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*Annual Financial Report  
at 31 December 2014  
Approved by the Shareholders'  
Meeting of 3 June 2015*

**English translation  
for convenience**

**FROM GENES TO THERAPY**

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**MOLMED S.p.A.**

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Share Capital Euro 19,841,682.30 fully paid - Office of Milan Company Registry number 1506630 - Tax identification number 11887610159



MOLMED S.p.A. is a medical biotechnology company focused on research, development and clinical validation of novel anticancer therapies.

MOLMED's pipeline includes two antitumour therapeutics in clinical development: TK is a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, in Phase III in high-risk acute leukaemia; NGR-hTNF is a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the tumour mass. TK is under evaluation by EMA for a Conditional Marketing Authorisation. NGR-hTNF is being investigated in a large clinical program, including 11 completed clinical trials (4 Phase I, 7 Phase II in mesothelioma, colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer), a Phase III study in second line malignant mesothelioma and 3 ongoing Phase II trials in malignant pleural mesothelioma (first line maintenance), ovarian cancer and soft tissue sarcomas.

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 is headquartered at the San Raffaele Biomedical Science Park in Milan, Italy.

The Company's shares are listed on the main market (MTA) of the Milan Stock Exchange. (Ticker Reuters: MLMD.MI)

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## *General Company 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 and Chief Executive Officer	Claudio Bordignon
Directors	Maurizio Carfagna Germano Carganico (executive) Alberto Luigi Carletti Riccardo Cortese (independent) Marina Del Bue (executive) Gianluigi Fiorendi Sabina Grossi Mario Masciocchi (independent, Lead Independent Director) Alfredo Messina Raffaella Ruggiero (independent) Lorenzo Salieri

*The Board of Directors was appointed by the Shareholders' Meeting held on 22 April 2013 and will remain in charge until the Shareholders' Meeting called to approve the Financial Statements at 31 December 2015. Marina Del Bue serves as "Director in charge of the internal control and risk management system".*

*On 1 August 2013, Riccardo Cortese was appointed as member of the Board in replacement of Marco Bregni, who resigned on 1 July 2013 with immediate effect, because of concurrent incompatible professional duties.*

*On 12 April 2014, Romolo Bardin, a non-executive and non-independent member representing Delfin Sarl, resigned with immediate effect.*

*On 1 August 2014, Maurizio Carfagna, non-executive director in representation of H-Equity and H-Invest Equity, resigned with immediate effect.*

*On 8 September 2014, the Extraordinary General Meeting after reducing the number of members of the Board of Directors from 13 to 12, has appointed Khalid Islam non-executive director.*

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

### Board of Statutory Auditors

Chairman	Fabio Scoyni
Auditors	Flavia Daunia Minutillo Enrico Scio
Deputy Auditors	Alberto Gallo Francesca Meneghel

*The Board of Statutory Auditors was appointed by the Shareholders' Meeting held on 22 April 2013 and will remain in charge until the Shareholders' Meeting called to approve the Financial Statements at 31 December 2015.*

### Committee for Control and Risks(\*)

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

*(\*) By Board resolution of 11 November 2010, the Committee for Control and Risks (formerly Internal Control Committee) also carries out the function of Committee for Transactions with Related Parties.*

### *Remuneration Committee*

Chairman

Raffaella Ruggiero (independent)

Members

Mario Masciocchi (independent)

Sabina Grossi

*As above-mentioned, on 19 March 2015, Riccardo Cortese announced his resignation as non-executive independent director and member of the Remuneration Committee effective from 1 April 2015.*

### *External Auditors*

Deloitte & Touche S.p.A.

### *Scientific Advisory Board*

MolMed's Scientific Advisory Board (SAB), chaired by Professor Claudio Bordignon, is an independent advisory body, peculiar of Companies where the quality of projects is determined by the value of their scientific contents. The SAB contributes significantly to MolMed's decisions on its R&D pipeline by providing guidance on novel therapeutic strategies and external assessment of results obtained.

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

- Claudio Bordignon, Chairman - 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 many 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)
- Didier Trono - Deputy Director of the Swiss National Science Foundation's "Frontiers in Genetics" area, and Professor and Dean of the School of Life Sciences at the *École Polytechnique Fédérale* in Lausanne (Switzerland)

The professional profiles of the members of the Scientific Advisory Board are available on the Company website ([www.molmed.com](http://www.molmed.com)).



## Letter to the Shareholders

Dear Shareholders,

*I would like to thank you all for the trust and support you have given us and share with you progress made in 2014 in MolMed's three key areas of activity.*

*TK: it has been a particularly significant year as on March 26th, 2014 the European regulatory agency (EMA) validated our request for marketing authorisation through a special procedure called Conditional Marketing Authorisation, formally initiating the evaluation of the dossier based on efficacy and safety data obtained on more than 120 patients treated. Once obtained, the Conditional Marketing Authorisation allows the commercialisation of the therapy even though it is still in the clinical trial phase. Also in 2014 data on the first 24 TK treated patients of the phase III clinical trials were presented at ASCO and ASH, the two most important annual congresses in the hemato-oncology area, showing a diseases free survival rate at one year (study primary endpoint) of 74%. This result largely exceeds the predefined target of 52% for the TK arm. It is also worth mentioning that 86% of patients treated with TK were alive at one year (overall survival being the key secondary study endpoint) and the corresponding figures for patients who achieved immune reconstitution rose to 85% for disease free survival and 100% for overall survival. The therapeutic effect of TK cells was further confirmed by a very low incidence of relapse (16% - with no relapse in patients receiving higher TK cell doses) and a very low non-relapse mortality (10%). Furthermore, cumulative data on over 130 TK treated patients were presented at the two congresses, showing a relevant survival increase compared to historical data. Notably, a clear improvement of the quality of life was highlighted in patients with haploidentical donor, since TK allowed avoiding post-transplant immuno-suppression, a rapid immune reconstitution and GvHD control.*

*NGR-hTNF: at the beginning of May 2014 results of the Phase III relapse malignant pleural mesothelioma clinical trial (NGR015) were released. Despite not having met the primary endpoint of improving overall survival in the entire population, the study showed a statistically significant 40% improvement of both overall survival and progression free survival in 50% of patients presenting a more aggressive disease. Moreover, data showing the doubling of median survival in patients treated with NGR-hTNF for at least 3 months and results on additional two randomized Phase II studies on ovarian cancer and soft tissue sarcomas, clearly establishing the efficacy of NGR-hTNF on survival, were presented at ASCO. Based on the data obtained so far and the favourable tolerability profile of the drug, once the industrial development of product has been completed, the company intends initiating the process needed to request a Conditional Marketing Authorisation, from the European agency EMA, for the treatment in second line of pleural mesothelioma in the patients with poorer prognosis.*

*Third party activity: development and production activities in gene & cell therapy for third parties generated a 90.9% increase in revenues in 2014 compared to 2013, strengthening MolMed's technological leadership in the advanced therapy area. Our expertise was further validated by the strategic agreement signed in March 2015 with GlaxoSmithKline, representing a turning point in the collaboration started in 2011 and sets the stage for an important Company growth in the future. These results support the Company's strategy of expanding its manufacturing capacity, on the one hand to intensify the development and production activities in collaboration with third parties, and on the other to sustain the upcoming possible commercialisation of TK, through the completion of the new production facility based in the "OpenZone" scientific park in Bresso (Milan), that represents, both in terms of size and technical characteristics, the most advanced European structure in the field of gene and cell therapy.*

*Dear Shareholders, other important goals are foreseen for the Company in 2015: for TK, in conjunction with the continuation of the Phase III clinical trial, we envisage the completion of the Conditional Marketing Authorisation evaluation process by the European agency; while for NGR-hTNF, in addition to the completion of the Phase II randomised clinical trials, activities will continue to identify an industrial partner, aimed at an out-licensing agreement and the industrialisation of the manufacturing process. Lastly, the Company recently significantly strengthened its pipeline in the field of immune-gene therapy of cancer through the acquisition, from the San Raffaele Hospital, of the Intellectual Property of the CAR-CD44v6 product, a project that represents the new frontier in this therapeutic area and whose clinical development will benefit from the important knowhow acquired by our Company during the development of the TK technology*

*2015 will be an intense and important year; hence, I wish to thank you for the support that you have always*



*provided and that you have shown with the participation in the recent capital increase. Thanks to you we have developed and continue to develop cutting-edge technologies and products that will benefit patients who, to date, do not have adequate treatment options.*

*As in past years, let me assure you - on behalf of myself and all my colleagues - that we will continue to strive and devote our best efforts to pursue this goal, in the common interest of patients and investors.*

*I would like to thank you all once again for the trust and support you have shown this far.*

*[Signed by]*

*Claudio Bordignon,  
President and CEO*

## *Report on Operations*

### *1. Corporate information*

MolMed is a medical biotechnology Company established in 1996, focused on research, development and clinical validation of innovative therapies to cure cancer. 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).

MolMed was born as a spin-off of the San Raffaele Scientific Institute in the field of gene and cell therapy applied to rare genetic diseases and to haematological malignancies, with the first clinical trials on patients suffering from leukaemia. From year 2000, MolMed started its evolution 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.

MolMed has a unique pipeline in terms of novelty, diversification of therapeutic approaches and technological peculiarity. Its investigational therapies are new, completely original, first-in-class investigational therapeutics building up new therapeutic classes. At the beginning of 2014, MolMed had two proprietary products in Phase III clinical trials, a unique case among Italian Biotech Companies:

TK, a cell-based therapy enabling bone marrow transplants from partially compatible donors, in absence of post-transplant immune-suppression, in Phase III in high-risk acute leukaemia. At the beginning of March 2014, the Company filed to the European Medicines Agency an application for Conditional Marketing Authorisation for the TK therapy (Zalmoxis). EMA validated the submission at the end of March, starting the review of the submitted dossier. The Conditional Marketing Authorisation represents an expedite path for early market authorisation ahead of completion of the pivotal registration studies

NGR-hTNF, a novel therapeutic agent for solid tumours which displays antitumor activity through its specific binding to blood vessels feeding the tumour mass. NGR-hTNF is being investigated in a large clinical program, including 12 completed clinical trials (4 Phase I, 7 Phase II in mesothelioma, colorectal, lung (small-cell and non-small-cell), liver and ovarian cancer), one pivotal Phase III in malignant pleural mesothelioma - second line) and three ongoing Phase II trials in malignant pleural mesothelioma (first line maintenance), ovarian cancer and soft tissue sarcomas.

MolMed is based in Milan, within the San Raffaele Biomedical Science Park. This location offers important advantages, allowing MolMed to integrate its own R&D capabilities with the cutting-edge scientific, technological and clinical resources of its host institution. In particular, MolMed holds an option right to all IP generated from research projects run by the San Raffaele Scientific Institute in the field of gene and molecular therapy of cancer and AIDS. Moreover, an additional facility is in completion at the OpenZone Scientific Park in Bresso (MI) and will allow to increase the Company's actual manufacturing capacity.

At international level, since 2003 MolMed has entered into a strategic alliance with Takara Bio, an important Japanese biotechnology company listed on the Tokyo Stock Exchange, through a co-development and out-licensing agreement for MolMed's cell-based therapies in major Asian markets.

MolMed owns a formally authorised in-house GMP manufacturing facility for production and release of clinical-grade cell and gene therapy products, suitable for all product development stages, including pivotal clinical studies. Furthermore, in 2013 an agreement was signed for the future lease of real estate in the "Open Zone" scientific park located in Bresso (Milan, Italy) owned by the Chemical-Pharmaceutical Group Zambon, aimed at the expansion of the production capacity of the Company.

Thanks to the consolidated leadership in this field, MolMed has developed stable relationships with major players of cell and gene therapies market, including *Fondazione Telethon* and GlaxoSmithKline, with whom on 19 March 2015 a strategic agreement was signed under which MolMed will provide development, manufacturing and knowledge transfer services for the clinical application of gene therapies based on viral vector cell transduction.

MolMed's mission is primarily to 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.

## 2. *Fighting Cancer*

### 2.1 *A global challenge*

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.

Currently, according to a report published by IMS Health in 2013<sup>1</sup>, oncology represents the largest segment of the global pharmaceutical market, and the sixth 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.

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<sup>1</sup> IMS Health Top 20 Global Therapy Areas 2013, IMS Health, 2013.

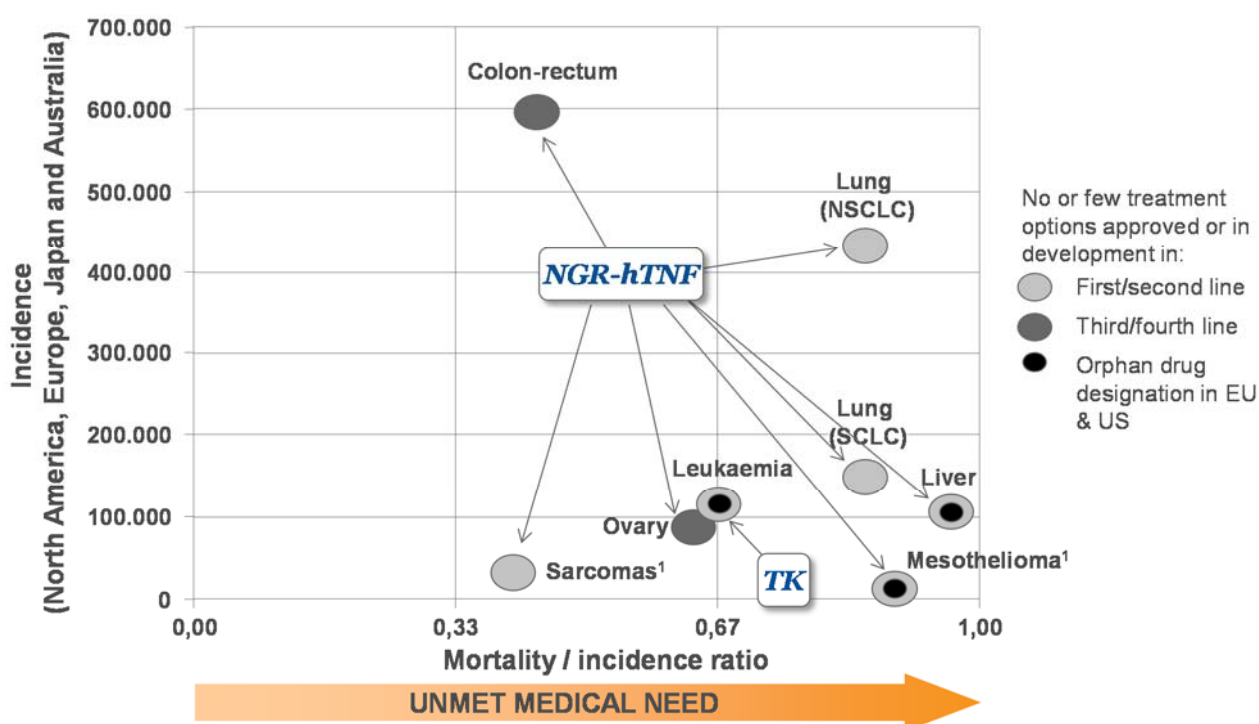
The molecular targets of novel therapeutics may be tumour type-specific, or common to different tumour types, or specific to the blood vessels feeding the tumour mass or to the factors supporting their formation and growth: in the second and third case, they offer the potential for application of a therapy in several different oncology indications.

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 developed by MolMed belong to the context of novel anti-tumour biologics.

## 2.2 MolMed's investigational therapies address severe oncology indications with high unmet medical need

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.



**Figure 1.** Indications addressed by of MolMed's investigational therapies in ongoing and completed clinical trials  
Sources: *Globocan Database 2012; 1MolMed estimate*

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 efficacious treatment lines left, MolMed devotes its efforts to offer a new therapeutic option.

To successfully address the cure of each of these tumours, MolMed is developing two distinct investigational therapies. Both are new, entirely original and giving origin to novel therapeutic classes, but each of them is relying on a different technological approach:

### FROM GENES TO THERAPY

- **TK**, a cell therapy product for blood tumours: this approach is aimed at making available to all patients the curative potential of transplants of haematopoietic stem cells derived from the bone marrow of a healthy donor, that is currently feasible in a safe and effective way only if the donor is fully compatible with the patient, a condition that can be satisfied only for approximately 50% of candidates to the transplant;
- **NGR-hTNF**, a biological drug targeting blood vessels for solid tumours: this approach is based on the use of a highly selective vascular targeting agent whose molecular target is a structure which is only present on blood vessels that feed the tumour mass. The antivascular effect of the drug cuts off supplies of oxygen and nutrients to the tumour, thus blocking its growth.



### 3. Pipeline

MolMed's product pipeline is characterised by two anticancer therapeutics in advanced clinical development, TK and NGR-hTNF. During 2014, most of the activities carried out by the Company functions were focused on the clinical and pharmaceutical development of these two investigational products.

