the date the asset is ready for use. The useful life is reviewed annually and any changes are recognized prospectively in profit or loss.

Intangible assets with an indefinite useful life are not amortized but are tested for impairment annually or more frequently if necessary.

#### Goodwill

Goodwill, equal to the portion of the acquisition cost exceeding the acquirer's portion of the fair value of the assets, liabilities and contingent liabilities recorded on the acquisition date, is classified as an asset with an indefinite useful life and is initially recognized at cost.

After acquisition, goodwill is not amortized, but it is tested for impairment annually or more frequently if indications of impairment exist. If the recoverable amount is lower than the carrying amount, the value of the assets is reduced to the recoverable amount. When goodwill has been allocated to a cash-generating unit that will be partially sold/divested, the related goodwill is considered for determining any gain/loss deriving from the transaction.

#### Other intangible assets

Other intangible assets are recorded at their historic acquisition cost, including directly attributable ancillary costs, or based on the costs directly incurred for their internal generation. They are amortized on a straightline basis over their residual useful life, estimated at ten years, except for certain costs regarding concessions, licenses and software, which are amortized over five years. In detail:

Concessions, licenses and trademarks

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

Patents and intellectual property rights

Patents that have been purchased are initially recognized at purchase cost and amortized on a straight-line basis over their expected useful life (ten years).

Research and development costs

Research costs are recognized in profit or loss in the period in which they are incurred. In-house costs for the development of new products are classified as intangible and are recognized under assets only if the following conditions are met:



- it is technically feasible to complete the asset so that it will be available for use or sale and there is the intention to do so;
- the Company is able to use or sell the asset;
- there is evidence that the costs incurred will generate probable future economic benefits. This
  evidence may consist in a market for the output of the asset or if it is to be used internally, the
  usefulness of the intangible asset;
- there are adequate technical and financial resources to complete the development and to internally use or sell the intangible asset;
- the expenditure attributable to the intangible asset during its development can be reliably measured.

In light of the Company's operations and the characteristics of the trials carried out, research and development costs are fully expensed as incurred. Based on the current product development stage, research and development costs are prudentially not capitalized.

#### Non-current financial assets

Non current financial assets include items such as guarantee deposits that the Company intends and is able to hold until maturity. These assets do not fulfill the requirements for classification as cash equivalents. They are recognized in and derecognized from the Financial Statements based on the date of negotiation. Such assets are initially recognized at fair value and subsequently measured at amortized cost, net of any impairment losses.

#### Receivables

Receivables are initially recognized at par value (representing the fair value of the transaction). They are then measured at amortized cost, net of any write-down recognized in profit or loss, if evidence shows that impairment has occurred.

Write-downs are equivalent to the difference between the carrying amount of receivables and the present value of estimated future cash flows, discounted at the effective interest rate. In particular, measurement of short-term trade receivables, for which the time effect is not significant, at amortized cost 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. Purchase 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 use 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. They include 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.

#### Other current financial assets

Financial assets are classified as "available-for-sale" and measured at fair value. As required by IAS 39, accumulated changes in fair value are recognized in a specific equity reserve until reversal or impairment, with



recognition of any gain or loss in profit or loss. The fair value is equivalent to the listing price at the end of the reporting period for securities listed on regulated markets.

Financial asset purchases and sales are recorded at the trading or settlement date.

#### **Derecognition of financial instruments**

A financial asset is derecognized when the rights to the cash flows from it expire and substantially all risks and rewards of ownership are transferred or it is considered not recoverable after exhausting all collection procedures. A financial liability is derecognized when the relevant contractual obligation is extinguished. Receivables sold as a result of factoring transactions are derecognized only when substantially all risks and rewards of ownership have been 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 employees earned during the period is recognized in profit or loss under personnel costs, while the imputed financial cost the Company would incur for a loan of the same amount as the TFR is recognized under net financial income (charges). Actuarial gains and losses reflecting the effects of changes in the actuarial assumptions used are recognized in other comprehensive income accounting for 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 actuarial calculations, using the Projected Unit Credit Method. Costs arising from the increase in TFR present value (as the period for payment gets closer) are recognized under "Personnel costs".

Starting from January 1, 2007, the 2007 Budget Law, and the related implementation decrees, introduced significant changes in employee severance indemnity regulations, including the choice for employees of allocating their post-employment benefits either to supplementary pension schemes or to the fund managed by the Italian social security institution (INPS).

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

Liabilities relating to the employee severance indemnity (TFR) recognized in the statement of financial position as a defined benefit plan represent the present value of the defined benefit adjusted to include any actuarial gains and losses.

#### Stock option plans

The Company provides additional benefits to the Chairman, General Managers and specific categories of employees through stock option plans.

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

#### **Financial payables**

Financial payables, consisting of liabilities arising from finance leases, are initially recognized at cost, equal to



the fair value of the amount received, net of any ancillary costs. Subsequently they are measured at the amortized cost, based on the effective interest rate.

#### Payables

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

#### Provisions for risks and charges

They include liabilities arising from current (legal or implicit) obligations, relating to a past event, in relation to which a disbursement can be reliably estimated. If it is due to occur after the following year, 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 necessary, 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 liability 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 state of completion of the service only when the result can be reliably estimated.

Revenues relating to upfront payments from the sale of rights to third party companies relating to company products under development are recognized over the period from the signing of the related out-licensing contract and the subsequent development milestone based on management's estimates. Revenues relating to milestone payments based on achievement of set development objectives are fully recognized when the right to such payment arises.

Government grant income is recognized when it is reasonably certain that it will be received. This takes place when the grant is approved by the relevant public sector bodies. This income is recognized based on the costs actually incurred as a percentage of the total costs budgeted for the financed research projects.

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

Costs and charges are accounted for on an accrual basis when they concern goods and services purchased or used during the period or when they have no identifiable future benefit.

#### 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 assets and liabilities using the effective interest rate. Financial charges are accounted for on an accrual basis 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 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 tax assets and liabilities 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, using the "liability method".

Deferred tax liabilities are generally recognized for all taxable temporary differences, except in the case 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, on July 15, 2011, Law 111/2011 was approved adopting Decree Law 98/2011 which provided urgent measures for Italy's financial stability (Corrective Plan 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 (this means 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 years. This 80% quantitative limit is not applicable to tax losses generated in the first three years of the company's incorporation, on the condition that they relate to new production activity.

These assets and liabilities are not recognized if the temporary differences are due to goodwill or to initial recognition (not to business combinations) of other assets or liabilities involved in operations which do not have an impact on accounting or taxable results. The carrying amount of deferred tax assets is reviewed at the end of each reporting period and written down in the event that it is no longer probable that there will be sufficient future taxable income to permit 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 effective rates at the end of the reporting period. Should the conditions exist, deferred taxes are directly recognized in profit or loss, except for those concerning items directly recognized in equity. In such 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 operating costs.

#### Foreign currency transactions

Transactions in foreign currencies are initially recognized at the exchange rate at the date of the transaction. Monetary assets and liabilities are translated at the exchange rate prevailing 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 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 other contract that may entitle its holder to ordinary shares.

#### Use of estimates

In compliance with IFRSs, the preparation of Financial Statements and related notes requires that management make estimates and assumptions which 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 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 realistic and reasonable assumptions based on 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 the notes.

A description of critical estimates highly 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 emerge in the periods following the reporting period.

#### Write-down of assets

Tangible and intangible assets are written down when specific events suggest that the carrying amount is not recoverable. Write-down is calculated by comparing the carrying amount with the relevant recoverable value, 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. Management performs it by using estimates of expected cash flows arising from the use or disposal of the asset, as well as suitable discount rates to calculate the present value. If the non-current asset is considered to be impaired, the Company writes down the asset for the amount 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 Company plans.

When preparing the Financial Statements for the year ended December 31, 2014, and, more specifically, when testing tangible and intangible assets for impairment, the Company has taken into account the expected performance for 2015 and future years, as resulting from the approved business plans and based on the current economic and financial position.

No impairment losses were recognized in the reporting period. Models used for testing are based on the assumptions indicated in the paragraph on "Impairment".

In particular, with reference to intangible assets, the assumption of their recoverability has been assessed based on the business plans which, as previously indicated in the paragraph on "Impairment", assume that adequate financial resources will be found in the future to meet the investment planned in order to continue with the research and development activities, and which are currently uncertain. The uncertainty connected to this situation could lead to the need – currently not foreseeable – to write-down intangible assets which are not currently written down in these Financial Statements.

#### 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. This assessment requires an opinion since changes in the assumptions could have a material impact on the recognition of deferred tax assets.

#### Amortization and depreciation

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

#### Stock option plans

The Company provides 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 their remuneration package. Employee stock options are measured at fair value at the grant date, based on models that take into account a number of aspects 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 of the market conditions and future events that could impact the measurements are updated.

# Accounting standards, amendments and interpretations applicable to annual reporting periods beginning on or after January 1, 2015

- On May 20, 2013 IFRIC 21 Levies was issued. This interpretation provides guidance on when to recognize a liability for a levy (other than income tax) imposed by a government.
- On December 12, 2013 the IASB published "Annual Improvements to IFRSs: 2011-2013 Cycle", a set of amendments to some IFRSs as part of the annual standard improvement process (including: IFRS 3 Business Combinations Scope exception for joint ventures, IFRS 13 Fair Value Measurement Scope of portfolio exception, IAS 40 Investment Properties Interrelationship between IFRS 3 and IAS 40). These amendments shall apply for annual periods beginning on or after January 1, 2015.

# 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, 2015

- Amendment to IAS 19 "Defined Benefit Plans: Employee Contributions" (published on November 21, 2013): concerning the recognition in the financial statements of contributions made by employees or third parties to defined benefit plans. This amendment shall apply for annual periods beginning on or after February 1, 2015.
- Amendment to IFRS 11 Joint Arrangements "Accounting for acquisitions of interests in joint operations" (published on May 6, 2014): concerning the recognition of the acquisition of interests in a joint operation



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whose activities represent a business. The amendments are effective from January 1, 2016, with early application permitted;

- Amendment to IAS 16 Property, plant and Equipment and to IAS 38 Intangibles Assets "Clarification of acceptable methods of depreciation and amortisation" (published on May 12, 2014): according to which, revenues generated by activities that involve the use of the asset subject to depreciation generally reflect factors other than merely the consumption of the economic benefits of the asset itself, a requirement that is instead necessary for depreciation. The amendments are effective from January 1, 2016, with early application permitted;
- Amendment to IAS 1 "Disclosure Initiative" (published on December 18, 2014): these amendments aim to clarify a number of disclosures that can impair the intelligibility of financial statements. The amendments are effective from January 1, 2016, with early application permitted.

Finally, in the context of the annual improvement process of the standards, on December 12, 2013, the IASB published the documents, *Annual Improvements to IFRSs: 2010-2012 Cycle*" (including IFRS 2 *Share Based Payments – Definition of vesting condition, IFRS 3 Business Combination – Accounting for contingent consideration, IFRS 8 Operating segments – Aggregation of operating segments and Reconciliation of total of the reportable segments' assets to the entity's assets, IFRS 13 Fair Value Measurement – Short-term receivables and payables*) and on September 25, 2014 "*Annual Improvements to IFRSs: 2012-2014 Cycle*" (including: IFRS 5 – *Non-current Assets Held for Sale and Discontinued Operations, IFRS 7 – Financial Instruments: Disclosure and IAS 19 – Employee Benefits*), which partially supplement the existing standards. Such amendments must be applied at the latest as of the financial years starting on or after February 1, 2015 and starting from financial years starting on or after January 1, 2016, respectively.

The above-mentioned amendments will not have any significant effects on the financial statement items and relevant disclosures.

#### Accounting standards, amendments and IFRS interpretations not yet endorsed by the European Union

- IFRS 15 Revenue from Contracts with Customers (published on May 28, 2014), which will replace the standards IAS 18 Revenue and IAS 11 Construction Contracts, as well as the interpretations IFRIC 13 Customer Loyalty Programmes, IFRIC 15 Agreements for the Construction of Real Estate, IFRIC 18 Transfers of Assets from Customers and SIC 31 Revenues Barter Transactions Involving Advertising Services. The new revenue recognition model provided for by this standard will apply to all contracts with customers, except for contracts that are within the scope of other IASs/IFRSs such as leases, insurance contracts and financial instruments. The key steps to recognize revenue according to the new model are:
  - o identify the contract with the customer;
  - o identify the performance obligations in the contract;
  - o determine the transaction price;
  - o allocate the transaction price to the performance obligations in the contract;
  - o recognize revenue when a performance obligation is satisfied.

The new standard is effective from January 1, 2018, with early application permitted.

- Final version of IFRS 9 Financial instruments (published on July 24, 2014). This document contains the results of the steps relating to classification and measurement, *Impairment* and *Hedge accounting* of the IASB project aimed at the replacement of IAS 39:
  - ✓ it introduces new classification and measurement requirements for financial assets and liabilities;



- ✓ as for the impairment model, the new standards requires credit losses to be recognized based on expected losses (as opposed to incurred losses in IAS 39), using all supportable information, that is available without undue cost
- ✓ unreasonable efforts including historical, current, and forward-looking information;
- ✓ it introduces a new hedge accounting model (increase of the types of transactions eligible for hedge accounting, change in the accounting method for forward contracts and options when included in a hedge accounting relationship, changes to effectiveness testing).
- The new standard, which replaces the previous versions of IFRS 9, must be applied for financial statements. On January 13, 2016, the IASB published the standard IFRS 16 Leases which is aimed at replacing the standard IAS 17 Leases, as well as the interpretations IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases—Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease.

The new standard provides a new definition of lease and introduces a criterion based on the right of use of an asset to distinguish lease contracts from service contracts, identifying the following discriminating factors: identification of the asset, the right to replace the same, right to obtain essentially all economic benefits arising from the use of the asset and the right to direct the use of the asset underlying the contract.

The standard establishes a single model for the recognition and measurement of lease contracts by the lessee, which entails the posting of the asset subject to lease, including operating leases, under assets with an offsetting financial payable, also providing the possibility not to recognize as leases contracts referring to "low-value assets" and leases with a contractual term equal to or shorter than 12 months. On the contrary, the standard does not include significant changes for lessors.