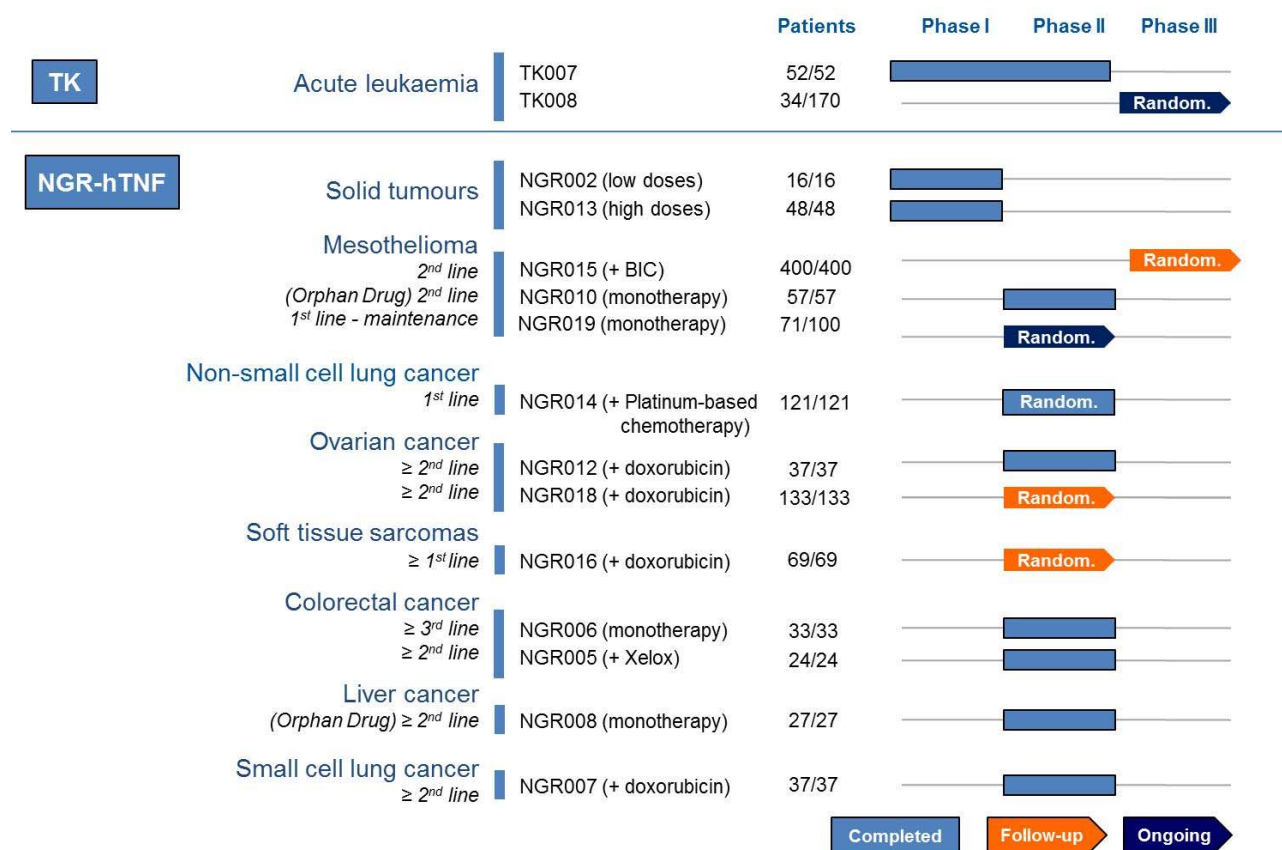
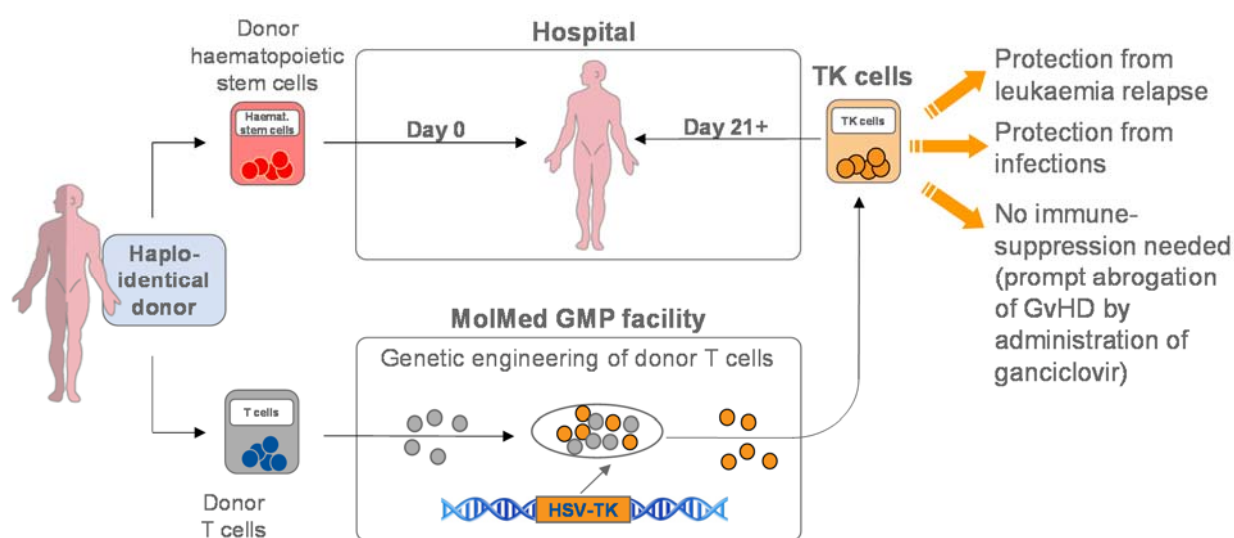


Figure 2. MolMed clinical development pipeline at 31 December 2014

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

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 leukaemic 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-versus-host 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 3.** Overview of TK therapy application in HSC transplant from a partially compatible donor

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. TK therapy consists in 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 a gene (TK) 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, 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.

TK was granted Orphan Drug designation both in the European Union and in the United States.

The outcome of a Phase II trial of TK (trial TK007), published by *The Lancet Oncology*<sup>2</sup>, demonstrated that TK add-backs after haplo-HSCT allow to achieve a rapid and efficient immune-reconstitution 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 TK show that patients treated (including the first patients enrolled in the ongoing Phase III trial) show a rapid post-transplant restoration of a fully functional immune system due to TK cells.

During 2014 the Company presented<sup>3</sup> data obtained on over 130 patients treated with the TK cell-gene therapy the TK on different academic studies, Phase I-II trials and the ongoing pivotal Phase III trial. The data show the ability the TK treatment has in providing patients with high-risk leukaemia, rapid immune reconstitution, an anti-leukaemia activity of TK cells and an effective control of GvHD in the context of haploidentical transplantation with an abolition of post transplantation immunosuppression. Overall, these effects led to a relevant increase in survival rates in treated patients compared to historical data.

In the same occasion were also illustrated data from the first patients treated with TK in the currently ongoing Phase III study (TK008), indicating a further increase in survival rates and an inverse correlation between cell dose administered and the probability of leukaemia relapse.

Further data were presented at the 50th annual meeting of the American Society of Clinical Oncology (ASCO) held in Chicago from May the 30th to June the 3rd 2014. The intent-to-treat analysis of the first 24 patients treated with TK in the randomised Phase III trial indicates a 74% 1-year disease free survival (DSF) as the primary study endpoint: this result largely exceeds the target of 52% DSF for the TK arm vs 30% for the control arm.

Notably, 86% of patients treated with TK were alive at one year (overall survival, the secondary endpoint of the trial) and the corresponding figures for patients who achieved immune reconstitution rose to 85% for disease free survival and 100% for overall survival.

The direct impact of TK cells on transplant outcome was confirmed by a very low incidence of relapse (16% - with no relapse in patients receiving higher TK cell doses) and non-relapse mortality (10% - with no deaths observed in patients achieving immune reconstitution).

Pivotal Phase III trial (TK008) currently ongoing involves adult patients affected by high-risk leukaemia and undergoing haplo-HSCT. The trial is aimed at assessing efficacy and safety of TK, and will compare the outcome of haplo-HSCT with or without TK add-backs, with a randomisation ratio of 3:1 in favour of TK 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](http://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

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

<sup>3</sup> *European Society for Blood & Marrow Transplantation (BMT) Tandem Meetings 2013, Salt Lake City (USA), 13-17 february 2013*

leukaemic 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 unmanipulated 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.

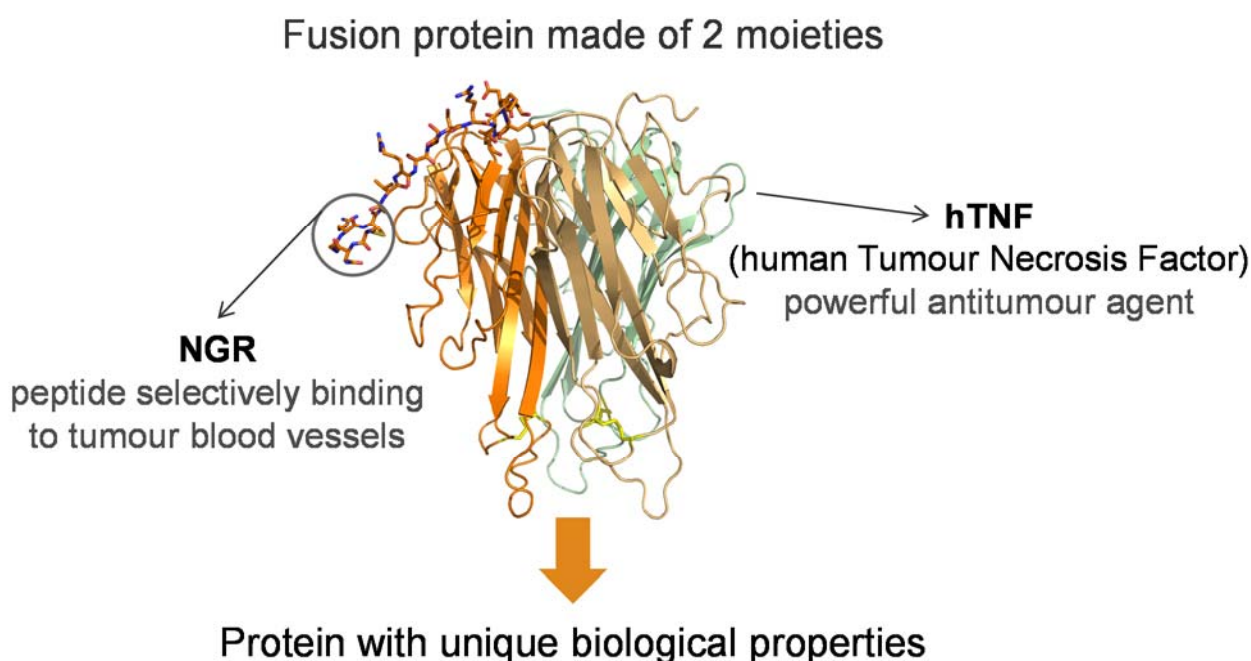
During 2014, the Company submitted the dossier for a market authorisation application for TK to the European Medicines Agency through a special procedure (Conditional Marketing Authorisation), based on Phase II clinical data. The submission was validated by EMA on March 26th, starting the data review of the submitted dossier. This request was possible for TK thanks to the rarity of the indication (TK has obtained Orphan Drug designation), the favourable risk/benefit rate and the demonstration of safety and clinical efficacy. The clinical efficacy data, and in particular those of long-term survival of patients treated with TK, will be used during the analysis and discussion of the dossier submitted to the European Medicines Agency.

Concerning TK manufacturing, in during 2014 MolMed continued the project for the development of an automated production process in collaboration with the German Company Miltenyi through the application of its CliniMACS Prodigy system to the TK process.

TK key publications are available on MolMed's website ([www.molmed.com](http://www.molmed.com)).

### 3.2 *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-in-class in the class of peptide-cytokine complexes targeting tumour blood vessels. It is a homotrimeric protein, where each of the three subunits is formed by combining a tumour homing peptide (NGR) with the human cytokine Tumour Necrosis Factor (hTNF). NGR targets a particular receptor complex including CD13, selectively expressed by endothelial cells of human tumour vessels.



**Figure 4.** The NGR-hTNF molecule: structure of a monomer and properties of its moieties

NGR-hTNF acts specifically on blood vessels feeding the tumour mass, inducing an anti-vascular effect that allows, inter alia, an improved penetration into the tumour tissue of other anticancer drugs administered in combination, thereby enhancing their therapeutic effectiveness. Therefore, NGR-hTNF can be used both as new single-agent therapeutic option, and in combinations with most cytotoxic-based chemotherapeutic regimens currently available.

Unlike all other drugs commonly classified as vascular targeting/disrupting agents (VTAs/VDAs), NGR-hTNF appears to exert its anti-vascular and antitumour activity without inducing harmful counter-regulatory mechanisms: neither increase at the tumour site of bone marrow-derived cell infiltrates nor increase in circulating growth factors are induced, i.e. two phenomena that stimulate angiogenesis, post-therapy tumour re-growth and metastasis.

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.

In 2012, the enrolment of 70% of the planned population of 390 patients allowed a very fast recruitment completion in pivotal Phase III trial for the treatment of relapsed malignant pleural mesothelioma (trial NGR015); over 40 centres in 12 different countries - in Europe, North America and Egypt - are participating in the trial. NGR015 is 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 is overall survival; secondary endpoints include progression-free survival, disease control rate, tolerability profile and patients' quality of life. The trial investigates 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](http://clinicaltrials.gov): NCT01098266).

At the beginning of May 2014 the Company reported top line results of such clinical trial: Despite not meeting its primary endpoint of improving overall survival (OS) in the entire population, the study showed a statistically significant (unstratified  $p=0.02$ ; stratified  $p=0.01$ ) 40% improvement of OS in patients with poorer prognosis who had progressed during or shortly after first-line chemotherapy. These patients represent 50% of the entire patient population and were identified by a pre-specified analysis based on prior treatment-free interval.

Further data presented at the at the 50th ASCO annual meeting showed that the impact of treatment with NGR-hTNF on survival was correlated to duration of therapy: this was particularly evident in patients treated for at least three months with NGR-hTNF, where the median survival time almost double compared to control patients: 16.5 vs 9.8 months, respectively.

The above mentioned data, mainly obtained in combination with either gemcitabine or vinorelbine in a very aggressive and chemo-resistant disease, assume particular relevance since they confirm the efficacy previously shown by NGR-hTNF plus gemcitabine in the first-line Phase II study in squamous lung cancer patients, generally characterised by a poorer prognosis compared to non-squamous histology.

On the basis of results obtained so far the Company plans to continue in its search for an industrial partner in order to outlicense the product and, in parallel, to request a pre-submission meeting with the European Medicines Agency so as to evaluate compliance with the requirements needed for submission of an application for Conditional Approval for NGR-hTNF in second line treatment of pleural mesothelioma in patients with poorer prognosis, once the industrial development of the product will be completed.

Two additional randomized Phase II studies reported at ASCO meeting clearly established the effect of NGR-hTNF on survival.

In the four-arm randomized Phase II study in sarcoma patients, the low-dose weekly NGR-hTNF plus doxorubicin regimen induced a statistically significant doubled survival time, as compared with the other schedules given at high dose in combination with doxorubicin or as monotherapy at 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 pretreated patients, thus confirming the elevated NGR-hTNF efficacy in more aggressive, chemo-resistant disease.

In the randomized Phase II study in resistant / refractory ovarian cancer patients, NGR-hTNF in combination with an anthracycline improved overall survival in patients with normal or high baseline lymphocyte counts, as compared to patients receiving an anthracycline alone.



Furthermore, NGR-hTNF confirmed in this large patient population its very favourable tolerability profile, also in combination with the different chemotherapeutic agents administered in the studies.

Taken together, these clinical evidence is also consistent with the drug mechanism of action, that also promotes an increased intratumoral chemotherapy uptake and interaction with the patient immune system. During 2014 continued the follow-up of patients enrolled in randomised Phase II and Phase III studies on soft tissue sarcoma (NGR016), ovarian cancer (NGR018) and mesothelioma (NGR015). Recruitment continued for the ongoing randomised Phase II trial in mesothelioma as first line maintenance treatment (trial NGR019), also in virtue of the extension to Eastern European countries - where the medical need could be highest in the next few years - through the enrolment in December of the first patient in Russia.

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

Posters and presentations of the results of NGR-hTNF clinical trials, as well as abstracts - or full-text in the case of open-source articles - of the key publications on NGR-hTNF are available on MolMed's website ([www.molmed.com](http://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* with a fermentation process. Manufacturing of the protein - representing the bulk drug substance, i.e., the active pharmaceutical ingredient, or "API" - and of the drug product in its final formulation are outsourced to external specialised CMOs. To date, a total of nine GMP batches of NGR-hTNF have been produced: seven batches of bulk drug substance were used for Phase I and Phase II trials, and the last two batches of bulk drug substance yielded two batches of drug product to cover randomised (Phase II and Phase III) trials. MolMed is working on further scale-up of the manufacturing process for commercial production of the drug, following the same outsourcing strategy.

#### *4. Development and GMP production activities in cell and gene therapy*

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

MolMed performs tailor-made activities in this field on behalf of 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 cGMP manufacturing of viral vectors and patient-specific genetically engineered cells.

During 2014, work continued under two major agreements signed in 2011 with Fondazione Telethon and GlaxoSmithKline (GSK), for the development and production of highly innovative gene therapy treatments for a total of seven rare genetic diseases, all caused by a single defective gene, thus making it possible to develop a potential cure by inserting the correct form of the gene into the patient's own stem cells derived from the bone marrow, through ex vivo gene transfer technology. Furthermore, in November 2013 MolMed and GSK signed an additional agreement for the production of the Adenosine Deaminase Deficiency – Severe Combined Immune Deficiency (ADA-SCID) investigational gene therapy for compassionate use. We highlight that on 19 March 2015 a strategic agreement was signed under which MolMed will supply development, manufacturing and technology transfer services aimed at the clinical application of gene therapies based on viral vector cellular 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 would be eligible for a minimum of € 34 million in the form of upfront, milestones, services and supply, over the next five years.

These activities are consolidating the company's technological leadership in this field and led to a 90.9% increase in third party services revenues in 2014 (reaching Euro 11.181 thousand) compared 2013 (Euro 5.856 thousand).

##### *4.1 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, development projects currently include implementing a technology platform for the large-scale, semi-stable and stable production of lentiviral vectors. This platform relies on a solid patent portfolio in cell and gene therapies consisting of ten patent families, which includes 97 granted patents and 41 pending applications, covering genes for the treatment of genetic diseases and tumours, methods and technologies for hematopoietic stem cells and T cells manipulation, viral vectors production systems and packaging cell lines for the production of retroviral vectors and for stable and semi-stable production of lentiviral vectors.

During 2014, work continued on the following activities related to development of investigational gene therapy treatments:

- development activities for the production of lentiviral vectors to be used in clinical trials of gene therapy treatments for beta-thalassemia and mucopolysaccharidosis type I (MPS I), as well as



support activities for the GMP validation of such vectors. These activities were carried out under the agreement with Fondazione Telethon;

- characterisation of two cell lines for the production of retroviral vectors to be used in manufacturing of ADA-SCID gene therapy, and development of analytical methods for GMP production of such vectors. These activities were carried out under the agreements with GlaxoSmithKline;
- development of a stable packaging cell line for the production of second- and third-generation lentiviral vectors. In particular, on February 12, 2014 the European Patent Office granted MolMed a patent protecting stable constitutive packaging systems for lentiviral vectors: the patent will provide protection until 2031 and will give right to market exclusivity in 40 European countries, including European Union member states, Eastern Europe countries, Switzerland and Turkey;
- development activities related to the production of lentiviral vectors to be used in clinical trials of gene therapy for metachromatic leucodystrophy (MLD) and Wiskott-Aldrich syndrome (WAS), and support to their GMP validation;
- development and optimisation of the production process of lentiviral vectors and transduction of haematopoietic stem cells for in vivo preclinical studies, under the EU-FP7 co-funded project CELL-PID.
- development and application of new gene targeting strategies to correct hereditary mutations and cancer immunotherapy strategies, under the EU co-funded project SUPERSIST;

## 4.2 GMP production

MolMed has 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, and qualified to support all stages of drug development of cell-based therapies, including pivotal clinical trials.