The standard must be applied starting from January 1, 2019 but early implementation is permitted solely for the Companies that have applied IFRS 15 - *Revenue from Contracts with Customers* in advance.

Investment Entities: Applying the Consolidation Exception (Amendments to IFRS 10, IFRS 12 and IAS 28) (published on December 18, 2014), including changes to issues arising from the adoption of the consolidation exception by investment entities. The amendments provided for by such document shall apply for annual periods beginning on or after January 1, 2016. Early adoption is allowed.

On September 11, 2014 the IASB issued **Sales or Contribution of Assets between an Investor and its Associate or Joint Venture (Amendments to IFRS 10 and IAS 28).** The document was published in order to resolve the current conflict between IAS 28 and IFRS 10 with regard to the measurement of the profit or loss resulting from the sale or contribution of non-monetary assets to a joint-venture or associate in exchange for a share in the capital of the latter. At present, the IASB has suspended the application of this amendment.

It should be noted that at present the Directors are assessing the possible effects arising from the introduction of these amendments.



## 3. Segment reporting

The business of MolMed, focused in the field of biotechnology, comprises a single sector of activity related to the research, development and production of innovative therapies that both products of their pipeline and for production activities on behalf of third parties

The essentially uniform nature of the activities and the progress of projects under development, will not allow the division into several sectors with different risks and returns from other business segments. The chief operating decision maker has been identified as the CEO for the most relevant decisions asking for approval to the Board of Directors and, if the problem is a medical / technical exists to support a Scientific Council composed of five members. Just because the research, development and production is considered a unit, the General Manager, who reports to the CEO, is responsible for NGR, TK, CAR, search and generic development and activities on behalf third parties. The latter is therefore the responsible managers of the operating area, which is the only sector 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, 2015 are shown in the table below:

(amounts in Euro thousand)	Balance at December 31, 2014	Purchases	Reclassifications	Disposals	Depreciation and write downs	Balance at December 31, 2015
Gross book value						
Plant and machinery	210	967		(3)	-	1,174
Industrial and commercial equipment	4,021	2,082	525	(89)	-	6,539
Leasehold improvements	4,354	1,337	3,939		-	9,630
Other tangible assets	1,075	534		(13)		1,596
Assets under construction and payments		00				
on account (Plant Bresso)	-	80	-	0	-	80
Assets under construction and payments						1,047
on account (Industrial equipment Bresso)	525	1,047	(525)	-	-	1,047
Assets under construction and payments						13
on account (Leasehold improvements Bresso)	3,952	-	(3,939)	-	-	
Total gross book value	14,137	6,047	-	(105)	-	20,080
Accumulated depreciation						
Plant and machinery	(210)	-	-	3	(12)	(219)
Industrial and commercial equipment	(3,092)	-	-	89	(302)	(3,305)
Leasehold improvements	(4,010)	-	-		(472)	(4,482)
Other tangible assets	(829)	-	-	13	(119)	(935)
Assets under construction and payments						
on account (Industrial equipment Bresso)	-	-	-			-
Assets under construction and payments						
on account (Leasehold improvements Bresso)	-	-	-	-		-
Total accumulated depreciation	(8,141)	-	-	105	(905)	(8,941)
Net book value						
Plant and machinery	-	967			(12)	956
Industrial and commercial equipment	931	2,082	525		(302)	3,236
Leasehold improvements	342	1,337	3,939		(472)	5,146
Other tangible assets	246	534			(119)	661
Assets under construction and payments						
on account (Plant Bresso)	-	80				80
Assets under construction and payments						1.047
on account (Industrial equipment Bresso)	525	1,047	(525)			1,047
Assets under construction and payments	<i>.</i>		(a			13
on account (Leasehold improvements Bresso)	3,952	-	(3,939)			
Total net book value	5,996	6,047	-	-	(905)	11,138

\* The depreciation showed in the table includes the portion for the leasehold improvements concerning the site in Bresso, totalling 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 lessor.

Tangible assets increased from Euro 5,996 thousand at December 31, 2014 to Euro 11,138 thousand at December 31, 2015, with a net increase of Euro 5,142 thousand. This significant increase was mainly due to investments related to the preparation and completion of leasehold improvements at the Bresso facility. In addition to the aforementioned investments, during the periodical usual renewal, where necessary, of laboratory equipment, the purchase of new equipment used in the production process, as well as works for the adjustment and optimization of the existing GMP system was carried out.

Below are the details of the main changes shown by asset category.

The increase in the item plant and equipment, amounting to Euro 967 thousand, is represented by the purchase of specific equipment and machinery used for the development of company products and the provision of services, installed at the new Bresso facility. The main investments in this category included a monitoring



system for "classified areas", where GMP activities are carried out, amounting to Euro 316 thousand, a nitrogen distribution system, amounting to Euro 275 thousand and a purified water system, amounting to approximately Euro 225 thousand.

"Industrial and commercial equipment", which rose from Euro 931 thousand at December 31, 2014 to Euro 3,236 thousand at December 31, 2015, includes tangible assets used in laboratories to develop the products in the pipeline and to provide services. The increase of Euro 2,607 thousand is attributable for Euro 2,082 thousand to acquisitions in financial year 2015 and for Euro 525 thousand to purchases relating to financial year 2014 reclassified under assets under construction. As for the categories commented above, the increase is almost entirely due to the set-up of the new laboratories at the Bresso facility.

"Leasehold improvements" include the cost of renovating the premises used by the Company, in particular its pharmaceutical laboratories and offices. The above-mentioned costs regarded building work and work on the systems that form an integral part of the premises. During 2015, assets under construction amounting to 3,939 thousand were reclassified as leasehold improvements, relating to costs incurred for the extraordinary construction works at the Bresso facility. The costs accounted for and invoiced to the property owner in accordance with the relevant agreements, relate to building work, and work planning services carried out by the "General Contractor". The aforementioned costs are depreciated over the term of the lease contract – 12 years. The depreciation of all areas included in the lease contract began following the delivery of the last part of the property dedicated to laboratory use in January 2015. It should be noted that, as better described in the 2014 annual report, the contract focusing on the lease of the aforementioned property sets forth that the costs necessary to renovate the property and make it fully operational, up to a maximum amount of Euro 4 million, will be borne by the property's owner. As provided for under the contract, the Company transferred the costs incurred for extraordinary maintenance work to the owner.

The item Other assets, which increased by Euro 534 thousand in 2015, refers mainly to the purchase of furniture and fixtures amounting to Euro 318 thousand and electrical and electronic equipment amounting to Euro 187 thousand. As for the previous categories, these increases were related to the setting up of the new Bresso site.

Assets under construction included the item Bresso laboratory equipment. As evident from the description, this item includes laboratory equipment for the new facility, the testing or commissioning of which is expected in the first months of 2016.

Overall depreciation totalled Euro 905 thousand, up compared to 2014 (Euro 356 thousand), because of the commissioning of the new facility in Bresso and the relevant equipment. The depreciation includes the portion for the improvements concerning the site in Bresso, totalling 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 lessor.

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

In the period no internal or external indicators were identified requiring assets to be tested for impairment.



#### Note 2 – Intangible assets and goodwill

The breakdown and change in intangible assets at December 31, 2015 are shown in the table below:

(amounts in Euro thousand)	Balance at December 31, 2014	Purchases	Reclassificat ions	Disposals	Depreciation and write downs	Balance at December 31, 2015
Merger with Genera S.p.A.	77	-	-	-	-	77
Goodwill	77	-	-	-	-	77
Patents and intellectual property rights	196	20	-	-	(40)	176
Concessions, licenses and trademarks	57		-	-	(14)	43
Assets under construction		85	-	-	0	85
Intangible assets	253	105	-	-	(54)	304
Total	330	105	-	-	(54)	381

"Goodwill" refers to the amount recorded subsequent to the merger of Genera S.p.A. in 2002.

For its IFRS first-time adoption, the Company decided not to apply IFRS 3 – Business Combinations on a retroactive basis to business acquisitions taking place before January 1, 2004. As a result, goodwill arising from acquisitions prior to the date of transition to IFRSs has been maintained at the amount determined under Italian GAAP at that date, after recognition of any impairment losses following an appropriate test. Recoverability is linked to the know-how of the technical personnel carrying out the research activities on the new product development projects and to any revenues that could be generated by their commercial development.

The increase in "Intangible assets" for a gross amount of Euro 105 thousand was mainly due to the validation in 19 countries of the European Patent which had been granted for a cell line for the semi-stable production of lentiviral vectors (Euro 21 thousand) and to the purchase of software to manage laboratory equipment in the new facility which is not yet operational (Euro 82 thousand).

Amortization amounted to a total Euro 54 thousand.

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

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 amounting to Euro 212 thousand consist of guarantee deposits. The Euro 205 thousand increase compared to December 31, 2014 was due to the payment of a guarantee deposit relating to the new lease contract entered into with the related party Ospedale San Raffaele S.r.l. for the Company's main offices in Milan, in Via Olgettina 58. For further details reference should be made to **Note 32**.

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

"Tax receivables (non-current)" amounting to Euro 2,457 thousand, refer to VAT receivables accrued by the company the refund of which has not yet been requested. As its costs exceed its revenues at this stage of business development, the Company regularly recognizes VAT receivables. This item did not changes substantially compared to the previous year.



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

"Other assets (non-current)" of Euro 1,500 thousand refer to the amount paid as an advance on future rents, to the owner of the property in the "Open Zone" scientific park in Bresso.

The change of Euro 86 thousand with respect to December 31, 2014, refers to the classification under "Other assets" in the non-current section of the consideration agreed to under the option agreement the Company has signed with the shareholder Science Park Raf in liquidation and its parent company Ospedale San Raffaele to purchase research projects. The agreement is effective as from the listing of the Company's shares on the Stock Exchange, which occurred on March 5, 2008. It is valid for eight years after this date. As from the above-mentioned date, the amount recorded under the item "Other assets", which originally totalled Euro 4,131 thousand, has started to decrease, pro rata temporis, with the related charge recorded in the income statement on a straight-line basis over the contract eight-year minimum duration. The above-mentioned agreement will be expired in March 2016.

#### *Note 6 - Inventory*

Inventory at December 31, 2015 is broken down as follows:

(amounts in Euro thousand)	December 31, 2015	December 31, 2014
Processing materials	221	258
Reagents	447	453
General materials	126	63
Total inventories	794	774

At December 31, 2015 inventory consists of materials and reagents used in the Company's laboratories. The book value of inventories is mainly in line with that recorded at 31 December, 2014.

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

At December 31, 2015, trade receivables and other commercial assets are broken down as follows:

(amounts in Euro thousand)	December 31, December 31,			
	2015	2014		
Trade receivables	3,405	1,760		
Prepayments	81	70		
Invoices to be issued	890	2,220		
Receivables from related parties	81	88		
Prepaid expenses concerning costs pertaining to future periods	1,175	226		
Total trade receivables and other commercial assets	5,632	4,364		

The increase in trade receivables and other commercial assets reflects the trend of the billing and collection dynamics for the services provided.

Prepaid expenses increased as a result of advances to suppliers for activities only partially carried out at December 31, 2015.

Receivables from related parties mainly concern the services provided by the Company to the related party Ospedale San Raffaele S.r.l.



They are recognized net of a bad debt provision of Euro 28 thousand, created in 2011 in relation to the impairment of receivables due from Fondazione San Raffaele del Monte Tabor in liquidation.

Receivables, with the exception of the above, did not show any overdue accounts.

#### Nota 8 - Tax receivables (current)

Tax receivables at December 31, 2015 are broken down as follows:

(amounts in Euro thousand)	December 31, 2015	December 31, 2014
VAT receivables	700	700
Tax crediti R&D costs	2,397	-
Withholding taxes	160	145
Total tax receivables	3,257	845

Under current tax receivables, the Company only shows the amount of VAT receivables that may offset other taxes under Italian tax law, as well as VAT receivables 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 receivables are recognized under non-current tax receivables – therefore reference should be made to **Note 4**.

Current tax receivables included a tax credit of Euro 2,397 thousand for research and development pursuant to Ministerial Decree of May 27, 2015, implementing Law No. 190 of December 23, 2014 (2015 Stability Law). Said law provides for the grant of a tax credit to all companies investing in research and development activities with effect from the tax year following that in progress at December 31, 2014 and until that in progress at December 31, 2019. Income arising from such tax credit was recognized in financial year 2015, the year in which the costs giving the right to credit were incurred.

#### Nota 9 - Other receivables and sundry assets

Other receivables and sundry assets at December 31, 2015 are broken down as follows:

(amounts in Euro thousand)	December 31, 2015	December 31, 2014
Price portion of option right	86	516
Accrued research and development grants	1,272	947
Prepayments relating to costs not pertaining to the period	217	240
Other receivables	1	31
Total other receivables and sundry asset	1,576	1,734

Other receivables and sundry assets of Euro 1,576 thousand and Euro 1,734 thousand at December 31, 2015 and at December 31, 2014, respectively, consist of Euro 86 thousand to be allocated to the income statement in the 12 months following the consideration agreed to under the option agreement the Company has signed with the shareholder Science Park Raf in liquidation and its parent company Ospedale San Raffaele, as detailed in **Note 5**. For further information, reference should be made to **Note 32**.

Furthermore, the item includes receivables of Euro 1,272 thousand for public sector research and development grants awarded and still to be received, in addition to prepaid expenses relating to:



- insurance premium costs of Euro 1 thousand;
- operating costs incurred for contracts based on "work progress" and maintenance and assistance fees for information services and other minor amounts of Euro 216 thousand

#### Nota 10 – Other financial assets

This item, amounting to Euro 18,168 thousand at December 31, 2015, compared to 6 thousand at December 2014, refers to the short-term use of corporate financial resources for investments in bonds whose nominal values amount to Euro 8,000 thousand, maturing in January 2016, and time deposits amounting to Euro 10,000 thousand expiring in August 2016. The item also includes accrued interest income on such investments amounting to Euro 138 thousand.

The sharp increase (Euro 18,162 thousand) from December 31, 2014 is due to the increase in cash related to the capital increase completed in April 2015.

#### Note 11 – Cash and cash equivalents

Cash and cash equivalents are broken down as follows:

(amounts in Euro thousand)	December 31, 2015	December 31, 2014
Bank and post office accounts	8,292	7,915
Bank and post office accounts - related parties	3,465	3,459
Cash on hand	13	10
Cash equivalents	-	-
Total cash and cash equivalents	11,770	11,384

At December 31, 2015 cash and cash equivalents amounted to Euro 11,770 thousand (Euro 11,384 thousand at December 31, 2014), including Euro 11,757 thousand of bank accounts and Euro 13 thousand of cash on hand.

#### Note 12 - Shareholders' equity

Shareholders' equity at December 31, 2015 totalled Euro 31,929 thousand. The detailed breakdown was as follows:

(Amounts in Euro thousand)	December 31, 2015	December 31, 2014
Share capital	19,842	11,019
Share premium reserve	45,764	5,635
Other reserves:		
Stock option plan reserve	416	644
Actuarial valuation reserve	(12)	(19)
Fair value valuation reserve		
Other	223	8,638
Retained earnings (accumulated losses)	(13,520)	(832)
Profit (loss) for the year	(20,784)	(13,003)
Total shareholders' equity	31,929	12,082



As more fully described in the previous paragraph *1.2 Other events occurred in 2015*, of this Report, a capital increase was performed in early April 2015. It ended with the full subscription of 187,711,408 shares, for an aggregate amount equal to Euro 49,825 thousand, of which Euro 8,823 thousand representing capital and Euro 41,002 thousand share premium. It should be noted that costs of Euro 873 thousand directly connected to the capital increase and relating to bank, consultancy and audit fees were deducted from the share premium reserve.

#### Capital

At December 31, 2015, the fully subscribed and paid-in capital amounted to Euro 19,842 thousand and consisted of 421,450,672 ordinary shares with no par value.

Shareholder	No. of shares (*)	%
Fininvest S.p.A.	107,173,138	25.43
Airain Lda	24,037,678	5.70
Science Park Raf S.p.A.	10,749,208	2.55
H-Equity S.r.I.	11,512,216	2.73
H-Invest S.p.A.	267,978,432	63.59
Total	421,450,672	100.00

\* based on Company data at December 11, 2015

\* based on Company data at June 03, 2015

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 totalled Euro 45,764 thousand. The net increase in the share premium reserve of Euro 40,129 thousand reflects the joint effect of the changes set out below:

- the increase connected to the share capital increase ended in April 2015 for Euro 41,002 thousand;
- the decrease relating to the deduction from this reserve of the costs of Euro 873 thousand directly connected to the share capital increase (bank, legal and audit fees).

#### Other reserves

Other reserves are broken down as follows:

#### a) Stock option plan reserve

The stock option plan reserve of 416 thousand was set up on January 1, 2006 upon first-time adoption of IFRSs, in order to include the fair value of stock option plans. Reserve was calculated by determining the fair value of the rights granted as at the granting dates. In later years, the stock option plan reserve has increased, and changes were recognized under personnel costs in the income statement. Changes in the period are the result of a Euro 87 thousand increase arising from the recognition of the amount accrued based on the new 2012 stock option plan pertaining to the period, and of Euro 315 thousand decrease due to the expiry of type A options of the above-mentioned plan. On April 9, 2015 the Board of Directors found that the vesting conditions for type A options were not met, therefore, all type A options shall be considered expired.



#### b) Actuarial valuation reserve

The actuarial valuation reserve at December 31, 2015 is negative to the tune of Euro 12 thousand, compared to a negative value of Euro 19 thousand at December 31, 2014.

#### c) Other Reserves

The item Other reserves of Euro 223 thousand mainly consists of the following reserves:

- The Reserve for Unexercised Rights from the 2014 capital increase (Euro 45 thousand) refers to the proceeds of the sale of the rights that were not exercised during the capital increase carried out in 2014.
- The Reserve for Unexercised Rights from the 2015 (Euro 178 thousand) capital increase refers to the proceeds of the sale of the rights that were not exercised during the capital increase carried out in 2015.

The Reserve for capital contribution on account of future issues of shares amounting to Euro 8,593 thousand at December 31, 2014 decreased to zero at December 31, 2015 following the 2015 capital increase.

#### Retained earnings (accumulated losses)

The item totalled Euro 13,520 thousand at December 31, 2015. The increase of Euro 12,688 thousand compared to the year ended December 31, 2014, was due to the recognition of:

- Euro 13,003 thousand increase relating to the loss for 2014 which was classified under accumulated losses as per the shareholders' meeting resolution of June 3, 2015;
- Euro 315 thousand decrease relating to the release of the Reserve relating to the A options of the 2012 stock option plan which expired in the period, as described in more detail above and in **Note 32**.

#### Main shareholders' equity items

(amounts in Euro thousand)	Balance at December 31, 2015	Purpose of use	Amount available
Reserves			
-Share premium reserve	45,764	A,B	45,764
-Stock option plan reserve	416	-	-
-Fair value reserve	-		-
-Other reserves			
- Shareholders' advance payment for share capital increase	-		-
- Actuarial valuation reserve	(12)	-	-
- Unexercised rights 2014 reserve	45	A,B	45
- Unexercised rights 2015 reserve	178	A,B	178
-Retained earnings (accumulated losses)	(13,520)	-	-

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 plans and other employee benefits following termination of the employment relationship or payable when certain requirements are met. It consists of accruals relating to the Company's employee severance indemnity (TFR).

Liabilities for pensions and employee severance indemnity totalled Euro 197 thousand at December 31, 2015 (Euro 208 thousand at December 31, 2014).

Changes in the period are reported below:

(amounts in Euro thousand)	December 31, 2015	December 31, 2014
Opening balance	208	184
Uses	(6)	(4)
Other movements	0	7
Financial loss	2	5
Actuarial (gain)/loss	(7)	16
Total liabilities for pensions and employee severance indemnity (TFR)	197	208

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, 2015, 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 for request of early payments;
- discounting, at the measurement date, of each probability-based payment.

More specifically, the following assumptions were adopted:

- Annual discount rate: 1.39%
- Annual inflation rate: 1.50% for 2016, 1.80% for 2017, 1.70% for 2018, 1.60% for 2019, 2% as from 2020
- TFR annual increase rate: 2.625% for 2016, 2.85% for 2017, 2.775% for 2018, 2.7% for 2019, 3% as from 2020



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Demographic assumptions

- Mortality rate: RG48 table
- Disability: INPS tables by age and sex
- Retirement age: 100% General Compulsory Insurance prerequisites met

Annual turnover and TFR advance payments

- Advance payment frequency, %: 5.00%
- Turnover frequency: 7.00%

The additional information required by the amended IAS 19 is shown below:

hypothesis variation						
TFR	turnover fr	equency	inflatio	on rate	discou	int rate
	-1%	1%	+ 1/4 %	- 1/4 %	+ 1/4 %	- 1/4 %
197	196	198	199	195	194	200

Below is an indication of the contribution for the subsequent year and the average financial duration for defined benefit plans:

- Cost service: 0
- Duration of the plan: 0.67

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

Trade payables (non-current), which at December 31, 2015 amounted to Euro 2,600 thousand, consisted entirely of the non-current portion of the deferred upfront payment by GSK in relation to the agreement signed on March 19, 2015, and recognized in the income statement over the term of the agreement. For further details, reference should be made to *1.1 Summary of activities during 2015*.

#### Note 15 – Other liabilities (non-current)

Other liabilities amounting to Euro 3,313 thousand at December 31, 2015, down Euro 2,004 thousand compared to December 31, 2014, mainly refer to non-current deferred income referring to leasehold improvements at the new facility in Bresso. The item Deferred income mainly includes all costs incurred for the new site up until December 31, 2015, where the Company is expanding its production capacity. Based on the contract focusing on the lease of the aforementioned property, the costs necessary to renovate the property and make it fully operational, up to a maximum amount of Euro 4 million, will be borne by the property's owner. As provided for under the contract, the Company will then transfer the costs incurred for extraordinary maintenance work to the owner. Costs are recorded under 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 starting from when the property progressively becomes ready for use. From May 2014, the depreciation of charges for assets already in use began as well as the closure of the related amounts of deferred income.

The Company reclassified most of said deferral as non-current following the formal delivery of the offices in



2014 and the laboratories in early 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, under current liabilities. For further details reference should be made to **Note 17**.

The above-mentioned decrease, as better described in **Note 17**, was due to the reclassification to "Other liabilities (current)" of the advance received from the European Union in relation to the CELL-PID and SUPERSIST projects, which are scheduled for completion in April 2016 and October 2016, respectively.

#### *Note 16 – Trade payables*

Trade payables amounted to Euro 13,559 thousand at December 31, 2015, compared to Euro 9,852 thousand at December 31, 2014, and are broken down as follows:

(amounts in Euro thousand)	December 31, 2015	December 31, 2014
Trade payables	10,210	9,414
Payables to related parties	154	151
Deferred income concerning revenues pertaining to future periods	3,195	287
Total trade payables	13,559	9,852

At December 31, 2015 trade payables included Euro 7,624 thousand due in Italy, Euro 2,247 thousand due in European Union countries and Euro 339 thousand due in other countries (mainly in USD).

Payables to related parties mainly consist of services provided to the Company based on agreements entered into with Ospedale San Raffaele.

Deferred income mainly refers to revenues from gene and cell therapy services, to be provided by the Company in the first months of 2016. The significant change of Euro 2,908 thousand, from Euro 287 thousand at December 31, 2014 to Euro 3,195 thousand at December 31, 2015, was largely due to the impact of the agreement entered into with GSK on March 19, 2015 leading to the recognition of deferred income in relation to the up-front payment and advances recognized in profit or loss over the agreement term and when the service is effectively provided, respectively.

#### Note 17 – Other liabilities

The item is broken down as follows:

(amounts in Euro thousand)	December 31, 2015	December 31, 2014
Amounts due to employees for holidays and bonuses	735	789
Amounts due to social security institutions	576	502
Tax payables	448	363
Amounts due to freelance consultants	51	22
Other payables	3,067	106
Deferred income (Bresso)	410	342
Total other liabilities	5,287	2,124



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 2015, but paid to the authorities the following month.

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

The increase in the item "Other current liabilities" of Euro 2,961 thousand is mainly related to the classification of Euro 1,961 thousand under such item for advances on the projects financed by the European Community CELL-PID and *SUPERSIST*, which will be completed within the next 12 months as well as the termination of the employment relationship with Ms. Marina Del Bue resulting from the aforementioned renewal process of the organizational structure which began in December 2015.

The item Deferred income is primarily represented by depreciation charges, amounting to Euro 333 thousand, which represents depreciation for the next 12 months of an amount equal to Euro 4 million, recorded under tangible assets, charged to the ownership of the premises at the Bresso "Open Zone". For further details reference should be made to **Note 15**.

#### 5. Notes to the Income Statement

#### *Note 18 – Revenues*

The Company's revenues are generated by the following services:

(amounts Euro thousand)	Year 2015	Year 2014
Revenues from development and production activities undertaken on behalf of third parties	13,576	11,181
Total operating revenues	13,576	11,181

GMP development and production activities on behalf of third parties generated revenues of Euro 13,576 thousand compared to Euro 11,181 thousand recorded in the previous year (21.4%), thanks to the abovementioned agreements with GlaxoSmithKline (GSK) and Fondazione Telethon, both in relation to GMP development and production activities for new gene therapy treatment of rare genetic diseases.

In this regard, as already noted, in 2015 a strategic agreement was entered into with GlaxoSmithKline (GSK) which had a positive impact on revenues for the year. In 2015 (i) contractual upfront payments were recorded in the income statement over the duration of the agreement (until March 2020) and (ii) the first milestone was recognized in the income statement after the contractual targets were reached; furthermore, revenues based on services provided in 2015 were recognized.

#### Note 19 – Other income

This item, amounting to Euro 3,188 thousand, mainly consists of public sector research and development grants and is broken down as follows:



(amounts in Euro thousand)	Year 2015	Year 2014
European Commission (Persist project)	-	38
European Commission (Optistem project)	-	107
European Commission (Cell - pid project)	138	215
European Commission (Supersist)	560	409
Region of Lombardy (ATP 2009)	-	294
Region of Lombardy (Innovazione Processi)	-	158
Other grants	21	14
Other revenues	2,469	6
Total other income	3,188	1,241

Public sector grants are accounted for based on the costs actually incurred for the research projects eligible for grants. Income from the most important grants recorded during 2015 related to two projects under the Seventh Framework Programme of the European Union.

The item "Other revenue" included a tax credit of Euro 2,397 thousand for research and development pursuant to the Ministerial Decree of May 27, 2015, implementing Law No. 190 of December 23, 2014 (2015 Stability Law). Income arising from such tax credit was recognized in financial year 2015, the year in which the costs giving the right to credit were incurred. For further details reference should be made to **Note 8**.

#### Note 20 – Purchases of raw materials and consumables

This item is broken down as follows:

	Year 2015	Year 2014
Processing materials	1,149	1,123
Reagents	2,043	1,282
General laboratory materials	809	418
Maintenance materials	83	43
Change in raw materials inventory	(21)	100
Total purchases of raw materials and consumables	4,063	2,966

The costs for raw materials and consumables, which largely consist of materials and reagents used in production and development activities, rose from Euro 2,966 thousand at the end of 2014 to Euro 4,063 thousand at the end of 2015.

The increase for Euro 1,097 thousand in the aforementioned costs (37.0%) was mainly due to the increase in GMP development and production activities on behalf of third parties and to the increased treatment on Zalmoxis® (TK) patients involved in the trial and to the industrial development of this product.