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 sqm - satisfies EMA and FDA requirements for the production of clinical-grade sterile investigational medicines.

Besides manufacturing 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 the use of its GMP facility, as well as building and maintaining strategic collaborations.

During 2014, work continued on the following activities ongoing since 2011:

- Development of the GMP manufacturing process for the ADA-SCID gene therapy and production of transduced cells for compassionate patients' treatment, under the agreements with GSK;
- production of cells transduced with lentiviral vectors for the investigational treatment of patients affected by MLD and WAS, again under the abovementioned agreement with Fondazione Telethon;

- production of cells for the investigational treatment of patients affected by Duchenne muscular dystrophy;
- Quality Control-related service activities (sterility assays according to Pharmacopoeia).

During 2014, work continued under three major agreements signed in 2011 and 2013 with GlaxoSmithKline and Fondazione Telethon for the development and production of new investigational gene therapy treatments to cure patients suffering from life-threatening hereditary diseases.

During 2014, work continued on the realization of a new production facility in the "OpenZone" scientific park located in Bresso (Milan, Italy). The Bresso site will provide MolMed with a further production facility of about 3,300 sqm, in addition to the existing facility (about 1,400 sqm) located in the via Olgettina site, more than tripling the current production capacity. This expansion is necessary to support the treatment of patients with TK therapy and, coupled with the technological leadership of the Company in developing therapies in the field of rare genetic diseases and immune-gene therapy of tumours, will allow MolMed to position itself as an ideal strategic partner for Biotech and big Pharma companies.

A first pool of about 40 MolMed's collaborators already started activities in the OpenZone Company offices in May 2014.

## **5. IP protection activities**

In the course of 2014, activities have been carried on for consolidation of the intellectual property covering the two more advanced experimental products TK and NGR-hTNF. In addition, further activities have been performed aimed to broaden the patent portfolio owned by the Company protecting the technologies for manufacturing and purification of vectors for gene therapy.

Particularly, regarding NGR-hTNF, the majority of patent applications claiming the product and its use at low dosage alone or in combination with other drugs have been granted. Therefore, during 2014, the activities were focused on maintenance of granted patents. Moreover, the patent claiming the use of NGR-TNF for the treatment of mesothelioma was granted in Australia and Japan, thus further extending the market exclusivity already obtained in the past years in Europe, Canada, China and Russia. The corresponding patent application in the United States is still under review.

Regarding TK, the key-patent on non-splicing variant of the gene at the base of TK, i.e. the variant for which information is recorded in a stable and non-modifiable way, was obtained in the United States of America and in Canada thus completing, in this way, the list of countries in which market exclusivity was obtained on the gene employed in the product.

Further, concerning the protection of technologies for the manufacturing of viral vectors, in 2014 MolMed received the grant of an important patent in Europe claiming a stable packaging cell line i.e. a new production tool made from a cell line stably modified in its genome to make a production of lentiviral vectors for gene therapy. The new patent is valid until 2031, and gives market exclusivity in the 38 countries belonging to the European Patent Convention, including all major European Union countries, some Eastern European countries, Switzerland, Turkey and other countries. In addition, MolMed has made its entry into the national phase for an international PCT patent application related to a process for the purification of viral vectors for gene therapy. The company carried out a strategy of filing that seeks to obtain a broad coverage including countries belonging to the main industrialized areas, as well as countries in Asia and South America with major emerging markets.

## ***6. Business development activities***

In 2014 the Business Development area continued to focus its activities on exploring collaboration agreement opportunities - from co-development to out-licensing - for MolMed's advanced investigational therapeutics TK and NGR-hTNF.

The prosecution of contacts with big pharma companies recorded a confirmation of their interest in the development of TK and NGR-hTNF, with particular regard to NGR-hTNF, for which MolMed's business model plans to enter into a partnership for its development and commercialisation.

In 2014 the Company continued to intensify long-term relationships with major pharmaceutical and biotech companies, through participation in major scientific, financial and business conferences. In line with the longterm trend of a steady expansion of the audience interested and informed about MolMed's investigational products, the Company also continued to open and strengthen communication channels, by involving the so-called big pharma and medium-sized companies, in order to increase the opportunities to maximise the economic value of its products.

The Business Development area also continued its contribution in support of the selection of suppliers for critical business activities related to the development and forthcoming commercialisation of MolMed's investigational therapeutics, and performed analyses for their positioning in the competitive scenario.

## ***7. Communication and Investor Relations activities***

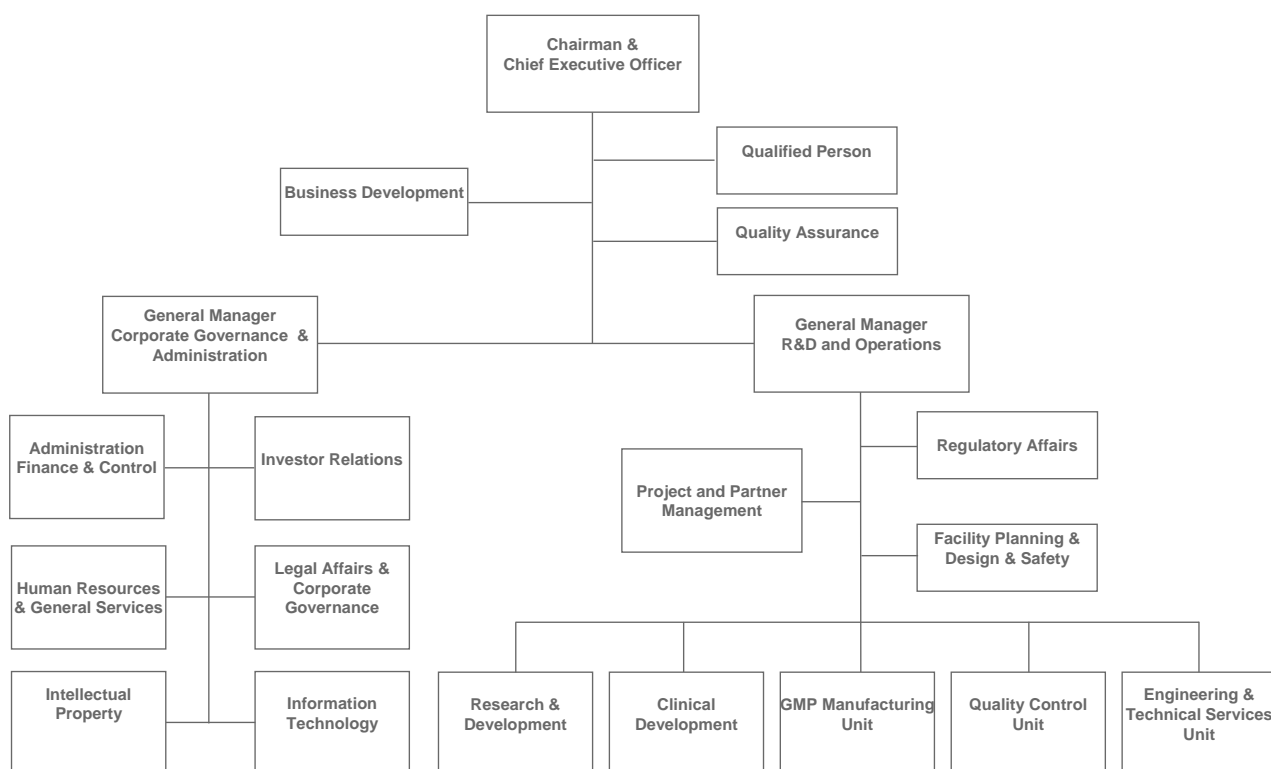
During 2014, the Company pursued contacts with investors and the financial community.

Moreover the Company participated to the European Biotech Week with an open door day on October the 9<sup>th</sup> when it has been it was possible to visit the development laboratories and the production facility.

MolMed also held company presentations at various international conferences aimed at bringing together public biotech Companies and institutional investors specialised or otherwise active in the biotech field: periodically these presentations - some of which with live and replay audio webcast - have been published on the home page of the Company's website.

## 8. Organisation and Human Resources

MolMed’s organizational chart at December 31, 2014 is shown below.



At December 31, 2014, the Company’s total staff consisted of 115 employees and 14 temporary staff members. MolMed is aware that staff members are a key element to successfully achieve its strategic objectives. Respect, fair treatment, professional development, team work, ongoing training are among the Company’s key values.

In 2014, staff training activities focused on examining some aspects of Italian Legislative Decree 231, through a seminar that illustrated the recent amendments made by Italian Law 190/2012 (the so-called "anti-corruption law") to Article 2635 of the Italian Civil Code, renamed “private-sector corruption”. In addition, some corporate functions playing an important role in the processing of confidential data participated in a workshop on Privacy entitled “Italian Personal Data Protection Code – Legislative Decree 196/2003 – Fundamentals of privacy protection”.

Development of staff’s skills continued as usual through the participation in courses, seminars and other events, according to the staff professional category or organizational area. The compulsory training program on safety also continued (pursuant to Italian Legislative Decree 81/08).

## 9. Research & Developments 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, which was officially launched in May 2013, has a duration of 36 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.

## *10. Corporate Governance*

MolMed complies with the Corporate Governance Code of 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 Codes of Conduct 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](http://www.molmed.com)). It was submitted to Borsa Italiana in compliance with applicable provisions.

### *10.1 Direction and coordination activities*

Due to MolMed's shareholding structure, no shareholder controls the majority of votes or has enough votes to exercise dominant influence over the Company. Furthermore, shareholders are not required to consolidate the Financial Statements.

### *10.2 Implementation of the Organisational, management and control model (pursuant to Legislative Decree 231/2001)*

As per Legislative Decree 231 dated June 8, 2001, legal entities are subject to administrative liability in relation to offenses committed by Directors, officers or employees to the benefit or advantage of the entity, unless the adoption and effective implementation of an organization, management and control model suitable to prevent such offenses from being committed is proven, among other things.

In order to comply with current provisions, in 2007 the Company approved the adoption of an Organization, Management and Control Model aimed at preventing offenses from being committed, and established a Supervisory Body complying with the autonomy, independence and professionalism requirements, and vested with inspection and control powers as well as of the functions and powers provided for by the above-mentioned model. The Company also prepared the Anti-Corruption Code following the recent introduction of private-sector corruption offenses among the predicate offenses included in Italian Legislative Decree 231/2001.

During 2014, the Supervisory Body once again audited the individual corporate Functions, defining further examination procedures on a test basis to verify the actual implementation of all the procedures defined in Italian Legislative Decree 231. Specifically, it examined:

- the impact of the project to expand the corporate facility and relocate the Company's secondary offices to the "Open Zone" site in Bresso. It found that the move did not change/increase the risk of committing workplace safety offenses;
- the impact on MolMed's share price of the publication of the preliminary results from the Phase III trial of NGR-hTNF in mesothelioma patients (NGR-015 trial). It found that no insider information leaked in advance of the official announcement, confirming that there are measures in place limiting the risk of committing offenses in this specific area;
- the new internal regulation governing the use of MolMed's IT systems. The Supervisory Body deemed the document thorough and suitable for implementing the measures necessary to prevent potential offenses; in addition, it stated it has neither received reports nor is it aware of any breaches of the IT system and the personal data protection code;
- the content of the Anti-Corruption Guidelines, which the Company adopted in July 2014 with the favorable opinion of the Supervisory Body and the Board of Directors. Overall, the Supervisory Body deemed the document was thorough, detailed, and well-organized; nonetheless, it stressed the importance of implementing the Guidelines by: (i) properly training the individuals at risk of corruption (namely, the heads of the individual corporate functions, who are responsible for supervising employees' compliance with the rules and adopt the measures necessary to prevent breaches); (ii) supplementing the disciplinary code (Annex 7 to the Special Part of the Model); (iii) acting on the Guidelines by preparing a specific protocol for MolMed and integrating them with existing 231 procedures (Annex to the Special Part of the Model). Finally, in 2014 the Supervisory Body held a workshop for the Company's top executives on the most relevant topics in Italian Legislative Decree 231 relating to the adoption of the Anti-Corruption Guidelines, such as the private-sector corruption offenses.

The Organization Model is available on the Company's website ([www.molmed.com](http://www.molmed.com)).

### *10.3 Transactions with related parties*

MolMed adopted the new Procedures for transactions with related parties unanimously approved by the Board of Directors on November 11, 2010 and updated and supplemented on February 6, 2012, following the favorable opinion of the relevant Committee formed by the three Independent Directors.

The Procedures were adopted by MolMed to implement the provisions of Resolution 17221 of March 12, 2010, amended by Resolution 17389 of June 23, 2010, with which Consob, pursuant to Article 2391-bis of the Italian Civil Code as well as Articles 113-ter, 114, 115 and 154-ter of Legislative Decree 58 of February 24, 1998 (Consolidated Law on Finance) issued the "Regulations containing provisions relating to transactions with related parties", and taking account of the indications and guidelines as set out in Consob Communication DEM/10078683 of September 24, 2010.

The updated and current version of the Procedures for transactions with related parties is available on the Company's website ([www.molmed.com](http://www.molmed.com)). Detailed information on transactions with related parties is provided in the Notes to the Financial Statements to which reference should be made.



## **11. *Main risks and uncertainties to which MolMed is exposed***

### **11.1 *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.

## ***11.2 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.



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 and Chief Executive Officer, Mr. Claudio Bordignon, on the Director and General Manager, Ms. Marina Del Bue, on the Director and Business Development & Strategic Affairs Manager, Mr. Germano Carganico, and on the General Manager, Mr. G. Paolo Rizzardi, 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.

### **11.3 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 2014 was 13,003 thousand Euro, reached 5,166 thousand Euro from the 18,169 thousand Euro loss recorded in the previous year.

The Board of Directors agreed on the strategy of the 2015-2017 business plan on December 19, 2014 and approved it on April 9, 2015 based on the most recent available information following the end of the capital increase on April 9, 2015. The business plan, assuming it becomes fully operational, provides for the following to be achieved in the 2015-2017 period:

- continuing the clinical and industrial development of the main experimental products;
- pursuing operations and investments aimed at boosting production capacity;
- selecting further products as clinical candidates to be developed;
- investing in preclinical research or the acquisition of additional technologies and products under licensing agreements;

- increasing investments beyond current levels to create a sales network and expand production capacity by fully automating the production of TK cell therapy.

The Company will require high cash flow to implement these activities.

The Company has met its liquidity requirements from its incorporation up to the date of these Financial Statements through contributions from its shareholders. Furthermore, as at the date of this Report, the Company has finalized the capital increase described in paragraph *13.2 Capital increase of 5 million Euro completed in April 2014 and capital increase of 50 million Euro completed in April 2015*, as well as *15.1 Significant events after the reporting period*. The capital increase ended on April 9, 2015, raising a gross amount of 49,825 thousand Euro (including 10,145 thousand Euro received from the main shareholders as capital contributions on account of future issues of shares).

Based on the above and on the analysis of future cash flows projected by the 2015-2017 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, 2014, 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.

## *12. Other information*

### *12.1 Treasury shares*

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

### *12.2 Protection of sensitive data and information*

In light 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 the applicable regulations provided for by the Personal Data Protection Code (Legislative Decree 196/2003).

In 2014, 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, together with its consultants, the Company continued reviewing a number of corporate processes handling potentially sensitive information and the relevant data flows.

In any case, it should be noted that in 2014 there were no omissions, deletion or any other situation that might have threatened the safety of anyone's personal data within the Company.

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

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

The Company has adopted safety procedures for the management and disposal of waste in accordance with Italian Legislative Decree 81/08 and Italian Legislative Decree 206/01 on management of genetically modified microorganisms (GMMs). The Company's laboratories have been registered with the Ministry of Health and a specific authorization has also been requested for each GMM used. MolMed has containment level 2 and 3 laboratories for the use of class 2 and 3 GMMs, respectively.

All personnel have been provided with specific training on the issue and comply with procedures aimed at minimizing 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 have been implemented for all employees, distinguishing general training from specific training and additional training for personnel in charge of safety.

Operations require the Company to use chemical agents for which a specific risk assessment (low for safety and irrelevant for health) was performed pursuant to Italian Legislative Decree 81/2008 – Title IX. When handling chemical agents, staff uses personal protective equipment in line with the industry-standard practices. Potentially infected or chemical waste is disposed of in compliance with current regulations (Italian Legislative Decree 152/06), based on a specific procedure, with the support of a specialized firm.

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

There are no particular environmental issues that might affect the Company's use of its tangible assets.

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

Pursuant to Article 79 of the Consob Issuers' Regulations, MolMed specifies that, based on information received at December 31, 2014, the following shares were held by Directors, General Managers, Statutory Auditors and Executives with strategic responsibilities, as well as by their spouses who are not legally separated, and their underage children, either directly or through a subsidiary, fiduciary business or any other intermediary.