#### *Note 21 – Costs for services*

The breakdown of this item at December 31, 2015 and at December 31, 2014 is as follows:

(amounts in Euro thousand)	Year 2015	Year 2014	
Outsourced development costs	12,054	5,220	
Option rights	516	516	
Consultancy and technical fees	940	428	
License and patents consultancy fees	414	916	
Maintenance	549	325	
Transport and storage of laboratory materials	455	328	
Utilities	1,083	507	
Directors and statutory auditors' fees	439	446	
Audit	81	88	
Legal, administrative and managerial fees	773	556	
Listing consultancy fees and other listing costs	151	105	
Supervisory board fees	155	142	
Communications agency fees	255	275	
IT assistance and other IT costs	410	299	
Other general and administrative costs	684	578	
Ttravel, staff training and othe personnel costs	631	436	
Total costs for services	19,590	11,165	

Costs for services rose from Euro 11,165 thousand at December 31, 2014 to Euro 19,590 thousand at December 31, 2015. The increase of Euro 8,425 thousand recorded in the period is attributable to the following combined effects:

- increase in outsourced development costs from Euro 5,220 thousand in 2014 to Euro 12,054 thousand in 2015, mainly due to (i) the acquisition on April 13, 2015 of the CAR-CD44v6 research project from Ospedale San Raffaele for Euro 3.2 million by exercising the option mentioned above (in the paragraph 3. *MolMed's activities: research, development and production* of this Report) and (ii) the continuation of the industrial development of one of the products in the pipeline;
- increase in costs for technical consulting and collaborations, from Euro 428 thousand in 2014 to Euro 940 thousand in 2015, mainly attributable to costs related to the enrolment of patients for the product Zalmoxis® (TK) and costs related to technical consultancy for the setting up of the new facility;
- decrease of Euro 502 thousand (-54.81%) in costs for "License fees" and patent costs from Euro 916 thousand in 2014 to Euro 414 thousand in 2015, mainly due to the recognition in the prior-year period of a milestone payment in relation to the regulatory process of a product in the pipeline;
- increase in maintenance costs from Euro 325 thousand at the end of 2014 to Euro 549 thousand at the end of 2015, mainly due to the costs incurred from the ordinary revamping of the production systems in the current GMP facility;
- increase in costs related to the transport and storage of materials, from Euro 328 thousand at December 31, 2014 to Euro 455 thousand at December 31, 2015, relating to the treatment of Zalmoxis® (TK) patients and the continuation of NGRhTNF clinical studies;



- increase in utility costs from Euro 507 thousand in 2014 to Euro 1,083 thousand in 2015, linked to expansion of the surface area occupied by MolMed at the Open Zone in Bresso;
- Increase of Euro 217 thousand in costs for legal and administrative consultancy from Euro 556 thousand at December 31, 2014 to Euro 773 thousand at December 31, 2015. The change is mainly due to the increase in legal advice for the drafting of contracts relating to major projects for the company and activities related to corporate governance;
- increase of Euro 111 thousand for IT support costs from Euro 299 thousand at December 31, 2014 to Euro 410 thousand at December 31, 2015. This increase is due to the advice required by the company for the implementation of the new Bresso site.

It should be pointed out that the costs relating to option rights include the share, pertaining to the period, of costs arising from the option agreement for the purchase of research projects entered into in December 2001 by the Company with the shareholder Science Park Raf in liquidation and its parent company, Ospedale San Raffaele.

#### Note 22 – Costs for use of third-party assets

(amounts in Euro thousand)	Year 2015	Year 2014
Rental of premises	1,247	1,106
Other rentals	167	129
Total costs for use of third-party assets	1,414	1,236

"Costs for use of third-party assets", amounting to Euro 1,414 thousand in 2015, increased by Euro 178 thousand compared to the prior-year period following the commencement of the lease of the secondary office in Bresso in May 2014.

#### *Note 23 – Personnel costs*

These costs are broken down as follows:

(amounts in Euro thousand)	Year 2015	Year 2014	
Wages and salaries	8,861	6,729	
Social security contributions	2,059	1,866	
Defined contribution plans	436	368	
Stock option costs	87	161	
Other personnel costs	29	21	
Total personnel costs	11,472	9,145	

Personnel costs increased (+25.4%) compared to the previous year, from Euro 9,145 thousand in 2014 to Euro 11,472 in 2015. This increase was related to both the increase in the number of employees with operational roles, as well as the termination of the employment relationship with Ms. Marina Del Bue resulting from the aforementioned renewal process of the organizational structure, which began in December 2015. The remuneration component arising from stock option plans refer to plans with Company shares as underlying securities and represent the notional cost recognized as an offsetting entry to a specific shareholders' equity reserve (see **Note 12**).



Personnel costs include the fees paid to Prof. Bordignon, totalling Euro 750 thousand per year. This amount refers to the agreement between the Company and Prof. Bordignon for the activities carried out on the basis of powers conferred to him by the Shareholders' Meeting and by the Board of Directors on April 22, 2013. During 2015, the average number of employees was 132 (compared to 122 in the first half of 2015 and 105 in 2014). At December 31, 2015, the Company had 152 employees, of which 132 on open-ended contracts and 20 on fixed-term contracts. They are broken down as follows:

	2015	2014
Executives	10	8
Middle management	36	28
Clerical staff	102	75
Technicians	4	4
Total	152	115

#### *Note 24 – Other operating costs*

The item "Other operating costs", amounting to Euro 137 thousand at December 31, 2015, is in line with the previous year.

(amounts in Euro thousand)	Year 2015	Year 2014	
Printed and promotional materials	1	1	
Stationery	18	18	
Entertainment costs	24	17	
Membership fees	46	31	
Donations	26	52	
Books and magazines	9	3	
Other costs	13	5	
Total other operating costs	137	127	

#### Note 25 – Amortization, depreciation and impairment

Amortization, depreciation and impairment totalled Euro 626 thousand in 2015, showing an increase of Euro 215 thousand compared to the prior year following the beginning of the amortization and depreciation period of the assets relating to the new facility at Bresso. Investments of Euro 6,152 thousand in 2015 were almost entirely due to the secondary offices in Bresso, to routine replacement of laboratory equipment and the purchase of new machinery to be used in the Zalmoxis® (TK) manufacturing process, as well as to maintenance and improvement work on the GMP facility.

(amounts in Euro thousand)	Year 2015	Year 2014	
Amortization of intangible assets	54	75	
Depreciation of tangible assets	572	336	
Total amortization, depreciation & write-downs	626	411	



#### *Note 26 – Financial income and charges*

This item is broken down as follows:

(amounts in Euro thousand)	Year 2015	Year 2014	
FINANCIAL INCOME:			
Interest and other financial income	33	51	
Gains on securities	80	0	
Exchange gains	47	19	
Total financial income	160	70	
FINANCIAL CHARGES:			
Exchange losses	(250)	(176)	
Finance lease interest expense	-	(2)	
Other interest expense	-	(150)	
Other charges	(156)	(117)	
Total financial charges	(406)	(445)	
Total financial income (charges)	(246)	(375)	

The Company's financial activities were negative to the tune of Euro 246 thousand, showing a positive change of Euro 129 thousand on 2014.

Financial income of Euro 160 thousand (Euro 70 thousand at December 31, 2014) mainly arose from the management of the Company's cash resources through temporary low-risk investments.

Financial charges, amounting to Euro 406 thousand in 2015, decreased (-8.8%) compared to financial year 2014. The decrease recorded during the period is attributable to the commissions recognized during the previous year in relation to the transfer without recourse of VAT receivables collected within the year 2014.

#### *Note 27 – Income taxes*

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

Taking into account the Company's operations and the outlook provided by business plans, as in the previous reporting period, the Company did not recognize the tax credit that could arise from calculation of deferred taxes on temporary differences deductible in future years. At December 31, 2015 the tax losses to be carried forward totalled Euro 173,197 thousand and the theoretical deferred tax assets totalled Euro 42,669 thousand. With reference to deferred tax assets there is no reasonable assurance as regards recoverability and relevant timings, due to a lack of adequate elements for forecasting.

In implementation of the 2016 Stability Law (Law 2018/2015), published in Official Gazette 302 of December 30, 2015, among the many interventions, the corporate income tax rate shall decrease from 27.5% to 24% as of 2017.

The following table provides a summary of the temporary differences at December 31, 2015 and 2014:

# MOLMED

(amount in Euro thousand)	December 31, 2015			December 31, 2014		
	Temporary differences amount	Rate	Tax effect	Temporary differences amount	Rate	Tax effect
Directors' fees	50	24.00%	12	22	27.50%	6
Manteinance in exceeds	198	24.00%	48	151	27.50%	42
Other temporary differences	2,760	24.00%	662	130	27.50%	36
Upfront & milestone revenues differences	29	24.00%	7	479	27.50%	132
Tax losses carried forward as perArticle 84, par. 2 TUIR (start up losses)	1,552	24.00%	372	1,552	27.50%	427
Tax losses carried forward as perArticle 84, par. 1 TUIR	173,197	24.00%	41,567	151,617	27.50%	41,695
Total deferred tax assets	177,787		42,669	153,951		42,337
Other temporary differences	-	24.00%	-	1	27.50%	-
Total deferred tax liabilities	-		-	1		-

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

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

(amounts in Euro)	Year 2015	Year 2014
Basic earnings/(loss) per share	(0.0553)	(0.0566)
Diliuted earnings/(loss) per share	-	-

As required under IAS 33, diluted earnings (loss) per share take into account the effects of all dilutive potential ordinary shares. The Company has set up two stock option plans, which offer call options on Company's shares at a set strike price.

The Company has not calculated the diluted loss per share, since with reference to the 2008 Plan the strike price is higher than the average market price in the period, and therefore the options would not be exercised, while in relation to the 2012 Plan, the strike price is lower than the average market price in the period, and therefore, an anti-dilutive effect would be generated that should not be indicated.

The calculation of the basic earnings (loss) per share is based on the net loss recorded in 2015 and 2014 - Euro 20,784 thousand and Euro 13,003 thousand, respectively – and on the weighted average number of ordinary shares outstanding in the relevant periods – 237,375,358 and 375,765,820, 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, 2015	December 31, 2014	
Cash on hand	14	10	
Other cash	11,756	11,374	
Cash equivalents	-	-	
A. Total cash and cash equivalents	11,770	11,384	
B. Current financial receivables and other financial assets	18,168	6	
Finance lease payables	-	-	
Current financial Debts	-	-	
C. Current financial debt	-	-	
D. Net current financial position (A+B+C)	29,938	11,390	
Finance lease payables	-	-	
Non current financial Debts	-	-	
E. Non-current financial debt	-	-	
F. Net financial position (D+E)	29,938	11,390	

Net financial position was positive to the tune of Euro 29,938 thousand at December 31, 2015, almost fully consisting of cash and cash equivalents and current financial receivables consisting of bonds, with no financial debt. Net financial position was positive to the tune of 11,390 thousand at December 31, 2014 and the change in 2015 (Euro 18,548 thousand) was mainly due to (i) income of Euro 39,858 thousand from the capital increase, (ii) Euro 1,552 thousand received in February 2015 from shareholders parties to the shareholders' agreement as a capital contribution on account of future issues of shares (offset by the 2015 capital increase), (iii) income from the aforementioned agreement entered into with GSK on March 19, 2015 and (iv) the purchase of the CAR-CD44v6 research project for Euro 3,904 thousand, including VAT.

#### Note 30 – Contingent liabilities, commitments, and guarantees

#### Contingent liabilities

At present, the Company has no positions, which may result in contingent liabilities.

#### Commitments and guarantees

Commitments and guarantees are broken down as follows:

(amounts in Euro thousand)	December 31, 2015	December 31, 2014	
Guarantees	7,300	8,048	
Commitments			
Total guarantees and commitments	7,300	8,048	



Guarantees mainly consist of bank guarantees for the refund of VAT receivables (Euro 6,946 thousand). Furthermore, Euro 199 thousand refer to the guarantees issued for the payment of real estate leases, Euro 153 thousand refer to the guarantees issued in favour 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

The Company's Extraordinary Shareholders' Meeting of October 29, 2007 resolved a capital increase by consideration in cash of up to a total Euro 772,178.60, through the issue of up to 3,728,034 ordinary shares. These shares will be reserved, pursuant to Article 2441, last paragraph, of the Italian Civil Code, for the employees of the Company and of any subsidiaries or parent companies, as part of the relevant stock option plans and, pursuant to Article 2441, paragraph 5, of the Italian Civil Code, for the executive officers and consultants of the Company and of any subsidiaries or parent companies, as part of the relevant stock option plans. Pursuant to Article 2439, second paragraph, of the Italian Civil Code, this capital increase does not require all shares to be subscribed and may be performed in several installments by December 31, 2023. The Shareholders' Meeting also resolved to vest the Board of Directors with the powers to prepare one or more incentive schemes regulations, to identify the beneficiaries of options among the executive officers, consultants and employees of the Company (or any subsidiaries or parent companies) and to determine the number of options to be granted to each beneficiary, as well as the subscription price that will be determined each time that options are granted, at an amount equal to the "normal value" of the newly-issued ordinary shares, pursuant to Article 9, fourth paragraph, letter a), of Presidential Decree 917/1986, at the grant date.

Pursuant to the powers granted by the Shareholders' Meeting of January 7, 2008, the Board of Directors approved the adoption of incentive scheme regulations, subject to the start of trading of the Company's shares on the MTA (Mercato Telematico Azionario), a screen-based trading system. The scheme provides for two different types of options that may be granted to beneficiaries to be identified by the Board of Directors – or by the Shareholders' Meeting, when required by law – from among the executive officers, consultants and employees of the Company (and of any subsidiaries and parent companies):

- 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 the 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.

The Board of Directors approved an initial allocation of options to the Company management, in accordance with the stock option plan and the relevant regulations. It granted a total of 2,400,000 options, giving the right to subscribe for one ordinary share each, for a total par value of Euro 497,106.24, at a price per share equal to the Offering Price, specifically:

- for type A options, a total of 600,000 options;
- for type B options, a total of 1,800,000 options.

The Board of Directors established that type B options will vest in several tranches, depending on achievement of business objectives over three- and five-year periods.



The options are granted free of charge. They are registered, personal and non-transferable, except upon death or incapacity. They are not subject to any restrictions – specifically with regard to pledges and guarantees – and will cease to be valid in the case of just cause dismissal of any option holder who is a manager of the Company or removal from office based on just cause of any option holder who is a director of the Company; they shall also cease to be valid if the option holder resigns.

Under the regulations of the aforementioned incentive scheme, in the event of any extraordinary transactions – e.g. changes in capital or mergers and/or spin-offs – the Company's Board of Directors shall, insofar as necessary to maintain the substantial value of the options, adjust the strike price and/or the number of shares underlying the options not yet exercised, in accordance with the rules commonly accepted as normal practice on financial markets (pursuant to the regulations), or it shall implement a new plan with the same conditions.

Following the capital increase more specifically described above, on October 11, 2010 MolMed's Board of Directors approved a change to the regulations for the stock option plans in force, aimed at ensuring that the substantial value of the options is maintained as envisaged by the regulations.

In particular, the strike price of unexercised options was adjusted, by using the same adjustment factor as applied by Borsa Italiana in order to adjust the value of shares on the market at the time of capital increase disclosure.

The strike prices were therefore adjusted as follows:

	Strike price before the capital increase (€)	K adjustment factor	Adjusted strike price (€)
2008 Options	2.15000	0.68825301	1.47974

On May 9, 2011 the Board of Directors noted in reference to March 5, 2011:

- the end of the vesting period established in the stock option plan regulations, in relation to type A options;
- that, on the contrary, vesting of the first tranche of type B options (provided for by the same resolution) did not occurred; therefore 1,260,000 options (i.e. 70%) must be considered as expired.

Having received a significant number of stock options in 2010 that subsequently expired, the Chairman/Chief Executive Officer had not been included in the MBO nor in the medium-/long-term monetary plan. For the same reason, the Business & Administration General Manager had not been included in the monetary LTIP.

It should be noted that type A stock options previously granted to Messrs. Cappelli and Neecke expired during 2013 following their resignation.

On June 24, 2013 the Board of Directors noted in reference to March 5, 2013:

 that vesting of the second tranche of type B options, for a total of 540,000 options (30%), did not occur and therefore they shall be considered as expired.

There is no prejudice to all the other conditions, terms and agreements as set out in the Stock option plan regulations and subsequent amendments.

Below is a summary of the options originally granted within the 2008 stock option plans, with specific details of the options that are to be considered as expired at today's date.



Name, Surname and po	osition held at the moment of assignment	N. stock options 2008 A	N. stock options 2008 B	N. stock options 2008	N. stock options expired at December 31, 2014	N. residual options at December 31, 2014	N. stock options expired in 2015	N. residual options at December 31, 2015	Strike price (Euro)
Claudio Bordignon	Board Chairman, Chief Executive Officer	-	750,000	750,000	750,000	-	-	-	1.47974
Marina Del Bue	Executive Officer, General Manager B&A	-	450,000	450,000	450,000	-	-	-	1.47974
Enrico Cappelli	Chief Financial Officer	180,000	110,000	290,000	290,000	-	-	-	1.47974
Holger Neecke	Business Development Director & IR	150,000	90,000	240,000	240,000	-	-	-	1.47974
Marco Dieci	Special Projects Director	70,000	60,000	130,000	130,000	-	-	-	1.47974
Antonio Lambiase	Clinical Development Director	80,000	70,000	150,000	70,000	80,000	-	80,000	1.47974
Paolo Rizzardi	R&D Director	70,000	60,000	130,000	60,000	70,000	-	70,000	1.47974
Daniele Pieraccioli	Intellectual Property Director	-	100,000	100,000	100,000	-	-	-	1.47974
Cynthia Giuliani	Human Resources Director	-	70,000	70,000	70,000	-	-	-	1.47974
Catia Traversari	Research Director	50,000	40,000	90,000	40,000	50,000	-	50,000	1.47974
		600,000	1,800,000	2,400,000	2,200,000	200,000	-	200,000	

Following the capital increase more specifically described in paragraph *1.2 Other events occurred in 2015* on May 11, 2015 MolMed's Board of Directors approved a change to the regulations for the stock option plans in force, aimed at ensuring that the substantial value of the options is maintained as envisaged by the regulations.

In particular, the strike price of unexercised options was adjusted, by using the same adjustment factor as applied by Borsa Italiana in order to adjust the value of shares on the market at the time of capital increase disclosure.

As regards the options relating to the 2008 stock option plan, the strike prices were therefore adjusted as follows:

	Strike price before 2015	K adjustment	Adjusted strike price post
	capital increase (€)	factor	2015 capital increase (€)
2008 Options	1.47974	0.83372549	1.23370

#### 2012 stock option plan

On April 23, 2012, the Shareholders' Meeting approved a new stock option plan (the "Plan") involving a maximum number of 7,000,000 (seven million) options to be granted free of charge to beneficiaries identified by the Board of Directors from amongst the Company's executive officers, general managers and directors and allowing the subscription for an equal number of Company's ordinary shares by consideration in cash.

Consequently, on the same day the Shareholders' Meeting also resolved to:

- increase the capital by consideration in cash up to Euro 1,449,892.95, without requiring all shares to be subscribed, issuing up to 7,000,000.00 (seven million) new ordinary shares, cum dividend, withdrawing subscription rights pursuant to Article 2441, paragraph five, of the Italian Civil Code and Article 134, paragraph two, of Italian Legislative Decree no. 58 of February 24, 1998. This capital increase is exclusively intended to service the incentive plans based on financial instruments in favor of MolMed S.p.A.'s Beneficiaries, to be identified by name, also in several stages, by the Board of Directors at the proposal of the Remuneration Committee. The deadline for subscribing is December 31, 2020;
- give the Board of Directors the power to implement the resolutions, including through several issues, and to attribute to the same body, with regard to each issue, the power to determine the subscription price of newly-issued shares by establishing, if it is in the interests of the Company, a share premium of an amount equal to the arithmetic mean of the Official Stock Exchange Price for ordinary shares for each trading day on the screen-based trading system (MTA, Mercato Telematico Azionario) organized and managed by Borsa Italiana S.p.A. in the period running with reference to each beneficiary and for each granting cycle from the day before the date of the decision made by the Board of Directors



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aimed at identifying the specific beneficiary to the same day of the previous month (such days included), and as may be amended from time to time;

- establish that the rights to subscribe for newly-issued shares will be personal and transferable inter vivos, and they will be allocated and will expire according to the provisions of the 2012 stock option plan;
- vest the Board of Directors with any necessary or useful powers to be transferred to one or more of its members – to prepare one or more set of regulations for incentive schemes.

The Board of Directors also meeting on April 23, 2012, based on the Remuneration Committee's proposal, therefore decided:

- to approve the regulations for the 2012 stock option plan;
- to identify the plan beneficiaries, as shown in the table below:

Name, Surname and po	esition held at the moment of assignment	n. options A assigned	n. options B assigned	Tot. Options assigned	Strike price (Euro)
Claudio Bordignon	Board Chairman, Chief Executive Officer	1,740,000	1,160,000	2,900,000	0.45140
Marina Del Bue	Executive Officer, General Manager B&A	630,000	420,000	1,050,000	0.45140
Germano Carganico	General Director R&D e Operations	630,000	420,000	1,050,000	0.45140
Enrico Cappelli	Chief Financial Officer	90,000	60,000	150,000	0.45140
Holger Neecke	Business Development Director & IR	150,000	100,000	250,000	0.45140
Marco Manoni	Facility Planning & Design Director	90,000	60,000	150,000	0.45140
Antonio Lambiase	Clinical Development Director	150,000	100,000	250,000	0.45140
Paolo Rizzardi	Research & Development Director	150,000	100,000	250,000	0.45140
Daniele Pieraccioli	Intellectual Property Director	90,000	60,000	150,000	0.45140
Cynthia Giuliani	Human Resources Director	90,000	60,000	150,000	0.45140
Catia Traversari	Research Director	90,000	60,000	150,000	0.45140
		3,900,000	2,600,000	6,500,000	

Furthermore, on November 11, 2013, the Board of Directors allocated 100,000 of the 500,000 options outstanding under the 2012 stock option plan, convertible at a 1-to-1 ratio, to Mr. Andrea Quaglino, Head of Administration, Finance and Control, setting the strike price at 0.75535 Euro.

Finally, it should be noted that following the resignation of Messrs. Enrico Cappelli and Holger Neecke in 2013, as well as of Mr. Pieraccioli effective from January 1, 2014, the options previously assigned to them expired. Here below is a summary of stock options at the reporting date:

Name, Surname and po	osition held at the moment of assignment	n. options A 2012 assigned	n. options B 2012 assigned	N. stock options 2012	N. stock options expired at December 31, 2014	N. residual options at December 31, 2014	N. stock options expired in 2015	N. residual options at December 31, 2015	Strike price (Euro)
Claudio Bordignon	Board Chairman, Chief Executive Officer	1,740,000	1,160,000	2,900,000	-	2,900,000	1,740,000	1,160,000	0.45140
Marina Del Bue	Executive Officer, General Manager B&A	630,000	420,000	1,050,000	-	1,050,000	630,000	420,000	0.45140
Germano Carganico	General Director R&D e Operations	630,000	420,000	1,050,000	-	1,050,000	630,000	420,000	0.45140
Enrico Cappelli	Chief Financial Officer	90,000	60,000	150,000	150,000	-	-	-	0.45140
Andrea Quaglino	Chief Financial Officer	60,000	40,000	100,000		100,000	60,000	40,000	0.75535
Holger Neecke	Business Development Director & IR	150,000	100,000	250,000	250,000	-	-	-	0.45140
Marco Manoni	Facility Planning & Design Director	90,000	60,000	150,000	-	150,000	90,000	60,000	0.45140
Antonio Lambiase	Clinical Development Director	150,000	100,000	250,000	-	250,000	150,000	100,000	0.45140
Paolo Rizzardi	R&D Director	150,000	100,000	250,000	-	250,000	150,000	100,000	0.45140
Daniele Pieraccioli	Intellectual Property Director	90,000	60,000	150,000	150,000	-	-	-	0.45140
Cynthia Giuliani	Human Resources Director	90,000	60,000	150,000	-	150,000	90,000	60,000	0.45140
Catia Traversari	Research Director	90,000	60,000	150,000	-	150,000	90,000	60,000	0.45140
		3,960,000	2,640,000	6,600,000	550,000	6,050,000	3,630,000	2,420,000	



It should be noted that on April 9, 2015 the Board of Directors found that the vesting conditions for type A options were not met: therefore, all type A options shall be considered expired.

Type B options can be exercised from the date of the approval of the 2015 Financial Statements until December 31, 2020, provided that Financial Statements for the year ending December 31, 2015 show a net profit.

It should be noted that the fair value of the options granted was determined by an independent expert on the date the plan was issued in accordance with the financial market conditions at that date.

The fair value of stock options was measured based on the binomial tree method, which is sufficiently flexible to reflect the exercise conditions and the structure of the technical basis used, and can therefore reflect the characteristics of the shares to be measured. Widely used to measure financial instruments according to the stochastic approach, this method refers to the discrete-time binomial models (proposed by Cox, Rubinstein and Ross in 1979) and follows the risk neutral assumption typical of these problems. The model was developed on daily time steps and includes dividend payments and possible exit, if any.

In particular, measurement was made taking into account the free risk rate curve, based on Euro swap rates at measurement date, the expected dividend rate equal to 0% for the full plan duration and the reasonable estimate of 1-year historic volatility equal to 40%. In addition, with regard to beneficiaries' turnover assumptions, considering their nature and historical trends, an annual probability of 5% was deemed appropriate. The fair value was also determined by estimating the probability that vesting takes place for the two different types of options.

The characteristics of the options measured and their relevant fair value by unit are provided below.

Type of Stock Options	Strike		Value at assignment	Annual volatility	Capital bonus rate	Annual turnover rate	Fair value	
Options A		0.4514	0.4633	40.00%	0.00%	5.00%	0.16983	
Options B		0.4514	0.4633	40.00%	0.00%	5.00%	0.16983	

Following the capital increase more specifically described in paragraph *1.2 Other events occurred in 2015* on May 11, 2015 MolMed's Board of Directors approved a change to the regulations for the stock option plans in force, aimed at ensuring that the substantial value of the options is maintained as envisaged by the regulations.

In particular, the strike price of unexercised options was adjusted, by using the same adjustment factor as applied by Borsa Italiana in order to adjust the value of shares on the market at the time of capital increase disclosure.

As regards the options relating to the 2012 stock option plan, the strike prices were therefore adjusted as follows:

	Strike price before 2015 capital increase €	K adjustment factor	Adjusted strike price post 2015 capital increase €
Opzioni 2012 B (emesse 2012)	0.4514	0.83372549	0.37634
Opzioni 2012 B (emesse 2013)	0.7554	0.83372549	0.62980



#### Summary of the options granted

The table below shows the options granted and held at December, 31 2015:

Name, Surnam moment of assig	e and position held at the gnment	Type of Stock Options assigned	N. of Options assigned	Strike price (Euro)	Options expired at December 31, 2015	Options exerciede 2015	Options held December 31, 2015
Claudio Bordignon	Board Chairman, Chief Executive Officer	Plan 2008 B	750,000	1.4797	750,000		-
		Plan 2012 A	1,740,000	0.4514	1,740,000		
		Plan 2012 B	1,160,000	0.4514			1,160,000
Marina Del Bue	Executive Officer, General Manager B&A	Plan 2008 B	450,000	1.4797	450,000		-
		Plan 2012 A	630,000	0.4514	630,000		
		Plan 2012 B	420,000	0.4514			420,000
Germano Carganico	General Director R&D e Operations	Plan 2012 A	630,000	0.4514	630,000		
		Plan 2012 B	420,000	0.4514			420,000
Enrico Cappelli	Chief Financial Officer	Plan 2008 A	180,000	1.4797	180,000		-
		Plan 2008 B	110,000	1.4797	110,000		-
		Plan 2012 A	90,000	0.4514	90,000		-
		Plan 2012 B	60,000	0.4514	60,000		-
Andrea Quaglino	Chief Financial Officer	Plan 2012 A	60,000	0.7554	60,000		-
-		Plan 2012 B	40,000	0.7554			40,000
Holger Neecke	Business Development Director & IR	Plan 2008 A	150,000	1.4797	150,000		-
	·	Plan 2008 B	90,000	1.4797	90,000		-
		Plan 2012 A	150,000	0.4514	150,000		-
		Plan 2012 B	100,000	0.4514	100,000		-
Marco Dieci	Special Projects Director	Plan 2008 A	70,000	1.4797	70,000		-
		Plan 2008 B	60,000	1.4797	60,000		-
Marco Manoni	Facility Planning & Design Director	Plan 2012 A	90,000	0.4514	90,000		
		Plan 2012 B	60,000	0.4514	,		60,000
Antonio Lambiase	Clinical Development Director	Plan 2008 A	80,000	1.4797			80,000
	·	Plan 2008 B	70,000	1.4797	70,000		-
		Plan 2012 A	150,000	0.4514	150,000		
		Plan 2012 B	100,000	0.4514			100,000
Paolo Rizzardi	Research & Development Director	Plan 2008 A	70,000	1.4797			70,000
	·	Plan 2008 B	60,000	1.4797	60,000		-
		Plan 2012 A	150,000	0.4514	150,000		
		Plan 2012 B	100,000	0.4514			100,000
Daniele Pieraccioli	Intellectual Property Director	Plan 2008 B	100,000	1.4797	100,000		-
		Plan 2012 A	90,000	0.4514	90,000		-
		Plan 2012 B	60,000	0.4514	60,000		-
Cynthia Giuliani	Human Resources Director	Plan 2008 B	70,000	1.4797	70,000		-
		Plan 2012 A	90,000	0.4514	90,000		-
		Plan 2012 B	60,000	0.4514			60,000
Catia Traversari	Research Director	Plan 2008 A	50,000	1.4797			50,000
		Plan 2008 B	40,000	1.4797	40,000		-
		Plan 2012 A	90,000	0.4514	90,000		
		Plan 2012 B	60,000	0.4514	,- 50		60,000
		Total	9,000,000	0.1011	6,380,000		2,620,000

#### Note 32 – Transactions with related parties

Transactions with related parties mainly refer to transactions between MolMed, its shareholder Science Park Raf S.p.A. in liquidation, its parent company (currently Ospedale San Raffaele S.r.I.), some associates and Fondazione Centro San Raffaele. MolMed has also performed bank transactions with Banca Esperia S.p.A.



and Banca Mediolanum S.p.A., which are both related parties of the shareholder Fininvest S.p.A.