Name	Role	Company in which stake is held	Shares held at 31.12.2013	Numero azioni acquistate o sottoscritte	Numero azioni vendute	Shares held at 31.12.2014
	Consigliere, Direttore Generale					
Marina Del Bue	Consigliere	MolMed S.p.A.	496,169	18,375	514,544	-
Alfredo Messina	Consigliere	MolMed S.p.A.	623,000	123,387	-	746,387

## 13. Main achievements in 2014

### 13.1 Research and development activities

#### Development activities on TK

- Submission in March for a market authorisation application for TK through a special procedure (Conditional Marketing Authorisation) to the European Medicines Agency. This request is based on the rarity of the indication (TK has obtained Orphan Drug designation), the favourable risk/benefit rate and the demonstration of safety and clinical efficacy;
- presentation in April at the 40th annual meeting of the European Society for Blood and Marrow Transplantation (EBMT) of data obtained on over 130 patients treated with the TK cell-gene therapy the TK on different academic studies, Phase I-II trials and the ongoing pivotal Phase III trial. The data show the ability the TK treatment has in providing patients with high-risk leukaemia, rapid immune reconstitution, an anti-leukaemia activity of TK cells and an effective control of GvHD in the contest of haploidentical transplantation with an abolition of post transplantation immunosuppression. Overall, these effects led to a relevant increase in survival rates in treated patients compared to historical data;
- presentation in June at the 50th annual meeting of the American Society of Clinical Oncology (ASCO) of the first data from the ongoing randomised pivotal Phase III study TK008. The intent-to-treat analysis of the first 24 patients treated with TK indicates a 74% 1-year disease free survival (DSF) as the primary study endpoint: this result largely exceeds the target of 52% DSF for the TK arm vs 30% for the control arm. Notably, 86% of patients treated with TK were alive at one year (overall survival, the secondary endpoint of the trial). The direct impact of TK cells on transplant outcome was confirmed by a very low incidence of relapse (16% - with no relapse in patients receiving higher TK cell doses) and non-relapse mortality (10% - with no deaths observed in patients achieving immune reconstitution);
- continuation of the industrialization activities for the TK manufacturing process, particularly focused on the automation of the production system.



The clinical efficacy data, and in particular those of long-term survival of patients treated with TK, will be used during the analysis and discussion of the dossier submitted to the European Medicines Agency (EMA), whose review officially started on March 26th, 2014.

### *Development activities on NGR-hTNF in mesothelioma*

In May 2014 results were obtained from the randomized pivotal Phase III trial in malignant pleural mesothelioma (NGR015). Despite not having met its primary endpoint on overall survival (OS) in the entire population, for the first time the study showed a highly significant clinical benefit in a relevant population of patients with poorer prognosis. The results presented at ASCO in June show:

- a statistically significant (unstratified  $p=0.02$ ; stratified  $p=0.01$ ) 40% improvement of overall survival in patients with poorer prognosis who had progressed during or shortly after first-line chemotherapy. These patients represent 50% of the entire patient population and were identified by a pre-specified analysis based on prior treatment-free interval;
- the impact of treatment with NGR-hTNF on survival correlated to duration of therapy was particularly evident in patients treated for at least three months with NGR-hTNF, with a median survival time almost double compared to control patients: 16.5 vs 9.8 months, respectively;
- a favourable tolerability profile in combination with the three different chemotherapeutic agents administered in this trial (gemcitabine, vinorelbine and doxorubicin).

The above mentioned data, mainly obtained in combination with either gemcitabine or vinorelbine in a very aggressive and chemo-resistant disease, assume particular relevance since they confirm the efficacy previously shown by NGR-hTNF plus gemcitabine in the first-line Phase II study in squamous lung cancer patients, generally characterised by a poorer prognosis compared to non-squamous histology.

Recruitment continued for the ongoing randomised Phase II trial in mesothelioma as first line maintenance treatment (trial NGR019), also in virtue of the extension to Eastern European countries - where the medical need could be highest in the next few years - through the enrolment in December of the first patient in Russia.

On the basis of results obtained so far the Company plans to continue in its search for an industrial partner in order to out license the product and, in parallel, to request a pre-submission meeting with the European Medicines Agency so as to evaluate compliance with the requirements needed for submission of an application for Conditional Marketing Approval for NGR-hTNF in second line treatment of pleural mesothelioma in patients with poorer prognosis, once the industrial development of the product will be completed.

### *Development activities on NGR-hTNF in the other indications*

During 2014 continued the follow-up of patients enrolled in randomised Phase II and Phase III studies on soft tissue sarcoma (NGR016), ovarian cancer (NGR018) and mesothelioma (NGR015). In June new data were presented at ASCO clearly establishing the effect of NGR-hTNF on patients survival:

- sarcoma: the low-dose weekly NGR-hTNF plus doxorubicin regimen resulted in a statistically significant survival time, double compared to the other schedules given at high dose in combination with doxorubicin or as monotherapy at low or high dose;

- resistant / refractory ovarian cancer: 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.

The results so far obtained in randomized Phase II trials for the treatment of various solid tumors support the therapeutic potential of the product, which may find application in a wide range of oncological indications.

### *Research and development activities in cell and gene therapy*

In 2014 activities continued in the development of a technological platform for semi-stable and stable large-scale production of lentiviral vectors. This platform relies on a solid patent portfolio in cell and gene therapies consisting of ten patent families, which includes 106 granted patents and 35 pending applications, covering genes for the treatment of genetic diseases and tumours, methods and technologies for hematopoietic stem cells and T cells manipulation, viral vectors production systems and packaging cell lines for the production of retroviral vectors and for stable and semi-stable production of lentiviral vectors.

In particular, on February 12, 2014 the European Patent Office granted MolMed a patent protecting stable constitutive packaging systems for lentiviral vectors: the patent will provide protection until 2031 and will give right to market exclusivity in 40 European countries, including European Union member states, Eastern Europe countries, Switzerland and Turkey.

### *Development and GMP production for third parties*

Activities of development and manufacturing of new gene and cell therapy treatments for third parties are consolidating the company's technological leadership in this field and led to a +90.6% increase in third party services revenues in 2014 (reaching Euro 11.181 thousand) compared to 2013 (Euro 5.856 thousand).

During 2014, work continued under three major agreements signed in 2011 and 2013 with GlaxoSmithKline and Fondazione Telethon for the development and production of new investigational gene therapy treatments to cure patients suffering from life-threatening hereditary diseases.

During 2014, work continued on the realization of a new production facility in the "OpenZone" scientific park located in Bresso (Milan, Italy). The Bresso site will provide MolMed with a further production facility of about 3,300 sqm, in addition to the existing facility (about 1,400 sqm) located in the via Olgettina site, more than tripling the current production capacity.

This expansion is necessary to support the treatment of patients with TK therapy and, coupled with the technological leadership of the Company in developing therapies in the field of rare genetic diseases and immuno-gene therapy of tumours, will allow MolMed to position itself as an ideal strategic partner for Biotech and big Pharma companies.

## *13.2 Capital increase of 5 million Euro completed in April 2014 and capital increase of 50 million Euro completed in April 2015*

### *Capital increase completed in 2014*

In 2014, the capital increase resolved by the Extraordinary Shareholders' Meeting of March 3, 2014, was successfully implemented and completed. The capital increase was concluded on April 4, 2014 with the full subscription of 8,252,092 newly-issued ordinary shares (1 new share for each 27 ordinary shares held), for



an overall amount of 4,969 thousand Euro, of which 389 thousand Euro credited to the capital account and 4,580 thousand Euro to the share premium account.

The main stages of the transaction are described in the following paragraphs.

On January 31, 2014, the Company's Board of Directors approved the statement of financial position at November 30, 2013 pursuant to Article 2446 of the Italian Civil Code, with overall losses, net of available reserves, of 16,585,450.41 Euro, i.e. more than a third of the subscribed and paid-in capital (equal to 27,070,992.30 Euro).

The Board of Directors then resolved to propose to the Extraordinary Shareholders' Meeting to fully cover the total losses, net of available reserves, of 16,585,450.41 thousand Euro at November 30, 2013 by approving a capital reduction from 27,070,992.30 thousand Euro to 10,485,541.89 thousand Euro, without the cancellation of any shares, given the absence of the relevant par value. During the same meeting, the Board of Directors also resolved to propose to the Extraordinary Shareholders' Meeting a capital increase by consideration in cash, without requiring all shares to be subscribed, for a total maximum amount of 4,999,999.00 Euro, including the relevant share premium, to be performed through the issue of ordinary shares with no par value, in dematerialized form, cum dividend, and with the same characteristics as the currently outstanding shares, to be offered with pre-emption rights to the Company's Shareholders pursuant to Article 2441, paragraph 1 of the Italian Civil Code.

The capital increase proposal required the issue price to be equal to the average of share reference prices recorded during the 30 days before the Extraordinary Shareholders' Meeting, after deducting a 5% discount.

Finally, pursuant to Article 2443 of the Italian Civil Code, Directors resolved to submit to the Extraordinary Shareholders' Meeting their proposal to vest the Board with the power to increase the Company's capital for a total maximum amount of 50,000,000.00 Euro including the relevant share premium, in one or more installments, without requiring all shares to be subscribed, by and no later than December 31, 2016 through the issue of ordinary shares with no par value, in dematerialized form, cum dividend, and with the same characteristics as the currently outstanding shares, to be offered with pre-emption rights to the Company's Shareholders pursuant to Article 2441, paragraph 1 of the Italian Civil Code.

The aforesaid recapitalization is part of a broader strategy aimed at strengthening the Company's capital, which also includes additional measures to be performed by the Company's Shareholders.

The Shareholders' Meeting held on March 3, 2014 approved the Board of Directors' proposal, vesting the Board with the power to determine the final total number of newly-issued shares and the relevant ratio according to pre-emption rights. The Board met on that same date at the end of the Shareholders' Meeting.

On March 28, 2014, following the end of the offer to existing shareholders from March 10 through March 28, 215,327,241 pre-emption rights were exercised, resulting in a total of 7,975,083 shares subscribed, i.e. 96.64% of the shares offered, worth 4,802,594.99 Euro. 7,479,243 pre-emption rights were not exercised, leaving 277,009 shares unsubscribed, i.e. 3.36% of the shares offered, worth 166,814.81 Euro.

Said rights were offered on the Stock Exchange on April 1, 2, 3, 4 and 7, 2014. On April 1, all 7,479,243 pre-emption rights were sold at a price of 0.0060 Euro, for a total amount of 44,875.46 Euro, relating to the subscription of 277,009 shares left from the capital increase by consideration in cash, thus completing ahead of schedule the offer on the Stock Exchange of the pre-emption rights that were not exercised.

### *Capital increase completed in 2015*

As previously noted, on March 3, 2014, pursuant to Article 2443 of the Italian Civil Code, the Extraordinary Shareholders' Meeting resolved to vest the Board with the power to increase the Company's capital for a total maximum amount of 50,000,000.00 Euro including the relevant share premium, in one or more installments, without requiring all shares to be subscribed, by and no later than December 31, 2016 through the issue of ordinary shares with no par value, in dematerialized form, cum dividend, and with the same characteristics as the currently outstanding shares, to be offered with pre-emption rights to the Company's Shareholders pursuant to Article 2441, paragraph 1 of the Italian Civil Code. Pursuant to the above resolution, on February 23, 2015, the Company's Board of Directors exercised said power, deciding to increase the Capital up to 50 million Euro, including in installments. On March 4, 2015, the Board of Directors decided the final terms of the capital increase: specifically, the Company will issue up to 187,311,408 new ordinary shares without par value, with the same characteristics of MolMed ordinary shares outstanding as at the date of the issue and cum dividend, offering the Company's existing shareholders the right to subscribe for 4 new shares for every 5 ordinary shares held, at an issue price of 0.2660 Euro per share (of which 0.0471 Euro credited to the capital account and the remainder to the share premium account), up to a total 49,824,834.53 Euro.

During the offer period, from March 9, 2015 through March 30, 2015, shareholders exercised 184,693,240 rights to subscribe for 147,754,592 Shares, i.e. 99.24% of all Shares on offer, worth 39,302,721.48 Euro overall net of 10,144,774.00 Euro received from Fininvest S.p.A., Airain Ltd, H-Equity S.r.l. and H-Invest S.p.A as capital contributions on account of future issues of shares. In 2014, following the Board of Directors' meeting of June 20, 2014, the Company called a first installment of the 12.7 million Euro committed by the Shareholders parties to the shareholders' agreement to support MolMed in implementing its growth and business plans. The Company called 8,593 thousand Euro overall, which were paid as capital contributions on account of future issues of shares. Fininvest paid 2,176 thousand Euro on June 30 and 4,393 thousand Euro on September 30, 2014; Airain and H-Equity (through the associate H-Invest) paid 1,255 thousand and 769 thousand Euro, respectively, in July.

After the reporting date, H-Equity and H-Invest paid the last installment of the capital contribution on account of future issues of shares, amounting to 1,552 thousand Euro.

After completing the capital increase, the above shareholders received the new shares at a price of 0.2660 Euro per share.

The Unexercised Rights were all sold in the second round of the Offering on the Stock Exchange on April 9, 2015 for a total 178,208.61 Euro. Following the Offering on the Stock Exchange, investors subscribed for 1,418,576 Shares deriving from the exercise of all previously Unexercised Rights, for a total 377,341.22 Euro.

MolMed's new capital is therefore equal to 19,841,682.30 Euro, comprising 421,450,672 ordinary shares with no par value.

As a result, the Company had to schedule the approval of the Draft Financial Statements at December 31, 2014 for April 24, 2015 and will have to convene the Ordinary Shareholders' Meeting within 180 days to meet specific needs in accordance with applicable laws as well as the Company By-Laws. In this case, said needs referred to the capital increase completed on April 9, 2015.

For further details, reference should be made to paragraph *15.1 Significant events after the reporting period*.

### *13.3 Signing of the “SEF – Stand-by Equity Facility” agreement with Société Générale*

On July 31, 2014, the Company's Board of Directors agreed to sign a “SEF - Stand-by Equity Facility” agreement with Société Générale.

On September 8, 2014, MolMed S.p.A.'s Extraordinary Shareholders' Meeting approved the proposal pursuant to Article 2443 of the Italian Civil Code to vest the Board of Directors with the power to increase the capital by consideration in cash, in one or more stages, without requiring all shares to be subscribed, no later than July 31, 2016, withdrawing subscription rights pursuant to Article 2441, paragraph four, second sentence of the Italian Civil Code, to be reserved to Société Générale, by issuing up to 46,000,000 ordinary shares, and in any case to the extent of 10% of the existing capital, including in several installments, according to the subscription terms and conditions in the so-called “SEF – Standby Equity Facility” agreement the Company and SG entered into on July 31, 2014.

Specifically, under said Agreement, Société Générale committed to subscribe to the Company's capital increase to be carried out in several installments, with the exclusion of the pre-emption right, pursuant to Article 2441, paragraph 4, second sentence, and Article 2443 of the Italian Civil Code. Without requiring all shares to be subscribed, the capital increase shall be completed no later than July 31, 2016, issuing up to 46,000,000 ordinary shares, i.e. 19.9% of MolMed's shares outstanding as at the date of the Agreement, based on subscription requests made by MolMed to the counterparty according to the terms and conditions of the Agreement. In any case, the Shares issued pursuant to each individual subscription request, combined with the ordinary shares issued in the 12 months prior to the date of the request, shall not exceed 10% of MolMed ordinary shares already admitted to trading on the MTA (Mercato Telematico Azionario) as at that date.

With the funds raised under the Agreement, the Company will be able to make its financial structure more flexible, diversifying the funding sources required to meet the Company's cash requirements over the period of the Agreement.

It should be noted that under the Agreement, the period for determining the price to subscribe for the Shares of each installment of the reserved capital increase is defined as the three trading days following the submission of each individual subscription request by the Company. Specifically, the price to subscribe for the Shares of each installment will amount to 95% of the Volume Weighted Average Price (VWAP) of the Company's ordinary shares registered during the Pricing Period.

For each individual Subscription Request, should the closing price for MolMed ordinary shares registered on the last trading day of the Pricing Period fall below 97% of the VWAP observed during the same Period, the Company and/or Société Générale will have the right to extend the end of the Pricing Period to the following trading day. Said right can be exercised up to five times.

As part of the Agreement, for each installment Société Générale committed to subscribe for a number of Shares equal to the lower of:

- (i) the number of shares specified in the Subscription Request presented by the Company;
- (ii) the difference between the maximum number of shares to be issued under the reserved capital increase and the number of Shares Société Générale already subscribed for in relation to previous subscription requests; and

- (iii) the guaranteed number of Shares, equal to the lower of (1) no. 8,000,000 Shares, (2) a number of Shares triple the daily average trading volume of MolMed shares through the fifteen days prior to the end of the Pricing Period (excluding over-the-counter transactions from the calculation of the daily average volume) and (3) a number of Shares equal to the ratio between 8,000,000 Euro and the Subscription Price.

However, Société Générale will retain the right to subscribe for the number of Shares specified by the Company in the subscription request also in the event said number exceeds the limit as set out in point (iii) above.

Pursuant to the Agreement, for each Subscription Request, MolMed shall pay Société Générale a fee ranging from 1% to 3% of the market value of the Shares concerned by the Subscription Request, according to the amount of shares subscribed.

On September 23, 2014, the Board of Directors exercised the power received pursuant to Article 2443 of the Italian Civil Code from the Extraordinary Shareholders' Meeting as described in the previous paragraph.

Therefore, on September 23, 2014, the Board of Directors submitted to SG a request for the subscription of the first installment of the reserved capital increase. The subscription price for the shares of the first installment, equal to 0.4887 Euro (of which 0.0471 Euro credited to the capital account and the remainder to the share premium account), was determined in the three trading days following the submission of the subscription request. It corresponds to 95% of the volume weighted average price ("VWAP") of the Company's ordinary shares registered in said period. SG confirmed it would subscribe for 3,080,670 ordinary shares, representing 1.32% of MolMed's capital, for a total 1,505,524 Euro.

## 14. Highlights

### 14.1 Income results

<i>(amounts in Euro thousands )</i>	Year 2014	Year 2013	Change	% change
Revenues	11,181	5,856	5,325	90.9%
Other revenue	1,241	858	383	44.6%
<b>Total operating revenues</b>	<b>12,422</b>	<b>6,714</b>	<b>5,708</b>	<b>85.0%</b>
Purchases of raw materials and consumables	2,966	2,446	520	21.3%
Costs for services	11,165	11,065	100	0.9%
Costs for use of third-party assets	1,236	1,088	148	13.6%
Personnel costs	9,145	8,822	323	3.7%
Other operating costs	127	168	(41)	(24.4%)
Depreciation of receivables of current assets	-	500	(500)	(100.0%)
Amortization and depreciation	411	549	(138)	(25.1%)
<b>Total operating costs</b>	<b>25,050</b>	<b>24,638</b>	<b>412</b>	<b>1.7%</b>
<b>Operating result</b>	<b>(12,628)</b>	<b>(17,924)</b>	<b>5,296</b>	<b>(29.5%)</b>
Financial income	70	122	(52)	(42.6%)
Financial charges	(445)	(367)	(78)	21.3%
<b>Net financial income (charges)</b>	<b>(375)</b>	<b>(245)</b>	<b>(130)</b>	<b>53.1%</b>
<b>Pre-tax result</b>	<b>(13,003)</b>	<b>(18,169)</b>	<b>5,166</b>	<b>(28.4%)</b>
Income taxes	-	-	-	-
<b>Profit (loss) for the year</b>	<b>(13,003)</b>	<b>(18,169)</b>	<b>5,166</b>	<b>(28.4%)</b>

#### Operating revenues

Operating revenues amounted to 12,422 thousand Euro in 2014, sharply up on the 6,714 thousand Euro of the prior-year period (+85.0%), mainly due to the intensification of GMP production and development activities carried out on behalf of third parties.

GMP development and production activities on behalf of third parties generated revenues of 11,181 thousand Euro compared with 5,856 thousand Euro recorded in the previous year (+90.9%), thanks to the above-mentioned 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.

Other income of 1,241 thousand Euro mainly consisted of income deriving from subsidized projects and recorded a sharp increase on the previous year (+44.6%).

For further details, reference should be made to the Notes.

#### Operating costs

Operating costs amounted to 25,050 thousand Euro in 2014, increasing by 412 thousand Euro with respect to 2013 (24,638 thousand Euro). The 1.7% change is mainly due to the combination of the increase in purchases of raw materials and consumables, as well as the costs for the use of third-party assets and personnel costs, and the decline in the bad debt provision as well as depreciation and amortization.

The 21.3% increase (from 2,446 thousand Euro at December 2013 to 2,996 thousand Euro at December 2014) in costs for raw materials and consumables is mainly due to the increase in the purchase of materials related to the industrial development of NGR-hTNF and TK, and to the above-mentioned intensification of GMP development and production activities on behalf of third parties.

Costs for services were in line with 2013 figures.

The cost for use of third-party assets (from 1,088 thousand Euro in 2013 to 1,236 thousand Euro in 2014; +13.6%), was mainly attributable to the lease contract for the new facilities in Bresso starting from May 2014. This item basically includes the costs relating to the rental of the premises which house the Company's registered offices in Milan and the secondary offices (in Segrate until April 30, then in Bresso).

Personnel costs at December 31, 2014 rose by 323 thousand Euro (+3.7%) on the previous year. This rise was mainly due to the increase in the number of employees within the organization.

Other operating costs of 127 thousand Euro in 2014 dropped on the previous year (-24.4%), mainly due to lower funding of research scholarships.

Amortization and depreciation amounted to 411 thousand Euro at December 31, 2014, decreasing by 138 thousand Euro (-25.1%) on the previous year, due to the end of the amortization/depreciation period for some assets.

### **Operating result**

The operating result was negative to the tune of 12,628 thousand Euro in 2014, significantly improving by 29.5% compared to 2013 (negative to the tune of 17,924 thousand Euro). Specifically, this positive impact derives mainly from the remarkable increase in revenues from operations on behalf of third parties, allowing to absorb a greater proportion of fixed costs and, more generally, curb expenses.

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 in the income statement as incurred.

### **Net financial income (charges)**

The Company's financial activities were negative to the tune of 375 thousand Euro, showing a negative change of 130 thousand Euro on the year 2013.

Financial income of 70 thousand Euro (122 thousand Euro at December 31, 2013) mainly arose from the management of the Company's cash resources. The decrease was mainly due to the progressive reduction of available financial resources due to the cash absorbed by ordinary operations, as well as to the marked decrease of market return rates.

Financial charges of 445 thousand Euro in 2014 increased on the previous year and were mainly due to the non-recourse factoring of VAT receivables completed in the second quarter of 2013 and 2014.

### **Profit (loss) for the year**

The result for 2014 was a loss of 13,003 thousand Euro, compared to a loss of 18,169 thousand Euro recorded in 2013.

## 14.2 Equity and financial results

The table below shows the Company's reclassified statement of financial position based on sources and use of funds:

<i>(amounts Euro thousands )</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
<b>Non-current assets</b>		
Fixed assets and other non-current assets	10,476	8,132
<b>Total non-current assets</b>	<b>10,476</b>	<b>8,132</b>
<b>Net working capital</b>		
Inventories	774	676
Trade receivables and other commercial assets	4,364	5,588
Tax receivables	845	837
Other receivables and current assets	1,734	1,731
Trade payables	(9,852)	(9,480)
Other liabilities	(2,124)	(2,172)
<b>Total net working capital</b>	<b>(4,259)</b>	<b>(2,820)</b>
<b>Non-current liabilities</b>		
Other non-current liabilities	(5,525)	(2,707)
<b>Total non-current liabilities</b>	<b>(5,525)</b>	<b>(2,707)</b>
<b>TOTAL USES</b>	<b>692</b>	<b>2,605</b>
<b>Shareholders' equity</b>	<b>12,082</b>	<b>10,133</b>
<b>Net financial position</b>	<b>11,390</b>	<b>7,528</b>
<b>TOTAL SOURCES</b>	<b>692</b>	<b>2,605</b>



**Non-current assets**

Non-current assets at December 31, 2014 and December 31, 2013 are detailed in the table below:

<i>(amounts Euro thousands )</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>	<b>Change</b>	<b>% change</b>
Tangible assets	5,996	1,724	4,272	247.8%
Goodwill	77	77	-	0.0%
Intangible assets	253	221	32	14.3%
Financial assets	7	7	-	0.0%
Tax receivables	2,557	4,000	(1,443)	(36.1%)
Other assets	1,586	2,103	(517)	(24.6%)
<b>Total non-current assets</b>	<b>10,476</b>	<b>8,132</b>	<b>2,343</b>	<b>28.8%</b>

Non-current assets amounted to 10,476 thousand Euro at December 31, 2014.

Such increase is mainly due to investments of 4,734 thousand Euro made in 2014, essentially relating to renovation work at the new Bresso facilities (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.

Tax receivables mainly consisted of VAT receivables, down in 2014 mainly as a result of the refunds granted by the Tax Authority.

Other non-current assets include an advance on future rents of 1,500 thousand Euro 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.

It should be noted that the item "Other assets" in the non-current section also includes the last non-current portion (86 thousand Euro) of the consideration agreed to under the option agreement for the purchase of research projects entered into with the shareholder Science Park Raf S.p.A. in liquidation and its parent company Ospedale San Raffaele S.r.l. Under this agreement, the Company is entitled to purchase from the contracting parties the research projects they conduct in the field of gene and molecular therapies for cancer and AIDS. The effectiveness of the agreement, for which net consideration of 4,131 thousand Euro had to be paid, was subject to the precondition of admission of the Company's shares to trading on a regulated market, which occurred on March 5, 2008. The agreement is effective for eight years after this date, with the possibility of renewal every four years. On February 10, 2015, Ospedale San Raffaele notified the Company and Science Park it would terminate the option agreement effective March 4, 2016. Reference should be made to the Notes for the accounting treatment of this agreement.

## Net working capital

Net working capital at December 31, 2014 and December 31, 2013 is broken down as follows:

<i>(amounts Euro thousands )</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>	<b>Change</b>	<b>% change</b>
Inventories	774	676	98	14.5%
Trade receivables and other commercial assets	4,364	5,588	(1,224)	(21.9%)
Tax receivables	845	837	8	1.0%
Other receivables and current assets	1,734	1,731	3	0.2%
Trade payables	(9,852)	(9,480)	(372)	(3.9%)
Other liabilities	(2,124)	(2,172)	48	2.2%
<b>Total net working capital</b>	<b>(4,259)</b>	<b>(2,820)</b>	<b>(1,439)</b>	<b>51.0%</b>

Net working capital at December 31, 2014 was negative to the tune of 4,259 thousand Euro, down from the previous year (negative to the tune of 2,820 thousand at December 31, 2013). This was mainly the result of the 1,224 thousand Euro decrease in trade receivables and the 372 thousand Euro increase in trade payables. This reflects the trends in invoicing of services and is the result of a careful credit management process generating a reduction in the average collection period.

## Non-current liabilities

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

<i>(amounts Euro thousands )</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>	<b>Change</b>	<b>% change</b>
Liabilities for pensions and employee severance indemnity (TFR)	208	184	24	30.2%
Other liabilities	5,317	2,523	2,794	110.7%
<b>Total non-current liabilities</b>	<b>5,525</b>	<b>2,707</b>	<b>2,818</b>	<b>104.1%</b>

Non-current liabilities increased by 2,818 thousand Euro compared to year-end 2013. Other liabilities mainly refer to the advance received from the European Union in 2013 in relation to the subsidized SUPERSIST project (for further details reference should be made to the Notes) and to the 3,356 thousand Euro non-current portion of deferred income relating to the Bresso leasehold improvements.

Such deferred income includes the medium-/long-term portion of all the costs incurred up to December 31, 2014 in relation to the Bresso project, i.e. the Company's new industrial site in the "Open Zone" scientific park, belonging to the Zambon chemical-pharmaceutical group, where the Company has been expanding its operations in order to increase 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 4 million Euro, 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. Starting from May 2014, when the first part of the

property housing the Company's administrative offices was delivered pursuant to the contract, the Company started depreciating the portion of assets already in use and canceled the relevant deferred income.

The Company reclassified most of said deferral as non-current following the formal delivery of 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 305 thousand Euro, representing the depreciation for the next 12 months, under current liabilities. Further details are provided in the Notes.

### Shareholders' equity and capital transactions

Details about changes in shareholders' equity from January 1, 2014 to December 31, 2014 are provided in the table below:

<i>(amounts in Euro thousands)</i>	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
<b>Balance at January 1st 2014</b>	<b>27,071</b>	<b>3,378</b>	<b>3</b>	<b>490</b>	<b>(65)</b>	<b>-</b>	<b>(2,575)</b>	<b>(18,169)</b>	<b>10,133</b>
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 expenses 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 period	-	-	-	-	(16)	-	-	(13,003)	(13,019)
<b>Balance at December, 31 2014</b>	<b>11,019</b>	<b>5,635</b>	<b>8,638</b>	<b>644</b>	<b>(19)</b>	<b>-</b>	<b>(832)</b>	<b>(13,003)</b>	<b>12,082</b>

In 2014 the following capital increase transactions were approved and subsequently carried out:

- Reduction of capital as previously described at paragraph *13.2 Capital increase of 5 million Euro completed in April 2014 and capital increase of 50 million Euro completed in April 2015*.
- Capital increase resolved by the Extraordinary Shareholders' Meeting of March 3, 2014. The capital increase was concluded on April 4, 2014 with the full subscription of 8,252,092 newly-issued ordinary shares (1 new share for each 27 ordinary shares held), for an overall amount of 4,969 thousand Euro, of which 389 thousand Euro credited to the capital account and 4,580 thousand Euro to the share premium account.
- Payment totaling 8,593 million Euro as a capital contribution on account of future issues of shares. Fininvest paid 2,176 thousand Euro on June 30 and 4,393 thousand Euro on September 30, 2014, and Airain and H-Equity (through the associate H-Invest) 1,255 thousand and 769 thousand Euro, respectively, in July after the Company called a first installment of the capital committed by some Shareholders parties to the shareholder's agreement to support MolMed in implementing its growth and business plans.
- Capital increase finalized through the "SEF – Standby Equity Facility" agreement the Company entered into with Société Générale ("SG") on July 31, 2014. On September 23, 2014, under said agreement, the Board of Directors submitted to SG a request for the subscription of the first installment of the reserved capital increase. SG confirmed it would subscribe for 3,080,670 ordinary shares, representing 1.32% of MolMed capital, for a total 1,506 thousand Euro, including 145 thousand Euro credited to the capital account and 1,361 thousand Euro to the share premium account. The transaction was completed on September 29, 2014.

**Net financial position**

<i>(amounts Euro thousand )</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Cash on hand	10	11
Other cash	11,374	8,551
Cash equivalents	-	-
<b>A. Total cash and cash equivalents</b>	<b>11,384</b>	<b>8,562</b>
<b>B. Current financial receivables and other financial assets</b>	<b>6</b>	<b>1</b>
Finance lease payables	-	(3)
Current financial Debts	-	-
<b>C. Current financial debt</b>	<b>-</b>	<b>(3)</b>
<b>D. Net current financial position (A+B+C)</b>	<b>11,390</b>	<b>8,560</b>
<b>Finance lease payables</b>	<b>-</b>	<b>-</b>
Non current financial Debts	-	(1,032)
<b>E. Non-current financial debt</b>	<b>-</b>	<b>(1,032)</b>
<b>F. Net financial position (D+E)</b>	<b>11,390</b>	<b>7,528</b>

Net financial position was positive to the tune of 11,390 thousand Euro at December 31, 2014 almost fully consisting of cash and cash equivalents (11,384 thousand Euro).

The net financial position was mainly affected by the following items:

- income of 4,969 thousand Euro resulting from the capital increase finalized in the first four months of 2014;
- collection of 2013 VAT receivables factored (1,032 thousand Euro), and of the relevant price adjustment resulting from the collection of receivables from the Inland Revenue by the factor (220 thousand Euro);
- 8,593 thousand Euro received from some shareholders parties to the shareholders' agreement as a capital contribution on account of future issues of shares;
- income of 1,506 thousand Euro resulting from the stand-by equity facility (SEF).

In addition, please note that in 2014 the cash flows used in the Company's operations amounted to 13,498 thousand Euro.

## 15. Outlook

### 15.1 Subsequent events

#### *Capital increase completed in April 2015*

As previously noted at paragraph *13.2 Capital increase of 5 million Euro completed in April 2014 and capital increase of 50 million Euro completed in April 2015* of this Report, on January 31, 2014, pursuant to Article 2443 of the Italian Civil Code, Directors resolved to submit to the Extraordinary Shareholders' Meeting their proposal to vest the Board with the power to increase the Company's capital for a total maximum amount of 50,000,000.00 Euro including the relevant share premium, in one or more installments, without requiring all shares to be subscribed, by and no later than December 31, 2016 through the issue of ordinary shares with no par value, in dematerialized form, cum dividend, and with the same characteristics as the currently outstanding shares, to be offered with pre-emption rights to the Company's Shareholders pursuant to Article 2441, paragraph 1 of the Italian Civil Code.

As previously illustrated, on March 3, 2014, pursuant to Article 2443 of the Italian Civil Code, the Extraordinary Shareholders' Meeting resolved to vest the Board with the power to increase the Company's capital for a total maximum amount of 50,000,000.00 Euro including the relevant share premium, in one or more installments, without requiring all shares to be subscribed, by and no later than December 31, 2016 through the issue of ordinary shares with no par value, in dematerialized form, cum dividend, and with the same characteristics as the currently outstanding shares, to be offered with pre-emption rights to the Company's Shareholders pursuant to Article 2441, paragraph 1 of the Italian Civil Code. Pursuant to the above resolution, on February 23, 2015, the Company's Board of Directors exercised said power, deciding to increase the capital up to 50 million Euro, including in installments. On March 4, 2015 the Board of Directors decided the final terms of the capital increase: specifically, the Company will issue up to 187,311,408 new ordinary shares without par value, with the same characteristics of MolMed ordinary shares outstanding as at the date of the issue and cum dividend, offering the Company's existing shareholders the right to subscribe for 4 new shares for every 5 ordinary shares held, at an issue price of 0.2660 Euro per share (of which 0.0471 Euro credited to the capital account and the remainder to the share premium account), up to a total 49,824,834.53 Euro.

The capital increase was authorized by Consob, which on March 6, 2015 approved the Registration Statement, the Prospectus, and the Summary relating to the rights offering and the admission to the Mercato Telematico Azionario organized and managed by Borsa Italiana S.p.A.

The following should be noted:

- H-Equity announced it will subscribe for its share of the capital increase as at the date of the relevant resolution to the extent of the amount formally committed on January 31, 2014, that is approximately 1.1 million Euro (excluding the amount exercised by the associate H-Invest, replacing H-Equity). On February 18, 2015, H-Equity paid the above amount of nearly 1.1 million Euro as a capital contribution on account of future issues of shares.
- H-Invest announced it will subscribe for its share of the capital increase as at the date of the relevant resolution to the extent of the amount formally committed on January 31, 2014, that is approximately 1.2 million Euro. On February 18, 2015, H-Invest paid the remaining portion of the above commitment to support the Company, totaling nearly 0.4 million Euro, as a capital contribution on account of future issues of shares.

- Airain announced it will subscribe for its share of the capital increase as at the date of the relevant resolution, absorbing the remaining financial support committed on January 31, 2014, amounting to approximately 2.6 million Euro.
- Fininvest announced it is available to subscribe for its share of the capital increase.

The rights offer period ended on March 30, 2015. During the offer period, from March 9, 2015 through March 30, 2015, shareholders exercised 184,693,240 rights to subscribe for 147,754,592 Shares, i.e. 99.24% of all Shares on offer, worth 39,302,721.48 Euro overall net of 10,144,774.00 Euro received from Fininvest S.p.A., Airain Ltd, H-Equity S.r.l. and H-Invest S.p.A as capital contributions on account of future issues of shares. Specifically, Fininvest, Airain, H-Equity and H-Invest subscribed for the capital increase in accordance with the announced terms and conditions.

MolMed offered the 1,773,220 rights that were not exercised during the Offer Period, concerning the subscription of 1,418,576 new shares – 0.76% of total Shares and worth 377,341.22 Euro overall – on the Stock Exchange in accordance with Article 2441, paragraph three of the Italian Civil Code through Banca IMI S.p.A. on April 1, 2, 7, 8, and 9, 2015.

The Unexercised Rights were used to subscribe for the Shares – with the same characteristics of shares outstanding and cum dividend – at the price of 0.2660 Euro per share (including 0.0471 Euro credited to the capital account and the remainder to the share premium account), in the ratio of 4 Shares for every 5 Unexercised Rights.

Following this transaction, MolMed's new capital is therefore equal to 19,841,682.30 Euro, comprising 421,450,672 ordinary shares with no par value.

### *Strategic partnership agreement with GSK to develop, manufacture and transfer gene therapy technologies*

On March 19, 2015, MolMed entered into a strategic agreement with GlaxoSmithKline (GSK), under which it will supply technological development, manufacturing, and transfer services for the clinical application of gene therapies based on cell transduction using viral vectors.