For the sake of disclosure, it should be noted that the shareholder Science Park Raf S.p.A. started voluntary liquidation proceedings on December 3, 2012, and changed its company name to Science Park Raf S.p.A. in liquidation.

These transactions do not qualify as either atypical or unusual and are part of the Company's ordinary business. These transactions are regulated at market conditions, taking account of the features of the goods and services provided.

#### Transactions with Science Park Raf in liquidation, its parent company and some associates

#### Introduction

Fondazione Centro San Raffaele del Monte Tabor in liquidation, parent company of Science Park Raf in liquidation, experienced economic and financial troubles and in October 2011 was forced to file an arrangement with creditors with the Court of Milan. This was intended to ensure the continuation of hospital as well as clinical and scientific research activities. As stated in the Decree of October 28, 2011, the Chairman of the Court of Milan accepted the proposal submitted, and the relevant operating procedures.

On the basis of these procedures, the Foundation transferred to a new company "Ospedale San Raffaele S.r.l" ("Ospedale San Raffaele") the business consisting of the hospital, clinic and research facilities, the relationships, including contract relationship, as well as staff involved in the hospital, clinical, scientific and research activities carried out by the Foundation, in addition to the control over Science Park Raf in liquidation, which, in turns, has stakes in MolMed.

On May 11, 2012, Ospedale San Raffaele, in addition to transferring the aforementioned business, also acquired ownership of all the authorizations required in the health industry and at relevant Institutions – with the necessary agreements being entered into with the relevant local health authorities. As part of this procedure, it was also classified as a Research Hospital (Istituto di Ricovero e Cura a Carattere Scientifico, IRCCS) as had the Foundation been since 1972 (most recently confirmed on December 11, 2009) for the area of Molecular Medicine ("Research Hospital Classification").

It should be noted that, on the date of this transfer, following a single binding offer, the Foundation assigned all the shares of Ospedale San Raffaele to Velca S.p.A.

In light of the above, the contracts governing the relationships described below with the Foundation were transferred to Ospedale San Raffaele effective from May 11, 2012, when the transfer was formalized.

It should also be pointed out that from May 10, 2012 Fondazione Centro San Raffaele del Monte Tabor changed its name to "Fondazione Centro San Raffaele del Monte Tabor in liquidazione e in concordato preventivo" (in liquidation and under arrangement with creditors), and that from the same date the Foundation ceased to be a MolMed related party. In 2014, there were no significant changes in these relations.

#### **Transaction description**

In December 2001 MolMed, Science Park Raf in liquidation and Ospedale San Raffaele entered into an agreement, under which Science Park Raf in liquidation and Ospedale San Raffaele have granted MolMed an option right to purchase or to license or sublicense research projects involving genetic or molecular therapies for cancer and AIDS, as well as the rights to take economic advantage of these projects, plus any technology or know-how that are part of or otherwise instrumental to said projects, with the right for MolMed to access any and all information regarding such projects. The effectiveness of the agreement, under which the Company



paid a fee of Euro 4,131 thousand plus VAT in 2008, was subject to the admission of the Company's shares to trading on a regulated market. This condition being met in March 2008, the contract is effective for eight years, with the possibility of renewal on a four-year basis.

As Ospedale San Raffaele raised some concerns about said agreement, the two parties met to clarify a number of issues relating to their previous exchange as well as to discuss potential improvements to the methods for exercising the right. Following this meeting, on December 16, 2013 an additional agreement was signed to further simplify the performance of said agreement, making it easier for MolMed to exercise its option right as well as reducing the overall burden of administrative and bureaucratic requirements to be complied with by Ospedale San Raffaele.

The fairness of the consideration for the transaction in relation to market values was confirmed by an opinion issued by an independent expert.

The acquisition qualifies as a related party transaction, as Ospedale San Raffaele owns 100% of Science Park Raf S.p.A. in liquidation, which, based on the evidence as at April 9, 2015, holds a 1.48% interest in MolMed; furthermore, pursuant to the shareholders' agreement ended in March 2015, two members of MolMed's current Board of Directors (whose term will end with the approval of the Financial Statements at December 31, 2015), on the list of candidates proposed by the parties to the agreement, were nominated by them.

In this regard, on April 15, 2015, the Company published the Information document on significant transactions with related parties pursuant to Article 5 of the "Regulation containing provisions on transactions with related parties" adopted by Consob with resolution no. 17221 of March 12, 2010 as subsequently amended by resolution no. 17389 of June 23, 2010.

On February 10, 2015, Ospedale San Raffaele notified the Company and Science Park it would terminate the option agreement effective March 4, 2016.

Following the termination of the option agreement, MolMed, although it can continue cooperating and working with Ospedale San Raffaele to access its intellectual property, will now do so exclusively at arm's length, as any other company in the industry and therefore at market rates. These could be less favourable than the previous terms. In particular, during the first half of 2015, as better described in section *3. Activities: research, development and production*, the Company exercised its option right in relation to the purchase of the "CAR-CD44v6" project.

Between 2001 and 2008 MolMed signed in-licensing contracts with Science Park Raf in liquidation and its parent company, by which it acquired (exclusive and non-exclusive) rights over patents or claims on patents owned by related parties, in order to be able to develop its products, both those which are currently in the clinical stage, such as Zalmoxis® (TK) and NGR-hTNF, and those which are in the preclinical stage. The duration of these contracts is linked to the expiry of the patent. These contracts establish different types of payment (up-front payments, milestones and royalties), based on the product development stages.

MolMed also signed scientific research and cooperation agreements, which are generally associated with inlicensing contracts, by which the Company commissioned Science Park Raf in liquidation and Ospedale San Raffaele to carry out fee-based research projects, making use of the know-how of their researchers, in order to develop technologies and products on behalf of and which are held by MolMed. A number of contracts signed by MolMed and Ospedale San Raffaele focus on some Zalmoxis® (TK) and NGR-hTNF clinical trials. The fees for the purchase of these services are in line with market prices for contracts signed with other clinical centres.

MolMed signed a lease with Science Park Raf S.p.A. in liquidation for the premises located in Milan, Via Olgettina 58, where the Company has its headquarters. This contract, which was signed at the start of 2010,



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annulled and replaced the previous leases which were in force up to 2009. The new contract, expiring at the end of 2015, represents an improvement for the Company compared to the previous version. After said premises were transferred to Ospedale San Raffaele S.r.l. and subsequently negotiating with the counterparty, the Company entered into a new agreement on even more favourable terms, which superseded the previous one. It will last for six years (2015-2020). In calculating the rental fee, a series of services offered by the San Raffaele Science Park are taken into account, such as security and reception services, maintenance service, and access to animal research laboratories, the library and the cafeterias by MolMed's staff. As part of facility management services, Science Park Raf S.p.A. in liquidation and Ospedale San Raffaele S.r.l. agreed to provide maintenance of scientific equipment, and health physics and radiation safety services.

As part of the Company's operations involving its GMP facility, MolMed signed a series of contracts with Ospedale San Raffaele under which it supplies cell manipulation services, as well as services involving the development and GMP production of materials for clinical trials managed by the facility researchers. Economic conditions set in the agreements are decided by the Company, based on the relevant costs incurred, plus the portion of overheads attributable to the service performed and a suitable profit margin.

As part of its operations, MolMed has commercial relationships with Diagnostica e Ricerca San Raffaele S.p.A. (merged into Ospedale S. Raffaele since April 1, 2014) and HSR Resnati S.p.A., which are directly or indirectly controlled by Ospedale San Raffaele.

Specifically, Diagnostica e Ricerca San Raffaele S.p.A. (merged into Ospedale S. Raffaele since April 1, 2014) performed microbiological analyses on the samples generated by MolMed's clinical trials, while HSR Resnati S.p.A. carries out diagnostics and clinical tests for MolMed's personnel and consultants, in compliance with the provisions on workers' health and safety. Services provided also include other occupational medicine activities, such as definition and management of a healthcare protocol for preventive and periodic monitoring of the personnel's health conditions.

#### Transactions with other related parties

The Company has current and deposit account with Banca Esperia S.p.A and a current and deposit account with Banca Mediolanum S.p.A.. Part of these relationships is the management of the investment of liquidity which exceeds the Company's operating needs. Transactions are regulated at market conditions.



#### Income and equity impact

#### Income impact

The following table shows the effect of transactions with related parties, identified in accordance with IAS 24, on the Company's Income Statement and Statement of Financial Position for the year 2015:

(amounts in Euro thousand)	Financial income	Costs for services	Costs for use of third-party assets
Science Park Raf S.p.A. in liquidazione	-	66	-
Fondaz. M.te Tabor in liquidazione	-	-	-
Fondazione Centro S.Raffaele	-	-	-
Ospedale San Raffaele S.r.l.	-	4,115	663
Diagnostica San Raf S.p.A	-	-	-
HSR Resnati S.p.A.	-	20	-
Banca Esperia S.p.A.	8	-	-
Banca Mediolanum S.p.A.	-	-	-
Alba Servizi Aerotrasporti S.p.A.	-	-	2
Life Science Management GMBH	-	58	-
Didier Trono	-	2	-
Total	8	4,261	665
Financial statements item	160	19,590	1,414
% on financial statements item	5%	22%	47%

The costs for services, amounting to Euro 4,201 thousand, relate for Euro 3,200 thousand to the consideration paid to Ospedale San Raffaele for the above-mentioned purchase of the CAR—CD44v6 research project as well as to research agreements, contracts concerning the operation of clinical trials at Ospedale San Raffaele, some services related to the operation of MolMed's facility, as well as the recognition in profit or loss of the charge relating to the straight-line decrease in the fee paid for the option to acquire research projects entered into with Science Park Raf in liquidation and Ospedale San Raffaele.

The costs for use of third-party assets of Euro 663 thousand relate to lease payments provided for by the contracts signed with Ospedale San Raffaele for the premises occupied by the Company within the San Raffaele Science Park.



#### **Balance sheet impact**

(amounts in Euro thousand)	Trade receivables and other commercial	Other receivables and sundry assets	Cash and cash equivalents	Trade payables
Science Park Raf S.p.A. in liquidazione	-	11	-	-
Fondaz. M.te Tabor in liquidazione	110	-	-	59
Fondazione Centro S.Raffaele	-	-	-	-
Ospedale San Raffaele S.r.l.	-	75	-	87
Diagnostica San Raf S.p.A	-	-	-	-
HSR Resnati S.p.A.	-	-	-	8
Banca Esperia S.p.A.	-	-	3,190	-
Banca Mediolanum S.p.A.	-	-	275	-
Mediobanca S.p.A.	-	-	-	-
Gestipark S.Raffaele	-	-	-	-
Alba Servizi Aerotrasporti S.p.A.	-	-	-	-
Didier Trono	-	-	-	2
Total	110	86	3,465	156
Financial statements item	5,632	1,576	11,770	13,559
% on financial statements item	2%	5%	29%	1%

Other assets refer to the fee agreed for the option right to buy research projects signed with Science Park Raf in liquidation and Ospedale San Raffaele; this amount, which originally totalled Euro 4,131 thousand is subject to a *pro quota temporis* decrease and the related charge will be recognized in the Income Statement on a straight-line basis over the contract eight year duration with expiry in March 2016.

Trade receivables and payables reflect the trends in invoicing and payment of services linked to the abovementioned agreements.

It should be noted that at October 10, 2011, when Fondazione Centro S. Raffaele del Monte Tabor in liquidation filed its arrangement with creditors, receivables of Euro 95 thousand were due from the former to the Company, as shown in the relevant statement sent by the Company to the Receivers. Such receivables are recorded net of Euro 28 thousand allocation made in 2011.

Other receivables and sundry assets consist of a Euro 86 thousand fee agreed for the aforementioned agreement to buy research projects.

Cash and cash equivalents consist of bank deposit accounts.

For information on stock options assigned to Directors and Managers with strategic responsibilities, reference should be made to **Note 31**.

As for the main impacts on financial flows of transactions with related parties, it should be noted that these concern the dealings and transactions described above and a detailed breakdown is provided in the Statement of Cash Flows.



#### *Note 33 – Significant non-recurring events and transactions*

Pursuant to the Consob Communication of July 28, 2006, it should be noted that during 2015 the Company carried out the capital increase, which qualify as significant non-recurring transaction:

(amounts in Euro thousand)	Ec	Equity			Cash flow		
	Value	%	Value	%	Value	%	
Value	31,929	%	(20,784)	%	(386)	%	
Capital increase effect 2015	(41,410)	(130%)	(178)	1%	(41,410)	10728%	
Capital increase costs 2015	873	3%			873	(226%)	
Gross notional value	(8,608)		(20,962)		(40,923)		

#### 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 Company's net assets and of the minority shareholders, due to their significance/importance, the parties 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 11971 of May 14, 1999, as subsequently amended, concerning the adoption of regulations implementing Legislative Decree 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.

Name Surname	Position held	Term of office	Term of office expiry date	Defined Fee	Defined Fee Board of Director S	Fee for presence Board of Directors	Defined Fee Commite e	Fee for presence Commite e	Varial	ole fee	Non monetary fee	Other fee	Total	Fair value Equity fee	Allowance charge end or termination employment relationship
									Bonus and other	Partecip.					
DIRECTORS									incentives	in profit					
Claudio Bordignon	Chairman	01.01.2015-31.12.2015	on approval of 2015 Fin.Statements	750							77		827		
Germano Carganico	Director	01.01.2015-22.10.2015	on approval of 2015 Fin.Statements		10	12							22		
Alberto Luigi Carletti	Director		on approval of 2015 Fin.Statements		12	15							27		
Riccardo Cortese	Director	01.01.2015-01.04.2015	on approval of 2015 Fin.Statements		3		1						4		
Marina del Bue	Director		on approval of 2015 Fin.Statements		10	12							22		
Gianluigi Fiorendi	Director		on approval of 2015 Fin.Statements		12	15	16	6					49		
Sabina Grossi	Director	01.01.2015-31.12.2015	on approval of 2015 Fin.Statements		12	15	5	3					35		
Khalid Islam	Director	01.01.2015-31.12.2015	on approval of 2015 Fin.Statements		12	12							24		
Mario Masciocchi	Director		on approval of 2015 Fin.Statements		12	15	19	14					60		
Monica Masolo	Director		on approval of 2015 Fin.Statements		2	2							4		
Alfredo Messina	Director	01.01.2015-31.12.2015	on approval of 2015 Fin.Statements		12	15							27		
Riccardo Palmisano	CEO	22.10.2015-31.12.2015	on approval of 2015 Fin.Statements	25	2	3						20	50		
Raffaella Ruggiero	Director		on approval of 2015 Fin.Statements		12	15	21	15					63		
Lorenzo Salieri	Director	01.01.2015-22.10.2015	on approval of 2015 Fin.Statements		10	11							21		
Didier Trono	Director	22.10.2015-31.12.2015	Approv. bilancio es. 2015		2	3							5		
				775	123	145	62	38	-	-	77	20	1.240		-
STATUTORY AUDITOR			an annual of 0045 Ein Otatamanta	20											
Fabio Scoyni Enrico Scio	Sindaco effettivo		on approval of 2015 Fin.Statements on approval of 2015 Fin.Statements	30 20											
Flavia Daunia Minutillo			on approval of 2015 Fin.Statements	20											
GENERAL MANAGERS		01.01.2015-31.12.2015	on approval of 2015 Fin.Statements	20											
Marina Del Bue		01.01.2015-31.12.2015	la da fia ita	357	-	-		-	- 20	-	- 3		-	-	1.000
		01.01.2015-31.12.2015		237					20		2		277		1.000
Germano Carganico		01.01.2010-31.12.2015	indennite .	237 594					58		2		657		1.000
OTHER MANAGERS IN	ITH STRATEGIC RESPO			594					56	-	5	-	657		1.000
OTHER MANAGERS W	IIII SIRAIEGIC RESPU	01.01.2015-31.12.2015	Indefinite	1.017					159		16		1.192		
*Including the fee rece	ived in the role of r R&D	Director from January 1st		1.017	-		-	-	159		16		1.192		-
			manager R&D and operations from Ja				-	-	155		10	-	1.132		

On April 22, 2013, the Board of Directors decided to grant Euro 750 thousand to the Company's Chairman Claudio Bordignon by way of annual remuneration until the end of his term of office, and another Euro 750 thousand, gross of taxes, for a non-compete agreement effective for 24 months after the end of his term of office for any reason, to be settled at the end of his term of office and in case it is not renewed.



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Under the contract entered into on May 13, 2013 and based on the resolution of the Board of Directors' meeting of April 22, 2013, compensation equal to the overall annual remuneration, multiplied by the number of remaining years until the date of the Shareholders' Meeting convened to approve the 2015 Financial Statements will be paid, if:

- a) the Shareholders' Meeting revokes his appointment as a Director without just cause; or
- b) all or part of the powers and responsibilities granted by the Board of Directors are revoked and / or the powers or responsibilities attributed to other parties except for deputy powers and responsibilities assigned to another Director and powers and responsibilities assigned to the General Manager are, as a whole, essentially equivalent to those attributed to the Chairman and Chief Executive Officer, or, are of such importance that they would have a significant effect on his position and his role as head of the Company, without just cause; or
- c) the Company is put into liquidation.

Similarly, the Chairman will be entitled to receive said compensation in the event of his resignation with just cause corresponding to only just one of the circumstances set out in point b).

No agreements have been signed by other Directors, and no compensation was paid to Directors ceasing to hold office in the year.

#### 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 2015 and 2014 for the audit services and for other non-audit services provided by the External Auditors. No additional services were provided by other entities belonging to the external auditors' network.

	Entity that provided the service	Fees for 2015	Fees for 2014
Audit	Deloitte & Touche S.p.A.	71 (1)	79 (2)
Certification services	Deloitte & Touche S.p.A.	59 (3)	53 (4)
Total		130	132

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

(1) Audit of Statutory Financial Statements and limited review of the half-year report, limited review of the Report at September 30, 2014 verification that accounting records are properly mantained and reflect accurately operating events

(3) Activities relating to the signing of *Modello Unico* and *Modello* 770 tax returns and issuance of comfort letters on Registration document related to 2015 capital increase

4) Activities related to the signing *Modello Unico* and the *Modello 770* and the issuance of the report on the fairness of the issue price of the shares Molmed in relation to the capital increase with exclusion of option rights related to the contract of SEF - standby equity agreement with Societe Generale

#### 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 effect 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 rates or interest rates, or in the price of equity instruments.

#### Interest rate risk

The Company has no significant financial payables or receivables. Cash obtained by the listing has been invested in current account deposits and government securities and bonds, remunerated at a rate that is affected by changes in short-term interest rates. In order to limit the risk of default in the performance of obligations by the counterparties, the investments were made at various 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 may be measured through a sensitivity analysis, as provided for by the application of IFRS 7. Such analysis illustrates the effects caused by a given and assumed change in relevant variable levels on financial income and expenses and, at times, directly on shareholders' equity. The sensitivity analysis was carried out on the basis of the following assumptions:

- the analysis was performed by applying reasonably possible changes of the relevant risk variables to the figures of the Financial Statements at December 31, 2015 and 2014, 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 IAS 39;
- changes in value of floating rate financial assets generated by changes in the benchmark interest rates have an impact on financial income for the year.

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

(amounts inEuro thousand)	2015		2014		
	effect on financial income		effect on the fair value reserve		
Shift compared to zero-coupon	+1%	-1%	+1%	-1%	
Effect	298	(298)	-	-	

#### 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, which include 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 respected companies. In addition, investments were made at a number of different credit institutions, in order to diversify the counterparty risk. With regard to recent events involving Fondazione Centro San Raffaele del Monte Tabor in liquidation, reference should be made to **Note 32**.

#### **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 criteria applied and, in the case of financial instruments measured at their 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 and the amount recognized in the relevant reserve at December 31, 2015.

(amounts in Euro thousand)	Measure	Measurement criteria for financial instruments in the Statutory Financial Statements				I Statements	
		instruments at fair lue through	Financial instruments at	Book value at	Fair value at	of which fair	
Class of financial instruments	profit or loss	equity	amortized cost	December December 31, 2015 31, 2015		value reserve	
	(1)	(2)	(3)				
Assets							
Cash and cash equivalents	-	-	11,770	11,770	11,770	-	
Financial assets	-	-	18,000	18,168	18,168	-	
Trade receivables	-	-	5,632	5,632	5,632	-	
Liabilities							
Trade payables	-	-	16,159	16,159	16,159	-	
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

The following table includes the net financial income and charges relating to financial assets and liabilities broken down into the categories provided for by IAS 39, showing for each item the type of charge and income.

IAS 39 categories at December 31, 2015	From interest	From changes in fair value	From write- down at fair value	From shareholders' equity reserve	From other income and charges	Net profit (loss)
Assets						
Cash and cash equivalents	33	-	-	-	-	33
Financial assets	80	-	-	-	-	80
Trade receivables	-	-	-	-	-	-
Liabilities						
Trade payables	-	-	-	-	-	-
Finance lease payables	-	-	-	-	-	-
Other financial debts	-					-
IAS 39 categories - total	113	-	-	-	-	113



For further details on cash and cash equivalent, as well as on 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. The following levels can be identified:

- 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, 2015 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's indebtedness is not significant and, at December 31, 2015, it recorded a positive net financial position of Euro 29,938 thousand, mainly 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 cash flows for business operations and the net financial position, in order to implement necessary actions in a timely manner;
- monitoring of prospective liquidity conditions related to corporate planning.

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

#### *Note 38 – 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.* 



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# *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 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 11971 of May 14, 1999 and subsequent amendments and additions

The undersigned, Mr. Claudio Bordignon, Chairman, and Mr. Andrea Quaglino, 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 58 of February 24, 1998, hereby certify:

- the adequacy in relation to the characteristics of the Company; and
- the effective implementation of the administrative and accounting procedures applied in the preparation of the Company's Financial Statements during 2015.
- Measurement of the adequacy of the administrative and accounting procedures used for the preparation of the Financial Statements at December 31, 2015 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 at December 31, 2015:
  - 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 and subsequent amendments and additions;
  - 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 Report on Operations includes a reliable operating and financial review of the Company, as well as a description of the main risks and uncertainties to which it is exposed.

Milan, April, 18 2016

[Signed by]

[Signed by]

Claudio Bordignon Chairman of the Board of Directors Andrea Quaglino Executive Officer responsible for preparing company financial reports



Report of the external auditors

# **Deloitte.**

Deloitte & Touche S.p.A. Via Tortona, 25 20144 Milano Italia Tel: +39 02 83322111 Fax: +39 02 83322112 www.deloitte.it

#### INDEPENDENT AUDITORS' REPORT PURSUANT TO ART. 14 AND 16 OF LEGISLATIVE DECREE No. 39 OF JANUARY 27, 2010

To the Shareholders of MOLMED S.p.A.

#### **Report on the Financial Statements**

We have audited the accompanying financial statements of MolMed S.p.A. (the "Company"), which comprise the statement of financial position as at December 31, 2015, and the statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information.

#### Management's Responsibility for the Financial Statements

The Company's Directors are responsible for the preparation of these financial statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the European Union and the requirements of national regulations issued pursuant to art. 9 of Italian Legislative Decree  $n^{\circ}$  38/2005.

#### Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing (ISA Italia) issued pursuant to art. 11,  $n^{\circ}$  3, of Italian Legislative Decree 39/10. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation that give a true and fair view of financial statements 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 entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Directors, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Ancona Bari Bergamo Bologna Brescia Cagliari Firenze Genova Milano Napoli Padova Palermo Parma Roma Torino Treviso Verona

Sede Legale: Via Tortona, 25 - 20144 Milano - Capitale Sociale: Euro 10.328.220,00 i.v. Codice Fiscale/Registro delle Imprese Milano n. 03049560166 - R.E.A. Milano n. 1720239 Partita IVA: IT 03049560166

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#### Opinion

In our opinion, the financial statements give a true and fair view of the financial position of MolMed S.p.A. as at December 31, 2015, and of its financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union and the requirements of national regulations issued pursuant to art. 9 of Italian Legislative Decree  $n^{\circ}$  38/2005.

#### Emphasis of Matter Paragraph

Without qualifying our opinion, we draw attention to the information provided in the Report on Operations, "Risk associated with funding research and development activities" and in the Explanatory Notes, "Going Concern", regarding the fact that the Company has incurred a loss of Euro 20,784 thousand, greater for Euro 7,781 thousand than the loss recorded in the previous year, due to the higher research and development costs incurred in accordance with the business plan In this framework, the Directors state that, based on the analysis of future cash flows projected by the new business plan updated on the basis of the results achieved in 2015 and approved by the Board od Directors during December 2015, financial means and equity available can guarantee enough resources to continue its business operations for a foreseeable future of at least 12 months from the date of approval of the financial statements by the Board of Directors. As at today, no significant uncertainties were reported on the Company's ability to continue as a going concern.

#### **Report on Other Legal and Regulatory Requirements**

Opinion on the consistency of the report on operations and of certain information included in the report on corporate governance with the financial statements

We have performed the procedures indicated in the Auditing Standard (SA Italia) n° 720B in order to express, as required by law, an opinion on the consistency of the report on operations and of certain information included in the report on corporate governance required by art. 123-bis, n° 4, of Italian Legislative Decree n° 58/98, which are the responsibility of the Directors of MolMed S.p.A., with the financial statements of MolMed S.p.A. as at December 31, 2015. In our opinion the report on operations and the information included in the report on corporate governance referred to above are consistent with the financial statements of MolMed S.p.A. as at December 31, 2015.

Signed by Patrizia Arienti Partner

Milan, Italy March 25, 2016

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



## Report of the Board of Statutory Auditors to the Shareholders' Meeting of MolMed S.p.A. pursuant to art. 153 of Legislative Decree 58/1998

Dear Shareholders,

This Report illustrates the activities carried out by the Board of Statutory Auditors during the year 2015 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, 2015, the Board of Statutory Auditors of MolMed S.p.A. (hereinafter the "Company") performed the supervisory activities provided for under the law, also in consideration of the principles of conduct recommended by the Italian National Councils of Certified Public Accountants and Bookkeepers and the Consob's communications on company audits and activities of the Board of Statutory Auditors.