Under the agreement, MolMed will provide its expertise in process development as well as the manufacturing capabilities and competencies for the production of viral vectors as well as cell transduction.

MolMed will receive a minimum of 34 million Euro in upfront and milestone payments as well as services over the next 5 years. Specifically, over the 12 months following the agreement, GSK will pay MolMed about 6 million Euro in upfront and milestone payments.

### *Patenting of semi-stable lentiviral packaging cell lines*

On March 18, 2015, MolMed officially received a patent from the European Patent Office for semi-stable lentiviral packaging cell lines. The patent was published on the same date on the European Patent Bulletin. The new European patent (EP2480677) will join MolMed's portfolio that includes 12 patent applications and two existing patents for lentiviral packaging systems filed in the world's leading pharmaceutical markets, including the United States, Japan, Canada, Australia, and China. The patent is valid until 2031 and gives MolMed exclusive rights to market the technology in a number of European countries, which will be selected in accordance with the Company's strategy.

### *Pipeline extension*

On 13 April 2015 was exercised the option right for the purchase of the San Raffaele Hospital (OSR) immune-gene therapy project against cancer developed using the Chimeric Antigen Receptor CD44v6 (CAR-CD44v6) with potential application in several haematological and solid tumour indications. The CAR-CD44v6 is part of the CAR-T family: lymphocytes armed with chimeric receptors that have demonstrated high anti-tumour potential, also against tumours - above all haematological - which are particularly aggressive and resistant to traditional therapies.

The CAR-CD44v6 project, which has already been successfully tested in appropriate murine models, represents a product candidate with a particularly high therapeutic potential, as it specifically recognises variant 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, colon, pancreatic, head-and-neck and lung carcinomas.

## *15.2 Business outlook*

As already described in paragraph *11.6 Financial Risks*, the Board of Directors agreed on the strategy of the 2015-2017 business plan on December 19, 2014 and approved it on April 9, 2015 based on the most recent available information following the end of the capital increase on March 30, 2015. The business plan, assuming it becomes fully operational, provides for the following to be achieved in the 2015-2017 period:

- continuing the clinical and industrial development of the main experimental products;
- pursuing operations and investments aimed at boosting production capacity;
- selecting further products as clinical candidates to be developed;
- investing in preclinical research or the acquisition of additional technologies and products under licensing agreements;
- increasing investments beyond current levels to create a sales network and expand production capacity by fully automating the production of TK cell therapy.



### ***16. Loss allocation proposal for the year***

The 2014 Company's Financial Statements, as also described by this Report and the Notes, recognized a loss of 13,003 thousand Euro, which is proposed to be carried forward.

### ***17. Extension of the term for convening the shareholders' meeting for the approval of the Financial Statements at December 31, 2014***

The Company deemed it necessary to postpone the approval of the 2014 Annual Financial Report, without prejudice to the publications deadlines in Article 154-ter of Italian Legislative Decree 58/98, and to take advantage, as the relevant conditions were met, of the extension provided in Article 2364, paragraph two of the Italian Civil Code as well as Article 12 of the Company By-Laws, in light of the previously described extraordinary capital increase.

## Financial Statement at 31 December 2014

### 1. Statement of financial position

<i>(amounts in Euro thousands )</i>		December 31, 2014	December 31, 2013
<b>ASSETS</b>			
Tangible assets	1	5,996	1,724
Goodwill	2	77	77
Intangible assets	2	253	221
Financial assets	3	7	7
Tax receivables	4	2,557	4,000
Other assets	5	1,586	2,103
<b>TOTAL NON-CURRENT ASSETS</b>		<b>10,476</b>	<b>8,132</b>
Inventories	6	774	676
Trade receivables and other commercial assets	7	4,364	5,588
Tax receivables	8	845	837
Other receivables and sundry assets	9	1,734	1,731
Other financial assets	10	6	1
Cash and cash equivalents	11	11,384	8,562
<b>TOTAL CURRENT ASSETS</b>		<b>19,107</b>	<b>17,395</b>
<b>TOTAL ASSETS</b>		<b>29,583</b>	<b>25,527</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
Capital		11,019	27,071
Share premium reserve		5,635	3,378
Other reserves		9,263	428
Retained earnings (accumulated losses)		(832)	(2,575)
Profit (loss) for the year		(13,003)	(18,169)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>12</b>	<b>12,082</b>	<b>10,133</b>
Liabilities for pensions and employee severance indemnity (TFR)	13	208	184
Finance payables	14	0	1,032
Other liabilities	15	5,317	2,523
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>5,525</b>	<b>3,739</b>
Trade payables	16	9,852	9,480
Other liabilities	17	2,124	2,172
Finance lease payables	18	-	3
<b>TOTAL CURRENT LIABILITIES</b>		<b>11,976</b>	<b>11,655</b>
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		<b>29,583</b>	<b>25,527</b>

## 2. Income Statement

<i>(amounts in Euro thousands)</i>	Note	Year 2014	Year 2013
Revenues	19	11,181	5,856
Other revenue	20	1,241	858
<b>Total operating revenues</b>		<b>12,422</b>	<b>6,714</b>
Purchases of raw materials and consumables	21	2,966	2,446
Costs for services	22	11,165	11,065
Costs for use of third-party assets	23	1,236	1,088
Personnel costs	24	9,145	8,822
Other operating costs	25	127	168
Depreciation of receivables of current assets	26	-	500
Amortization and depreciation	27	411	549
<b>Total operating costs</b>		<b>25,050</b>	<b>24,638</b>
<b>Operating result</b>		<b>(12,628)</b>	<b>(17,924)</b>
Financial income		70	122
Financial charges		(445)	(367)
<b>Net financial income (charges)</b>	28	<b>(375)</b>	<b>(245)</b>
<b>Pre-tax result</b>		<b>(13,003)</b>	<b>(18,169)</b>
Income taxes	29	-	
<b>Profit (loss) for the year</b>		<b>(13,003)</b>	<b>(18,169)</b>
<hr/>			
<i>(amounts in Euro)</i>		<b>2014</b>	<b>2013</b>
Basic earnings (loss) per share		0,00566	0,0821
Diluted earnings (loss) per share		-	-

### 3. *Statement of comprehensive income*

<i>(amounts in Euro thousands)</i>	Year 2014	Year 2013
<b>Profit (loss) for the year</b>	<b>(13.003)</b>	<b>(18.169)</b>
<b>Other comprehensive income (not subsequently reclassified to the income statement)</b>		
Profit (loss) actuarial	(16)	(3)
<b>Other comprehensive income, net of taxes (not subsequently reclassified to the income statement)</b>	<b>(16)</b>	<b>(3)</b>
<b>Other comprehensive income (subsequently reclassified to the income statement)</b>		
Profit (loss) actuarial	-	(15)
<b>Other comprehensive income, net of taxes (subsequently reclassified to the income statement)</b>	<b>-</b>	<b>(15)</b>
<b>Total comprehensive income (loss) for the year</b>	<b>(13.019)</b>	<b>(18.187)</b>

#### 4. Statement of cash flow

<i>(amounts in Euro thousands )</i>		December 31, 2014	December 31, 2013
Cash and cash equivalents		8,562	10,421
<b>Opening cash and cash equivalents</b>	<b>A</b>	<b>8,562</b>	<b>10,421</b>
<b>Cash flow from operating activities:</b>			
Profit (loss) for the year		(13,003)	(18,169)
Amortization/Depreciation of intangible/tangible assets		411	549
Allowance for doubtful accounts		8	(19)
Non-cash costs for stock options		161	160
Change in liabilities for pensions and employee severance indemnity		-	500
Decrease in other assets due to option rights	(*)	516	516
Reversal of financial income and charges		375	245
<b>Cash flow from operating activities before changes in working capital</b>		<b>(11,532)</b>	<b>(16,218)</b>
<b>Changes in current assets and liabilities:</b>			
(Increase) decrease in inventories		(98)	(87)
(Increase) decrease in trade and other receivables	(*)	1,213	1,134
Increase (decrease) in trade and other payables	(*)	372	(39)
Increase (decrease) in other liabilities		(28)	650
<b>Total changes in current assets and liabilities</b>		<b>1,459</b>	<b>1,658</b>
(Increase) decrease in non-current tax receivables		1,443	927
Increase (decrease) in other liabilities		2,794	1,529
Increase (decrease) in other financial assets		(5)	-
Increase (decrease) in other activities		-	(1,500)
Interest paid		(391)	(331)
<b>Total cash flow generated (absorbed) by operating activities</b>	<b>B</b>	<b>(6,232)</b>	<b>(13,935)</b>
<b>Cash flow from investing activities:</b>			
Net (investment) divestment in tangible assets		(4,627)	(966)
Net (investment) divestment in intangible assets		(107)	(38)
Net (investment) in other financial assets		1	-
(investment) in other financial assets		-	-
Net divestment in other financial assets		-	7,000
Interest received		15	292
<b>Total cash flow generated (absorbed) by investing activities</b>	<b>C</b>	<b>(4,718)</b>	<b>6,288</b>
<b>Cash flow from financing activities:</b>			
Increases in capital and share premium reserve		6,475	4,993
Shareholders' advance payment for share capital increase		8,638	-
Other Equity movemenets (share increase cost)		(306)	(121)
Financial Debts variation		(1,032)	1,032
Change in finance lease payables		(3)	(116)
<b>Total cash flow generated (absorbed) by financing activities</b>	<b>D</b>	<b>13,772</b>	<b>5,788</b>
<b>Cash flow generated (absorbed) during the year</b>	<b>E=B+C+D</b>	<b>2,822</b>	<b>(1,859)</b>
<b>Closing cash and cash equivalents</b>	<b>A+E</b>	<b>11,384</b>	<b>8,562</b>
<b>(*) of which with related parties (as required by Consob Resolution no.15519 of July 27, 2006)</b>			
<i>(amounts in thousands of Euro)</i>		December 31, 2014	December 31, 2013
(Increase) decrease in trade and other receivables		(21)	93
(Increase) decrease in other non-current assets		516	516
(Increase) decrease in other financial assets		-	6,680
Increase (decrease) in trade and other payables		(259)	88

## 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
<b>Balance at December 31, 2011 (published data)</b>	43,609	20,696	-	1,025		(336)	1,400	(21,569)	44,825
Effects of IAS 19 emendment					(54)		46	8	
<b>Balance at January 1, 2012</b>	43,609	20,696	-	1,025	(54)	(336)	1,446	(21,561)	44,825
Allocation of prior year result	-	(20,696)	-	-	-	-	(874)	21,569	-
Personnel costs for stock options 2012	-	-	-	115	-	-	-	-	115
Decadence of stock options, Plan 2008	-	-	-	(59)	-	-	59	-	-
Profit (loss) for the year	-	-	-	-	(8)	351	8	(22,001)	(21,650)
<b>Balance at December 31, 2012</b>	43,609	-	-	1,081	(62)	15	639	(21,993)	23,289

(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
<b>Balance at December 31, 2012 (published data)</b>	43,609	-	-	1,081	-	15	585	(22,001)	23,289
Effects of IAS 19 emendment					(62)		54	8	
<b>Balance at January 1, 2013</b>	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 2013	-	-	-	160	-	-	-	-	160
Profit (loss) for the year	-	-	-	-	(3)	(15)	-	(18,169)	(18,187)
<b>Balance at December 31, 2013</b>	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
<b>Balance at January 1st 2014</b>	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 period	-	-	-	-	(16)	-	-	(13,003)	(13,019)
<b>Balance at December, 31 2014</b>	11,019	5,635	8,638	644	(19)	-	(832)	(13,003)	12,082

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

<i>(amounts in Euro thousand)</i>	Notes	December 31, 2014	December 31, 2013
<b>ASSETS</b>			
Tangible assets	1	5,996	1,724
Goodwill	2	77	77
Intangible assets	2	253	221
Financial assets	3	7	7
Tax receivables	4	2,557	4,000
Other assets	5	1,586	2,103
<i>of which with related parties</i>	33	86	603
<b>TOTAL NON-CURRENT ASSETS</b>		<b>10,476</b>	<b>8,132</b>
Inventories	6	774	676
Trade receivables and other commercial assets	7	4,364	5,588
<i>of which with related parties</i>	33	115	94
Tax receivables	8	845	837
Other receivables and sundry assets	9	1,734	1,731
<i>of which with related parties</i>	33	516	516
Other financial assets	10	6	1
<i>of which with related parties</i>	33	-	-
Cash and cash equivalents	11	11,384	8,562
<i>of which with related parties</i>	33	3,459	6,596
<b>TOTAL CURRENT ASSETS</b>		<b>19,107</b>	<b>17,395</b>
<b>TOTAL ASSETS</b>		<b>29,583</b>	<b>25,527</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
Capital		11,019	27,071
Share premium reserve		5,635	3,378
Other reserves		9,263	428
Retained earnings (accumulated losses)		(832)	(2,575)
Profit (loss) for the year		(13,003)	(18,169)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	12	<b>12,082</b>	<b>10,133</b>
Liabilities for pensions and employee severance indemnity (TF)	13	208	184
Financial debts	14	-	1,032
Other liabilities	16	5,317	2,523
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>5,525</b>	<b>3,739</b>
Trade payables	17	9,852	9,480
<i>of which with related parties</i>	33	151	410
Other liabilities	18	2,124	2,172
Finance lease payables	15	0	3
<b>TOTAL CURRENT LIABILITIES</b>		<b>11,976</b>	<b>11,655</b>
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>		<b>29,583</b>	<b>25,527</b>



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

<i>(amounts in Euro thousands )</i>	Notes	Year 2014	Year 2013
Revenues	19	11,181	5,856
<i>of which with related parties</i>	33	111	6
Other income	20	1,241	858
<b>Total operating revenues</b>		<b>12,422</b>	<b>6,714</b>
Purchases of raw materials and consumables	21	2,966	2,446
Costs for services	22	11,165	11,065
<i>of which with related parties</i>	33	837	1,043
Costs for use of third-party assets	23	1,236	1,088
<i>of which with related parties</i>	33	842	841
Personnel costs	24	9,145	8,822
Other operating costs	25	127	168
Depreciation of receivables of current assets	26	-	500
Amortization, depreciation and write-downs	26	411	549
<b>Total operating costs</b>		<b>25,050</b>	<b>24,638</b>
<b>Operating result</b>		<b>(12,628)</b>	<b>(17,924)</b>
Financial income		70	122
<i>of which with related parties</i>	33	17	85
Financial charges		(445)	(367)
<i>of which with related parties</i>	33	-	(44)
<b>Net financial income (charges)</b>	27	<b>(375)</b>	<b>(245)</b>
<b>Pre-tax result</b>		<b>(13,003)</b>	<b>(18,169)</b>
Income taxes	28	-	-
<b>Profit (loss) for the year</b>		<b>(13,003)</b>	<b>(18,169)</b>

## *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 non-current; 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 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 2014 was 13,003 thousand Euro, down 5,166 thousand Euro from the 18,169 thousand Euro loss recorded in the previous year.

The Board of Directors agreed on the strategy of the 2015-2017 business plan on December 19, 2014 and approved it on April 9, 2015 based on the most recent available information following the end of the capital increase on April 9, 2015. The business plan, assuming it becomes fully operational, provides for the following to be achieved in the 2015-2017 period:

- continuing the clinical and industrial development of the main experimental products;
- pursuing operations and investments aimed at boosting production capacity;
- selecting further products as clinical candidates to be developed;
- investing in preclinical research or the acquisition of additional technologies and products under licensing agreements;
- increasing investments beyond current levels to create a sales network and expand production capacity by fully automating the production of TK cell therapy.

Based on the above and on the analysis of future cash flows projected by the 2015-2017 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 write-down. 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 pre-tax 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 cash-generating 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, 2014, 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 12.85% and determined by considering a 2.87% free risk rate, a 5.60% market risk premium and a 1.07 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 value has been calculated.

For the purposes of the impairment test, the Company used the 2015-2017 business plan. The Board of Directors agreed on its strategy on December 19, 2014 and approved it on April 9, 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, 2014, 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 2013) 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 straight-line 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, 2014

- On December 16, 2011, the IASB issued a number of amendments to **IAS 32 – Financial Instruments: Presentation**, to clarify the requirements for offsetting financial assets and financial liabilities outlined in IAS 32.
- On May 29, 2013, the IASB issued a number of amendments to **IAS 36 – Impairment of Assets – Recoverable Amount Disclosures for Non-Financial Assets**. The amendments aimed at clarifying disclosure to be provided on the recoverable amount of assets (including goodwill) or cash generating units subject to impairment/reversal of impairment in the period, if such amount is based on fair value less costs to sell.
- On June 27, 2013 the IASB issued some amendments to **IAS 39 – Financial Instruments: Recognition and Measurement – Novation of Derivatives and Continuation of Hedge Accounting**. These amendments provide some exemptions to hedge accounting requirements defined by IAS 39 in the case that an existing derivative must be replaced with a new derivative that has a central counterparty (CCP), as a consequence of laws or regulations.

These amendments shall apply retrospectively for annual periods beginning on or after January 1, 2014. Their adoption had no impact on the Company's Financial Statements.

The IASB also issued the following standards and related amendments, applying to the Company:

- On May 12, 2011, the IASB issued **IFRS 10 – Consolidated Financial Statements**, which will replace IAS 27 – Consolidated and Separate Financial Statements, for the issues concerning the consolidated financial statements as well as SIC12 – Consolidation – Special Purpose Entities. The former IAS 27 was renamed Separate Financial Statements and regulates the accounting treatment of interests in separate financial statements.
- On May 12, 2011 the IASB issued **IFRS 11 – Joint Arrangements** which will replace IAS 31 – Interests in Joint Ventures and SIC 13 – Jointly Controlled Entities – Non-monetary Contributions by Venturers.
- On May 12, 2011 the IASB issued **IFRS 12 – Disclosure of Interests in Other Entities** which is a new and comprehensive standard on additional disclosures to be provided on each type of interest, including those in subsidiaries, joint arrangements, associates, special purpose entities and other unconsolidated SPVs.
- On October 31, 2012 the IASB issued Investment Entities (Amendments to IFRS 10, IFRS 12 and IAS 27), that introduce an exception to the consolidation of entities that an investment entity controls, except when the subsidiaries provide investment-related services.



**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, 2014**

- 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: 2010-2012 Cycle**, a set of amendments to some IFRSs as part of the annual standard improvement process. The most important issues addressed include:
  - ✓ IFRS 2 – Share Based Payments – Definition of vesting condition.
  - ✓ IFRS 3 – Business Combination – Accounting for contingent consideration in a business combination.
  - ✓ IFRS 8 – Operating Segments – Aggregation of operating segments.
  - ✓ IFRS 8 – Operating Segments – Reconciliation of the total of the reportable segments' assets to the entity's assets.
  - ✓ IFRS 13 – Fair Value Measurement – Short-term receivables and payables.
  - ✓ IAS 16 – Property, Plant and Equipment and IAS 38 – Intangible Assets – Revaluation method: proportionate restatement of accumulated depreciation;
  - ✓ IAS 24 – Related Parties Disclosures – Key management personnel. These amendments clarify that a management entity (not a physical person) providing key management services to a reporting entity is deemed to be a related party of the reporting entity.

These amendments shall apply for annual periods beginning on or after February 1, 2015.

- 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. The most important issues addressed include:
  - ✓ IFRS 3 – Business Combinations – Scope exceptions for joint ventures.
  - ✓ IFRS 13 – Fair Value Measurement – Scope of paragraph 52 (portfolio exception).
  - ✓ IAS 40 – Investment Property – Clarifying the interrelationship of IFRS 3 Business Combinations and IAS 40 Investment Property when classifying property as investment property or owner-occupied property.

These amendments shall apply for annual periods beginning on or after January 1, 2015.

- On November 21, 2013 the IASB issued an amendment to **IAS 19 – Defined Benefit Plans: Employee Contributions**, proposing to account for contributions (linked only to the employee's service rendered in the period) from employees or third parties to defined benefit plans as a reduction in the service cost in the same period in which they are paid. This proposal became necessary after the introduction of the new IAS 19 (2011), requiring to interpret these contributions as post-employment benefits, rather than short-term benefits, and thus to attribute them to the years of service. These amendments shall apply for annual periods beginning on or after February 1, 2015.

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**

At the date of these Financial Statements, the amendments and standards mentioned below had not been endorsed by the European Union yet.



- On January 30, 2014, the IASB published **IFRS 14 – Regulatory Deferral Accounts**, which permits exclusively first-time adopters of IFRSs to continue to recognize amounts related to rate regulation in accordance with their previous GAAP requirements. As the Company is not a first-time adopter, this standard does not apply.
- On May 6, 2014, the IASB issued some amendments to **IFRS 11 – Joint Arrangements – Accounting for Acquisitions of Interests in Joint Operations**, concerning how to account for the acquisition of an interest in a joint operation that constitutes a business as defined in IFRS 3.
- On May 12, 2014, the IASB issued **Clarification of Acceptable Methods of Depreciation and Amortization (Amendments to IAS 16 – Property, Plant and Equipment and IAS 38 – Intangible Assets)**. The amendments to IAS 16 clarified that the use of revenue-based methods to calculate the depreciation of an asset are not appropriate, since the revenue generated by an activity that includes the use of an asset generally reflects factors other than the consumption of the economic benefits embodied in the asset. The amendments to IAS 38 introduce a rebuttable presumption that a revenue-based amortization method is inappropriate for the same reasons as set out for the amendments to IAS 16. In the case of intangible assets, this presumption can be overcome only in limited and specific circumstances.

The amendments are effective from January 1, 2016, with early application permitted.

- On May 28, 2014, the IASB published **IFRS 15 – Revenue from Contracts with Customers**, 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 – Revenue – 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:
  - ✓ identify the contract with the customer;
  - ✓ identify the performance obligations in the contract;
  - ✓ determine the transaction price;
  - ✓ allocate the transaction price to the performance obligations in the contract;
  - ✓ recognize revenue when a performance obligation is satisfied.

The new standard is effective from January 1, 2017, with early application permitted.

- On July 24, 2014 the IASB published some amendments to **IFRS 9 – Financial Instruments**. The document brings together the classification and measurement, impairment, and hedge accounting phases of the IASB's project to replace IAS 39. The new standard, which replaces the previous versions of IFRS 9, is applicable for annual periods beginning on or after January 1, 2018. The standard introduces new classification and measurement requirements for financial assets and liabilities. Specifically, as for financial assets, the new standard uses a single approach based on the entity's business model for managing the financial instruments and the contractual cash flow characteristics of the financial assets to determine the measurement requirements, replacing the various rules in IAS 39. For financial liabilities, the main difference concerns the accounting treatment of changes in the fair value of a financial liability the entity had elected to measure at fair value through profit or loss, should these be caused by changes in the issuer's own credit risk. In accordance with the new standard such changes shall be recognized in Other comprehensive income and shall not be transferred to profit or loss.

As for the impairment model, the new standards requires credit losses to be recognized based on

expected losses (as opposed to incurred losses), using all reasonable and supportable information, including historical, current, and forward-looking information, that is available without undue cost or effort. The standard requires to apply this impairment model to all financial instruments, that is financial assets measured at amortized cost and at fair value through other comprehensive income, as well as lease receivables and trade receivables.

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

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

- On August 12, 2014, the IASB published the amendment to **IAS 27 - Equity Method in Separate Financial Statements**. The documents introduces the option for entities to use the equity method to account for investments in subsidiaries, joint ventures, and associates in their separate financial statements. The amendments are effective from January 1, 2016, with early application permitted.

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 to address the conflict between IAS 28 and IFRS 10. The amendments are effective from January 1, 2016, with early application permitted.

- On September 25, 2014 the IASB published **Annual Improvements to IFRSs: 2012-2014 Cycle**. The amendments provided for by such document shall apply for annual periods beginning on or after January 1, 2016.

Amendments concern the following standards:

- ✓ IFRS 5 – Non-current Assets Held for Sale and Discontinued Operations;
- ✓ IFRS 7 – Financial Instruments: Disclosure;
- ✓ IAS 19 – Employee Benefits;
- ✓ IAS 34 – Interim Financial Reporting.
- On December 18, 2014 the IASB issued **Disclosure Initiative (Amendments to IAS 1)** . These amendments aim to clarify a number of disclosures that can impair the understandability of financial statements. Amendments include the following:
  - ✓ Materiality and aggregation: clarifies that an entity must not obscure information by aggregating or disaggregating it, and that materiality considerations apply to the primary statements, notes and any specific disclosure requirements in IFRSs. The disclosures specifically required by IFRSs need to be provided only if the information is material;
  - ✓ Statement of financial position and statement of profit or loss and other comprehensive income: clarifies that the list of line items specified by IAS 1 for these statements can be disaggregated and aggregated as relevant. Additional guidance has been added on the presentation of subtotals in these statements;
  - ✓ Presentation of items of other comprehensive income (“OCI”): clarifies that an entity's share of OCI of equity-accounted associates and joint ventures should be presented in aggregate as single line items based on whether or not it will subsequently be reclassified to profit or loss;
  - ✓ Notes: clarifies that entities have flexibility when designing the structure of the notes and provides guidance on how to determine a systematic order of the notes, for instance:
    - giving prominence to those that are most relevant to an understanding of the entity's financial performance and position (e.g. grouping together information about particular activities);

- grouping together items measured similarly (e.g. assets measured at fair value);
- following the order of items in the primary statements.

The amendments provided for by such document shall apply for annual periods beginning on or after January 1, 2016.

- On December 18, 2014 the IASB published **Investment Entities: Applying the Consolidation Exception (Amendments to IFRS 10, IFRS 12 and IAS 28)**, 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.

At the moment, the Directors are assessing the potential impact of the introduction of these amendments on the Company's Financial Statements. They do not expect a material impact.

### *3. Segment reporting*

With regard to the income and financial disclosure by operating segment and geographical area, it should be noted that the Company's management has identified a single operating segment. The essentially uniform nature of the activities performed and the progress of projects under development do not allow to break down business by sector based on risks and benefits. Moreover, because of the services provided, the nature of the production processes and the type of clients for the Company's products, it is not possible to break down the Company's activities by operating segment. Therefore, the Company believes that, at present, specific disclosure by operating segment and geographical area would not better describe the business or its related risks and benefits.

#### 4. Notes to the Statement of Financial Position

##### Note 1 – Tangible assets

The breakdown and changes of tangible assets at December 31, 2014 are shown in the table below:

<i>(amounts in Euro thousand)</i>	Balance at December 31, 2013	Purchases	Reclassificatio ns	Disposals	Depreciation and write downs	Balance at December 31, 2014
<b>Gross book value</b>						
Plant and machinery	210	-	-	0	-	210
Industrial and commercial equipment	4,013	217	29	(237)	-	4,021
Leasehold improvements	3,992	-	360	-	-	4,354
Other tangible assets	1,070	117	-	(112)	-	1,075
Assets under construction and payments on account (Industrial equipment Bresso)	29	525	(29)	-	-	525
Assets under construction and payments on account (Leasehold improvements Bresso)	544	3,768	(360)	-	-	3,952
<b>Total gross book value</b>	<b>9,858</b>	<b>4,627</b>	<b>-</b>	<b>(349)</b>	<b>-</b>	<b>14,137</b>
<b>Accumulated depreciation</b>						
Plant and machinery	(210)	-	-	-	-	(210)
Industrial and commercial equipment	(3,114)	-	-	237	(215)	(3,092)
Leasehold improvements	(3,935)	-	-	-	(75)	(4,010)
Other tangible assets	(876)	-	-	(112)	(66)	(1,054)
Assets under construction and payments on account (Industrial equipment Bresso)	-	-	-	-	-	-
Assets under construction and payments on account (Leasehold improvements Bresso)	-	-	-	-	-	-
<b>Total accumulated depreciation</b>	<b>(8,135)</b>	<b>-</b>	<b>-</b>	<b>349</b>	<b>(356)</b>	<b>(8,366)</b>
<b>Net book value</b>						
Plant and machinery	-	-	-	-	-	-
Industrial and commercial equipment	899	217	29	-	(215)	931
Leasehold improvements	57	-	360	-	(75)	342
Other tangible assets	195	117	-	-	(66)	246
Assets under construction and payments on account (Industrial equipment Bresso)	29	525	(29)	-	-	525
Assets under construction and payments on account (Leasehold improvements Bresso)	544	3,768	(360)	-	-	3,952
<b>Total net book value</b>	<b>1,724</b>	<b>4,627</b>	<b>-</b>	<b>-</b>	<b>(356)</b>	<b>5,996</b>

\* The depreciation showed in the table includes the portion for the leasehold improvements concerning the site in Bresso, totaling 20 thousand Euro. 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.

The item "Plant and machinery", fully depreciated, includes specific plant and machinery used to develop the Company's products and to provide services.

"Industrial and commercial equipment" of a net amount of 930 thousand Euro includes tangible assets used in laboratories to develop the products in the pipeline and to provide services.

"Leasehold improvements" include the cost of renovating the premises used by the Company, in particular its pharmaceutical laboratories and offices. These premises are used under a lease agreement. The costs incurred generally regarded building work and work on the systems that form an integral part of the premises. In addition, 360 thousand Euro in assets under construction were reclassified to leasehold improvements –depreciated over the lease term, i.e. 12 years – following the delivery of part of the property and the relocation of the administrative offices to the new site in Bresso in early May 2014.

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

The item "Assets under construction and payments on account" mainly includes all the costs incurred up to December 31, 2014 in relation to the Bresso project. 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 4 million Euro, 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. As previously mentioned, 360 thousand Euro concerning the administration offices move to Bresso in early May 2014 were reclassified as "Leasehold improvements".

Investments of 4,627 thousand Euro were made in tangible assets in 2014. The most significant changes in the year are illustrated below:

- The increase in "Assets under construction and payments on account (Bresso project)" (3,768 thousand Euro) mainly includes all the costs incurred for renovation work made in relation to the Bresso facilities where the Company will increase its GMP production capacity. The costs accounted for to date, 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 increase in assets under construction and payments on account (525 thousand Euro) refers largely to the costs incurred to acquire the equipment for the laboratories at the new facility in Bresso;
- The increase in "Industrial and commercial equipment" of 217 thousand Euro is attributable to the normal periodic replacement of laboratory equipment, in addition to the upgrading and improvement work on premises and technical facilities aimed at ensuring that some GMP production areas comply with the new operational needs and specific regulatory requirements.

Overall depreciation totaled 356 thousand Euro, down on 2013 (446 thousand Euro), due to the end of the depreciation period for some assets.

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, 2014 are shown in the table below:

<i>(amounts in Euro thousand)</i>	Balance at December 31, 2013	Purchases	Reclassifications	Disposals	Depreciation and write downs	Balance at December 31, 2014
Merger with Genera S.p.A.	77	-	-	-	-	77
<b>Goodwill</b>	<b>77</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>77</b>
Patents and intellectual property rights	194	52	-	-	(50)	196
Concessions, licenses and trademarks	27	55	-	-	(25)	57
<b>Intangible assets</b>	<b>221</b>	<b>107</b>	<b>-</b>	<b>-</b>	<b>(75)</b>	<b>253</b>
<b>Total</b>	<b>298</b>	<b>107</b>	<b>-</b>	<b>-</b>	<b>(75)</b>	<b>330</b>

"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 is attributable to the validation of a patent concerning new technologies to produce lentiviral vectors for gene therapy in 40 European countries (52 thousand Euro) and to the acquisition of software licenses for the Bresso facilities.

Amortization amounted to a total 75 thousand Euro.

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 7 thousand Euro consist of guarantee deposits and a provision for employee reimbursements.

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

Non-current tax receivables mainly relate to VAT receivables accrued by the Company. As its costs exceed its revenues at this stage of business development, the Company regularly recognizes VAT receivables.

At December 31, 2014, Tax receivables amounted to 2,557 thousand Euro mainly consisting of accruing VAT receivables for which the Company has not yet claimed a refund. The 1,443 thousand Euro decline from December 31, 2013 was largely because in 2014 the Company submitted to the Inland Revenue the documentation for the VAT refund for both 2012 (amounting to 1,189 thousand Euro), which it received in September 2014, and 2013 (amounting to 1,189 thousand Euro), which it received in December 2014.

The Company had factored these receivables without recourse in the previous year and May 2014, respectively.

As the transactions did not meet the requirements of IAS 39, the Company continued recognizing the factored VAT receivables until the factor received the relevant refund from the Inland Revenue. Reference should be made to *Note 14* "Non-current financial payables" for further information.

Information on tax receivables classified under current assets is provided in *Note 8*.

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

Other non-current assets of 1,586 thousand Euro are broken down as follows:

- 1,500 thousand Euro 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 (Milan) belonging to the Zambon chemical-pharmaceutical group, where the Company is increasing its production capacity.
- 86 thousand Euro refer to the last portion of the consideration agreed to under the option agreement the Company 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, with the possibility of renewal every four years. As from the above-

mentioned date, the amount recorded under the item "Other assets" 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 (until early March 2016). This amount, originally equal to 4,131 thousand Euro, is classified under current assets, with respect to the portion to be allocated to the income statement within 12 months, with the remaining balance classified under non-current assets. On February 10, 2015, Ospedale San Raffaele notified the Company and Science Park it would terminate the option agreement effective March 4, 2016.

### *Note 6 – Inventory*

Inventory at December 31, 2014 is broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Processing materials	258	220
Reagents	453	400
General materials	63	56
<b>Total inventories</b>	<b>774</b>	<b>676</b>

At December 31, 2014 inventory consists of materials and reagents used in the Company's laboratories. The 98 thousand Euro increase from December 31, 2013 is attributable to the higher procurement of materials used in manufacturing activities on behalf of third parties.

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

At December 31, 2014, trade receivables and other commercial assets are broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Trade receivables	1,760	2,137
Prepayments	70	387
Invoices to be issued	2,220	1,974
Receivables from related parties	88	88
Invoices to be issued (Related parties)	-	6
Other activities	-	499
Prepaid expenses concerning costs pertaining to future periods	226	497
<b>Total trade receivables and other commercial assets</b>	<b>4,364</b>	<b>5,588</b>

The decrease in trade receivables and other commercial assets reflects the invoicing and collection trend relating to the provision of services, as well as invoicing of advances by suppliers for activities that were only partly completed at the end of the period. In particular, during the year the Company registered a reduction in the average collection period.

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 28 thousand Euro, created in 2011 in relation to the impairment of receivables due from Fondazione San Raffaele del Monte Tabor in liquidation.



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

Tax receivables at December 31, 2014 are broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
VAT receivables	700	700
Withholding taxes	145	137
<b>Total tax receivables</b>	<b>845</b>	<b>837</b>

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*.

### *Note 9 – Other receivables and sundry assets*

Other receivables and sundry assets at December 31, 2014 are broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Price portion of option right	516	516
Accrued research and development grants	947	968
Prepayments relating to costs not pertaining to the period	240	245
Other receivables	31	2
<b>Total other receivables and sundry asset</b>	<b>1,734</b>	<b>1,731</b>

Other receivables and sundry assets of 1,734 thousand Euro and 1,731 thousand Euro at December 31, 2014 and at December 31, 2013, respectively, consist of 516 thousand Euro attributable to the portion (to be recognized in the income statement within the following 12 months) of the consideration agreed to under the option agreement the Company signed with the shareholder Science Park Raf in liquidation and its parent company Ospedale San Raffaele to purchase research projects, as detailed in *Note 5*. For further information, reference should be made to *Note 34*.

Furthermore, the item mainly includes receivables of 947 thousand Euro for public sector research and development grants awarded and still to be received, in addition to prepaid expenses relating to:

- insurance premium costs of 9 thousand Euro;
- operating costs incurred for contracts based on “work progress” and maintenance and assistance fees for information services and other minor amounts of 231 thousand Euro.

#### *Note 10 – Other financial assets*

At December 31, 2014, the item amounted to 6 thousand Euro, consisting mainly of accrued interest income.

#### *Note 11 – Cash and cash equivalents*

Cash and cash equivalents are broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Bank and post office accounts	7,915	1,955
Bank and post office accounts - related parties	3,459	6,596
Cash on hand	10	11
Cash equivalents	-	-
<b>Total cash and cash equivalents</b>	<b>11,384</b>	<b>8,562</b>

At December 31, 2014 cash and cash equivalents amounted to 11,384 thousand Euro (8,562 thousand Euro at December 31, 2013), including 11,374 thousand Euro of bank accounts and 10 thousand Euro of cash on hand.