During 2015, 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 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, with the Board of Statutory Auditors' members being present, provides prior approval of significant or material transactions with related parties. 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 preclinical 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.

- Based on the Company bodies' disclosure and as a result of the Board of Statutory Auditors' analyses carried out during the performance of the relevant 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 –, essentially involved:
  - the continuation of the clinical and pharmaceutical development of two anti-tumor treatments in the trial stage:
  - Zalmoxis® (TK) It is a cell gene therapy product based on genetically engineered cells, allowing more safe and effective transplantation of haematopoietic stem cells (HSCT) even from a partially matched donor, which is the only potentially curative treatment available, especially for high-risk leukaemias. During 2015 the Company continued the trial stage with the enrollment of patients (including the Phase III trial currently underway) and preliminary activities to obtain the marketing authorization request from the EMA (European Medicines Agency) through a specific CMA (Conditional Marketing Authorization) procedure. The evaluation process is underway, the positive outcome of which will allow the marketing of Zalmoxis®.



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- NGR-hTNF It is a biological treatment meant to act on blood vessels affected by tumors. Its target is a structure which is only present on blood vessels that feed the tumor mass. The action of the treatment aims at a functional alteration of these blood vessels, thus cutting off supplies to the tumor and thus blocking its growth. Clinical data obtained to date by MolMed demonstrates the clinical efficacy of NGR-hTNF in seven different types of solid tumors, including two orphan indications and other more common types of neoplasia, for a total potential market of more than 1.4 million new cases per year in Europe, North America and Japan.
- GMP development and production activities In addition to the Manufacturing Authorization (certificato di Officina Farmaceutica) issued by AIFA (the Italian Medicines Agency) in 2003, in December 2015 MolMed obtained authorization to manufacture drugs to be marketed in relation to a specific gene therapy based on genetically modified stem cells and a cell therapy based on immune system engineering. These manufacturing activities and the services related to GMP production allow the Company to optimize its production capacity (TK cell therapy production) as well as to create and pursue strategic partnerships.
- Gene therapy research activities MolMed exercised its option right to purchase the CD44v6 immunogene therapy project from Ospedale San Raffaele. During the year, research and development activities related to such project began.
- Obtaining the financial resources necessary to support the Company's development plan In February 2015, the Company's Board of Directors exercised its delegated power (conferred by the Extraordinary Shareholders' Meeting of March 3, 2014) to increase the Share Capital to a maximum of 50 million Euro. On March 4, 2015, the Board approved the final terms of the transaction, as previously described in our Report to the 2014 Financial Statements to which reference should be made. On April 9, 2015, the share capital increase for a total of 49.8 million Euro was completed, with the entire sale of unexercised rights.

The Company's transactions outlined above are adequately illustrated in the Report on Operations and in the Notes.

The Board of Statutory Auditors confirmed that the transactions referred to above 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 and that they were not likely to 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 2015 or after the reporting period.

Information on transactions with related parties in 2015 and a description of their characteristics and economic effects is available in the Report on Operations (point 7.3), in the Notes (no. 32), in the Statement of Financial Position and in the Income Statement.

During 2015, the Board of Statutory Auditors, also through joint meetings with the Control and Risk Management Committee, verified whether the Company implemented actions aimed at ensuring both the procedural and substantive fairness and transparency of decision-making and operating processes involved in transactions with related parties. In particular, the Board monitored compliance with Code provisions for the performance of significant or material transactions with related parties, pursuant to Consob Regulation no. 17221 of March 12, 2010, as subsequently amended. The Board of Statutory Auditors monitored the compliance of the procedure adopted by the Company with the standards provided by Consob, as well as the effective enforcement thereof.



- Since no atypical and/or unusual transactions took place and taking into account the Company's size and structure, the Board of Statutory Auditors believes that the disclosure on Company's transactions with related parties, described in the Notes to the MolMed's Financial Statements for 2015, should be considered as adequate.
- 4. On the date hereof, the External Auditors Deloitte & Touche 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, 2015 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. The External Auditors have also certified that the Report on Operations and disclosure pursuant to paragraph 4 of Article 123-bis of the Consolidated Law on Finance (Testo Unico della Finanza, TUF) included in the Report on corporate governance and ownership structure are in line with MolMed S.p.A's Financial Statements at December 31, 2015. Finally, in order to provide a better understanding of the financial statements, the External Auditors "without stating any findings in their opinion, draws attention to what Directors described in the Report on Operations under the paragraph "Risks associated with funding research and development activities" and in the Notes under the paragraph "Going concern", with regard to the fact that during the year the Company recorded a loss of 20,784 thousand Euro, increasing by 7,781 thousand Euro compared to the previous year, and that such performance was a result of greater research and development costs incurred in line with the business plan. In this context, the Directors state that, taking into account the analysis of future cash flows expected under the new business plan updated in light of the results for 2015 and approved by the Board of Directors in December 2015, the financial means and equity available can guarantee enough resources to continue business operations for a foreseeable future of at least 12 months from the date of approval of the financial statements by the Board of Directors. As at today, no significant uncertainties are reported on the Company's ability to continue as a going concern".

The Board of Statutory Auditors shares and confirms the above on the basis of the documentation examined.

- 5. During the year, the Board of Statutory Auditors did not receive any notifications or reports.
- 6. During the year 2015, the Company assigned various tasks other than the financial statement audit to the External Auditors Deloitte & Touche. The relevant consideration, excluding VAT, is shown below:

Task	Consideration
Preparation of the Prospectus for the purposes of Italian legislation – issue of the first comfort letter	47,000
Update of the comfort letter on the Prospectus and any issues of bring down letters (the amount refers to each comfort letter and/or bring down letter issued)	10,000
Activities relating to the preparation of Modello Unico and Modello 770 tax returns	2,000

During 2015, MolMed S.p.A. did not assign any tasks to entities connected to Deloitte & Touche on the basis of continuing relations and/or to companies belonging to the Deloitte & Touche's network.

With the approval of the Financial Statements at December 31, 2015, the mandate conferred to the External Auditors Deloitte & Touche ends due to expiry of the term. The Board of Statutory Auditors

prepared the reasoned proposal for the appointment of the external auditor pursuant to Article 13 of Legislative Decree no. 39/2010 for years 2016-2024, which is submitted to the Shareholders' Meeting.

7. During the year 2015, pursuant to Article 2389, paragraph 3, of the Italian Civil Code, the Board of Statutory Auditors did not issue to the Board of Directors any opinion on the fees paid to the Directors with key responsibilities.

8. During the year 2015, the Company's Board of Directors held 15 meetings, all of which were attended by the Board of Statutory Auditors.

The Control and Risk Management Committee met 6 times. The Remuneration Committee met 3 times. The Board of Statutory Auditors participated in all meetings of both committees with at least one member present. The Board of Statutory Auditors held 11 meetings, 6 of them jointly with the Internal Control Committee. The Board of Statutory Auditors also took part in the Shareholders' Meetings held on June 3, 2015 and December 11, 2015.

9. 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 of the meetings of the Board of Directors, through interviews, direct observations and collection of information during meeting with members from 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 comply with the law and with the company by-laws, as well as that the resulting resolutions are 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 financial position and cash flows, and encouraged the Board of Directors to consider the most appropriate measure to strengthen them. 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 by the management staff responsible for it. The organizational structure is of fundamental importance to a rational business conduct, making possible both a specialization of functions and the coordination and harmonization of the activities undertaken by individual staff members in the performance of their assigned tasks. In particular, the Board of Statutory Auditors monitored the organizational changes introduced during 2015. The organizational structure of MolMed S.p.A at December 31, 2015 is shown in the Annual Report (paragraph 5, page 22), to which reference should be made.

As at December 31, 2015 total staff consisted of 152 employees and 10 external staff (collaboratori a progetto). In the section "Significant events after the reporting period" (paragraph 3, page 44) the optimization of the organizational structure is mentioned, with the significant change approved by the Board of Directors on January 29, 2016, which resulted in the elimination of the Corporate Governance & Administration Department, whose main functions are now carried out by the Chief Executive Officer.

The Board of Statutory Auditors expresses a positive opinion on the organizational structure as currently modified: it appears adequate to cover the functions necessary for the achievement of corporate targets and suitable with respect to the size of the Company, the activities to be performed and the coordination to be implemented.

Based on the assumption that people are the key factor to business success, the Company continued making a noteworthy effort to improve its styles of management, as well as the motivation and training of personnel. In particular, training activities continued as in previous years on the governance system adopted, the Organizational Model pursuant to Legislative Decree no. 231/2001, liability for insider trading offenses and market manipulation, in addition to specific scientific training programs and courses on IT, security and the protection of personal data.



10. The internal control system consists of a complex set of rules, procedures and organizational structures, all aimed – through an adequate process of identification, measurement, management and monitoring of the main corporate risks – at ensuring correct, coordinate and efficient management, as well as the constant pursuit of the Company's targets. An efficient internal control system is needed to develop within the Company transparent and reliable procedures and conduct which are linked to specific responsibilities. This system helps to ensure the effectiveness and efficiency of operations, further ensuring that they can be assessed and verified, that the financial disclosure provided is reliable, that laws and regulations are observed, that the company's assets are protected and that fraud to the detriment of the Company and financial markets is prevented.

The internal control system is composed of the following bodies:

- Board of Directors. with the support of the Control and Risk Management Committee, it defines the guidelines of the internal control system and verifies its adequacy, effectiveness and proper functioning. It aims at ensuring that the main corporate risks (operating, economic, financial and compliance risks) are adequately defined, monitored and managed.
- Executive Director, responsible for overseeing the functioning of the internal control system. He or she has the tasks of identifying the main corporate risks; implementing the guidelines established by the Board of Directors; arranging the design, formation and management of the internal control system, continuously checking on the basis of the trend in internal and external operating conditions its adequacy, effectiveness and efficiency and taking decisions on the corrective actions to be taken.
- Internal Audit Manager. This Manager is assigned the functions of checking the adequacy and efficiency of the system and, should anomalies be found, of putting forward corrective plans. The Board of Directors identified this role with the head of the Internal Audit function. The Manager depends on the Company's Chairman in terms of functions, reports to the Control and Risk Management Committee and cooperates with the Executive Director in charge of internal control.
- Control and Risk Management Committee. Together with the Executive Officer responsible for preparing MolMed's financial reports and the External Auditors, it assesses that accounting standards are correctly applied. At the request of the Executive Director responsible for controls, it expresses views on the identification of the corporate risks and on the design, formation and management of the internal control system. It assesses the work plans and the reports of the Internal Audit Manager and the External Auditors. It monitors the effectiveness of the audit process. It assists the Board of Directors in carrying out its tasks regarding corporate internal controls and, in particular: a) in defining the control guidelines so that the main risks are correctly identified and adequately measured, monitored and managed; b) in assessing, at least on an annual basis, the effectiveness and the actual operation of the internal control system.
- Internal Audit. It undertakes activities relating and functional to internal audit, in other words services that can verify and improve the effectiveness and efficiency of the internal control and risk management system.
- Executive Officer responsible for preparing company financial reports. His/her duties are specified in detail by Article 154-bis of Legislative Decree no. 58/1998.

The system is completed by the "231 Model", which governs the internal control system in relation to the provisions of Legislative Decree no. 231/2001 on the administrative liability of entities for offenses committed by their employees and other staff.

The internal control system is also supplemented by the activities of the External Auditors and the Board of Statutory Auditors.

During 2015, the Board of Statutory Auditors took note of the overall evaluation 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, 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.

11. 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 undertaken by the External Auditors Deloitte & Touche.

The Board of Statutory Auditors took note of 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 the 2015 Financial Statements.

Finally, the Board of Statutory Auditors monitored the financial disclosure process verifying, also by obtaining information from the Company's management, the adequacy and effectiveness of the procedure whereby information is produced and shared with the public.

12. The Board of Statutory Auditors ascertained, through direct assessments and based on information received from the External Auditors Deloitte & Touche, as well as from the Management, that the Financial Statements and the Report on Operations have been drafted in compliance with IASs/IFRSs (as well as with relevant rules and regulations). Specifically: i) with regard to the reporting by segment and by geographic area required under Consob regulations, the Company identified a single business segment (see the section Financial Statements at December 31, 2015 – Notes "Accounting standards and measurement criteria"); ii) disclosure pursuant to Consob Resolution no. 15519 of July 27, 2006, as well as Consob communication no. DEM/6064293 of July 28, 2006, was provided; iii) disclosure pursuant to document no. 2 of February 6, 2009 of the Bank of Italy, Consob and Isvap was supplied; in particular, Directors stated in the Report on Operations the financial risks to which the Company is exposed and, in the Notes, the activities carried out to cover financial needs.

13. The Board of Statutory Auditors monitored the actual implementation procedures of the corporate governance rules set forth in the Corporate Governance Code prepared by the Corporate Governance Committee of the Italian Stock Exchange in December 2012, as subsequently amended, which the Company adheres to.

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

The Board of Statutory Auditors verified the existence of the independence requirements for its members, pursuant to Article 148, paragraph 3, of the Consolidated Law on Finance, and of those provided for by the Corporate Governance Code of the Italian Stock Exchange.

14. The supervisory and control activities carried out by the Board of Statutory Auditors, as described earlier, did not result in further observations worthy of note to be pointed out in the Report to the Shareholders' Meeting or to be reported to the other supervisory bodies.

15. After acknowledging the Financial Statements at December 31, 2015, the Board of Statutory Auditors has no objections to raise regarding the resolution proposals submitted by the Board of Directors about carrying forward the loss for 2015.

16. We thank you for the trust you placed in us and we remind you that with the approval of the 2015 Financial Statements, the three-year mandate of the Board of Directors and the Board of Statutory Auditors currently in



office expires.

For this reason, you are asked to resolve on (i) the appointment of the Board of Directors' members, after determining their number, term of office and remuneration; and (ii) the appointment of the Board of Statutory Auditors' members and their remuneration. March 25, 2016

March 25, 2016

Board of Statutory AuditorsFabio Scoyni (Chairman of the Board of Statutory Auditors)Flavia Daunia Minutillo (Statutory Auditor)[Signature]Enrico Scio (Statutory Auditor)[Signature]

[Signature]