#### *Note 12 – Shareholders' equity*

Shareholders' equity at December 31, 2014 totaled 12,082 thousand Euro, broken down as follows:

<i>(Amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Share capital	11,019	27,071
Share premium reserve	5,635	3,378
<i>Other reserves:</i>		
Stock option plan reserve	644	490
Actuarial valuation reserve	(19)	(65)
Fair value valuation reserve		-
Other	8,638	3
Retained earnings (accumulated losses)	(832)	(2,575)
Profit (loss) for the year	(13,003)	(18,169)
<b>Total shareholders' equity</b>	<b>12,082</b>	<b>10,133</b>

It should be noted that:

- On January 31, 2014, the Company's Board of Directors approved the statement of financial position at November 30, 2013 pursuant to Article 2446 of the Italian Civil Code, with overall losses, net of available reserves, of 16,586 thousand Euro, i.e. more than a third of the subscribed and paid-in capital (equal to 27,071 thousand Euro).

The Board of Directors then resolved to propose to the Extraordinary Shareholders' Meeting to fully cover the total losses net of available reserves at November 30, 2013 by approving a capital reduction from 27,071 thousand Euro to 10,486 thousand Euro, without the cancellation of any shares, given the absence of the relevant par value.

- As detailed in the previous paragraph *13.2 Capital increase of 5 million Euro completed in April 2014 and capital increase of 50 million Euro completed in April 2015* as well as *15.1 Significant events after the reporting period* in this document, during 2014 the Company carried out a capital increase, completing it in early April. It ended with the full subscription of 8,252,092 shares, for an aggregate amount equal to 4,969 thousand Euro, of which 389 thousand Euro credited to the capital account and 4,580 thousand Euro to the share premium account. It should be noted that costs of 107 thousand Euro directly connected to the capital increase were deducted from the share premium reserve;
- As mentioned above in the paragraphs *13.2 Capital increase of 5 million Euro completed in April 2014 and capital increase of 50 million Euro completed in April 2015* and *15.1 Significant events after the reporting period*, following the request of the Board of Directors in accordance with the commitments made on January 31, 2014, the shareholders paid a total 8,593 million Euro to the Company as capital contributions on account of future issues of shares. Fininvest paid 2,176 thousand Euro on June 30, 2014 and 4,393 thousand Euro on September 30, 2014; Airain and H-Equity (through the associate H-Invest) paid 1,255 thousand and 769 thousand Euro, respectively, in July 2014. On February 18, 2015, H-Equity and H-Invest paid the last installment of the capital contribution on account of future issues of shares, amounting to 1,552 thousand Euro.
- in addition, as described in paragraph *13.3 Signing of the "SEF – Stand-by Equity Facility" agreement with Société Générale*, on July 31, 2014, the Company's Board of Directors resolved to enter into a SEF – Standby Equity Facility agreement with Société Générale. Under said agreement, on September 23, 2014, the Board of Directors submitted to SG a request for the subscription of the first installment of the reserved capital increase. The subscription price for the shares of the first installment, equal to 0.4887 Euro (including 0.0471 Euro credited to the capital account and the remainder to the share premium account), was determined in the three trading days following the submission of the subscription request. It corresponds to 95% of the volume weighted average price of the Company's ordinary shares in said period. SG confirmed it would subscribe for 3,080,670 ordinary shares, representing 1.32% of MolMed's capital, for a total 1,506 thousand Euro, including 145 thousand Euro credited to the capital account and 1,361 thousand Euro to the share premium account. The transaction was completed on September 29, 2014.

### Capital

At December 31, 2014, the fully subscribed and paid-in capital amounted to 11,019 thousand Euro and consisted of 234,139,264 ordinary shares with no par value.

Shareholder	No. of shares	%
Fininvest S.p.A.	59,540,634	25.43
Airain Lda	13,354,266	5.70
Science Park Raf S.p.A.	7,692,031	3.29
H-Equity S.r.l.	6,536,052	2.79
H-Invest S.p.A.	7,000,000	2.99
Other (<2%)	140,016,281	59.80
<b>Total</b>	<b>234,139,264</b>	<b>100.00</b>

\* based on Company data at March 3, 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 Extraordinary Shareholders' Meeting of March 3, 2014 resolved to reduce the capital (giving rise to the situation referred to in Article 2446 of the Italian Civil Code, based on the financial position at November 30, 2014). On the same occasion, the Meeting approved the above-mentioned capital increase of 5 million Euro, recognizing a share premium reserve of 4,580 thousand Euro, net of 107 thousand Euro in relevant expenses.

Furthermore, on September 29, 2014, after SG subscribed for 3,080,670 ordinary shares, representing 1.32% of MolMed's capital, for a total 1,506 thousand Euro, 1,162 thousand Euro were credited to the share premium reserve net of the relevant expenses, amounting to 199 thousand Euro.

### *Other reserves*

Other reserves are broken down as follows:

#### *a) Stock option plan reserve*

The stock option plan reserve was set up on January 1, 2006 upon first-time adoption of IFRSs, in order to include the fair value of stock option plans. 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 161 thousand Euro increase arising from the recognition of the amount accrued in the period based on the 2012 stock option plan, and of a 7 thousand Euro decrease due to the expiry of 150,000 options of the 2012 plan following retirement of a beneficiary.

#### *b) Fair value reserve*

The fair value valuation reserve reflects the fair value adjustment of financial assets available for sale. At December 31, 2014 the reserve was zero. At the date of this Report, the Company does not hold any financial assets available for sale.

#### *c) Other reserves*

Other reserves consist in the Reserve for capital contribution on account of future issues of shares, totaling 8,593 thousand Euro, and the Reserve for unexercised rights, amounting to 45 thousand Euro.

- The Reserve for capital contribution on account of future issues of shares, totaling 8,593 thousand Euro, includes:
  - ✓ 2,176 thousand Euro from the exercise of a first installment of the commitment made by Fininvest on January 31, 2014;
  - ✓ 1,255 thousand Euro and 769 thousand Euro as capital contributions on account of future issues of shares received from Airain and H-Equity, respectively, in July 2014;
  - ✓ 4,393 thousand Euro from the exercise of a second installment of the commitment made by Fininvest on January 31, 2014.

- The Reserve for Unexercised Rights from a capital increase refers to the proceeds of the sale of the rights that were not exercised during the 5 million Euro capital increase carried out in 2014.

#### d) Actuarial valuation reserve

At December 31, 2014, the Actuarial valuation reserve is negative to the tune of 19 thousand Euro, compared to a positive 65 thousand Euro at December 31, 2013, because of the application of the amendment to IAS 19 issued on June 16, 2011.

#### Retained earnings (accumulated losses)

At December 31, 2014, this item amounted to 832 thousand Euro as a result of the capital reduction approved by the Extraordinary Shareholders' Meeting on January 31, 2014 to absorb the losses for the first eleven months of 2013, only excluding the loss for December 2013, net of the 7 thousand Euro decrease in the stock option reserve due to the retirement of a beneficiary. For further details on the issue, reference should be made to [Note 9.3](#) of the Report on Operations.

Details completing the analysis of the items included in shareholders' equity are provided in the following table:

#### Main shareholders' equity items

(amounts in Euro thousand)	Balance at December 31, 2014	Purpose of use	Amount available
<b>Reserves</b>			
-Share premium reserve	5,635	A,B	5,635
-Stock option plan reserve	644	-	-
-Fair value reserve	-	B	-
-Other reserves			
-Shareholders' advance payment for share capital increase	8,593	A,B	8,593
-Actuarial valuation reserve	(19)		-
-Unexercised rights 2013 reserve	45	A,B	45
-Retained earnings (accumulated losses)	(832)	A,B,C	-

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 totaled 208 thousand Euro at December 31, 2014 (184 thousand Euro at December 31, 2013).

Changes in the period are reported below:

(amounts in Euro thousand)

	December 31, 2014	December 31, 2013
<b>Opening balance</b>	<b>184</b>	<b>203</b>
Uses	(4)	(15)
Other movements	7	-
Financial loss	5	4
Actuarial (gain)/loss	16	(8)
<b>Total liabilities for pensions and employee severance indemnity (TFR)</b>	<b>208</b>	<b>184</b>

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

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

Under IAS 19, at December 31, 2014, 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: 0.91%
- Annual inflation rate: 0.60% for 2015, 1.20% for 2016, 1.50% for 2017-2018, 2% as from 2019
- TFR annual increase rate: 1.950% for 2015, 2.4% for 2016, 2.625% for 2017-2018, 3% as from 2019

Demographic assumptions

- Mortality rate: RG48 table
- Disability: INPS tables by age and sex
- Retirement age: 100% achievement of the target required by compulsory general insurance (AGO)

Annual turnover and TFR advance payments

**FROM GENES TO THERAPY**

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

#### *Note 14 – Financial payables (non-current)*

At December 31, 2014, the Company had no financial payables. The 1,032 Euro decline from December 31, 2013 is attributable to the collection of the 2012 VAT receivable and the ensuing settlement of non-current payables due to Banca Sistema. Non-current financial payables recognized at December 31, 2013, refer to the amount paid by Banca Sistema (including interests) in relation to the 2012 VAT receivables factoring, completed in the first half of 2013.

The factoring agreement between MolMed and Banca Sistema provided for payment by Banca Sistema of the initial assignment price, paid at the same time as the agreement is entered into, and subsequent payment following receipt of the amounts from the Inland Revenue, inversely proportional to the amount of time it takes to receive payment.

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

Other liabilities, equal to 5,317 thousand Euro at December 31, 2014, essentially refer to the advance received for two projects financed under the Seventh Framework Program of the European Union (1,961 thousand Euro) and to the long-term portion for Euro 3,356 thousand of deferred income concerning leasehold improvements for the new Bresso facilities. For further details reference should be made to *Notes 1 and 17*.

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 term of the lease agreement. The Company continues recognizing 305 thousand Euro, representing the estimated depreciation for the next 12 months, under current liabilities.

The 2,794 Euro increase from the prior-year period is attributable to:

- 3,356 thousand Euro increase in non-current deferred income referring to leasehold improvements (Bresso), as previously mentioned;
- 562 thousand Euro decrease in advance payments for the Optistem and Persist projects funded by the European Union as well as the ATP 2009 project funded by the Regional Government of Lombardy, which ended during the year.

#### *Note 16 – Trade payables*

Trade payables amounted to 9,852 thousand Euro at December 31, 2014, compared to 9,480 thousand Euro at December 31, 2013, and are broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Trade payables	9,414	8,035
Payables to related parties	151	410
Deferred income concerning revenues pertaining to future periods	287	1,035
<b>Total trade payables</b>	<b>9,852</b>	<b>9,480</b>

At December 31, 2014 trade payables included 6,989 thousand Euro due in Italy, 1,891 thousand Euro due in European Union countries and 534 thousand Euro 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 future financial years.

### *Note 17 – Other liabilities*

The item is broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Amounts due to employees for holiday and bonus	789	617
Amounts due to social security institutions	502	469
Tax payables	363	387
Amounts due to freelance consultants	22	82
Other payables	106	93
Deferred income (Bresso)	342	524
<b>Total other liabilities</b>	<b>2,124</b>	<b>2,172</b>

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 2014, 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 and, therefore, has no current tax payables.

The item “Deferred income” mainly includes all costs incurred up to December 31, 2014 in relation to the Bresso project, i.e. the Company’s new industrial site in the “Open Zone” scientific park in Bresso (Milan), belonging to the Zambon chemical-pharmaceutical group, where the Company has been expanding its operations in order to increase 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 4 million Euro, 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. Starting from May 2014, when the first part of the property housing the Company’s administrative offices was delivered pursuant to the contract, the Company started depreciating the share of assets already in use and canceled the relevant 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 continues recognizing 305 thousand Euro, representing the depreciation for the next 12 months, under current liabilities. For more details reference should be made to *Notes 1* and *15*.

### *Note 18 – Finance lease payables*

At December 31, 2014, there were no finance lease payables following the end of the leases for laboratory equipment.

## 5. Notes to the Income Statement

### Note 19 – Revenues

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

<i>(amounts Euro thousand )</i>	<b>2014</b>	<b>2013</b>
Revenues from development and production activities undertaken on behalf of third parties	11,181	5,856
<b>Total operating revenues</b>	<b>11,181</b>	<b>5,856</b>

GMP development and production activities on behalf of third parties generated revenues of 11,181 thousand Euro compared to 5,856 thousand Euro recorded in the previous year (+90.9%), thanks to the above-mentioned 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.

### Note 20 – Other income

This item, amounting to 1,241 thousand Euro, mainly consists of public sector research and development grants and is broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>2014</b>	<b>2013</b>
European Commission (Persist project)	38	10
European Commission (Optistem project)	107	12
European Commission (Attract project)	-	65
European Commission (Cell - pid project)	215	110
European Commission (Supersist)	409	108
Region of Lombardy (ATP 2009)	294	134
Region of Lombardy (Innovazione Processi)	158	41
Other grants	14	10
Other revenues	6	368
Gains	-	-
<b>Total other income</b>	<b>1,241</b>	<b>858</b>

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 received during 2014 related to four projects under the Seventh Framework Programme of the European Union (the PERSIST, OPTISTEM, CELL-PID and SUPERSIST projects) and to the ATP 2009 and Process innovation projects financed by the Region of Lombardy.

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

This item is broken down as follows:

	2014	2013
Processing materials	1,123	871
Reagents	1,282	1,115
General laboratory materials	418	479
Maintenance materials	43	67
Change in raw materials inventory	100	(86)
<b>Total purchases of raw materials and consumables</b>	<b>2,966</b>	<b>2,446</b>

The costs for raw materials and consumables, which largely consist of materials and reagents used in production and development activities, rose from 2,446 thousand Euro at the end of 2013 to 2,966 thousand Euro at the end of 2014.

The 520 thousand Euro increase (+21.2%) in said costs is largely due to the rising purchases of materials for the industrial development of NGR and TK as well as the mentioned intensification of GMP development and production activities on behalf of third parties.

### *Note 22 – Costs for services*

The breakdown of this item at December 31, 2014 and at December 31, 2013 is as follows:

<i>(amounts in Euro thousand)</i>	2014	2013
Outsourced development costs	5,220	5,237
Option rights	516	516
Consultancy and technical fees	428	709
License and patents consultancy fees	916	416
Maintenance	325	588
Transport and storage of laboratory materials	328	531
Utilities	507	319
Directors and statutory auditors' fees	446	546
Audit	88	72
Legal, administrative and managerial fees	556	529
Listing consultancy fees and other listing costs	105	83
Supervisory board fees	142	147
Communications agency fees	275	170
IT assistance and other IT costs	299	201
Other general and administrative costs	578	477
Travel, staff training and other personnel costs	436	524
<b>Total costs for services</b>	<b>11,165</b>	<b>11,065</b>

Costs for services amounted to 11,165 thousand Euro at December 31, 2014 in line with 2013 figures.

Costs relating to outsourced development and transport and storage of materials at December 31, 2014 are slightly down (-203 thousand Euro) on the prior-year period. The decline is mainly attributable to the high concentration of the costs related to the NGR015 trial in the first three quarters of 2013.

Consultancy and technical fees are down 281 thousand Euro (39.7%) from 709 thousand Euro at December 31, 2013 to 428 thousand Euro at December 31, 2014, largely because of the one-off upgrade to the laboratories and production equipment at the current GMP facility made by the Company in 2013.

The increase in “License fees and patent costs” in 2014 compared to the prior-year period was substantially the result of a milestone payment in relation to the regulatory process of a product in the pipeline.

The decrease in “Maintenance” costs, equal to 588 thousand Euro at December 31, 2013 and 325 thousand Euro at December 31, 2014, is mainly due to the revamping of the production systems in the current GMP facility, which began in the second quarter of 2013 and ended in December 2013.

Utility costs rose from 319 thousand Euro at December 31, 2013 to 507 thousand Euro at December 31, 2014, and other general and administrative costs from 477 thousand Euro at December 31, 2013 to 578 thousand Euro at December 31, 2014, mainly because of the commissioning of the new facility in Bresso.

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 in liquidation.

The item “Directors and statutory auditors’ fees” of 446 thousand Euro does not include the remuneration of 750 thousand Euro paid to the Chairman and CEO, recorded under personnel costs. “Directors and statutory auditors’ fees” include reimbursements for the expenses incurred to attend the meetings of the Board of Directors and the Board of Statutory Auditors.

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

<i>(amounts in Euro thousand)</i>	<b>2014</b>	<b>2013</b>
Rental of premises	1,189	979
Other rentals	47	109
<b>Total costs for use of third-party assets</b>	<b>1,236</b>	<b>1,088</b>

“Costs for use of third-party assets”, amounting to 1,236 thousand Euro, are up 13.6% from the previous year (1,088 thousand Euro) following the commencement of the lease of the secondary office in Bresso in May 2014.

### Note 24 – Personnel costs

These costs are broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>2014</b>	<b>2013</b>
Wages and salaries	6,729	6,472
Social security contributions	1,866	1,771
Defined contribution plans	368	392
Stock option costs	161	161
Other personnel costs	21	26
<b>Total personnel costs</b>	<b>9,145</b>	<b>8,822</b>

Personnel costs rose 3.7% from 8,822 thousand Euro in 2013 to 9,145 thousand Euro in 2014. This rise was mainly due to the increase in the number of employees performing operating tasks within the organization. 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, totaling 750 thousand Euro for the year. This amount refers to the agreement between the Company and Prof. Bordignon for the discharge of the responsibilities delegated to him by the Shareholders' Meeting and the Board of Directors on April 22, 2013. The remuneration received as member of the Board of Directors, similarly to the other members of the Board, is included under "Directors and statutory auditors' fees".

During 2014, the average number of employees was 105 (compared to 112 in the first half of 2014 and 95 in 2013). At December 31, 2014, the Company had 115 employees, of which 103 on open-ended contracts and 12 on fixed-term contracts. They are broken down as follows:

	<b>2014</b>	<b>2013</b>
Executives	8	9
Middle management	28	24
Clerical staff	75	68
Technicians	4	4
<b>Total</b>	<b>115</b>	<b>105</b>

### *Note 25 – Other operating costs*

The item "Other operating costs" sharply decreased from 168 thousand Euro in 2013 to 127 thousand Euro in 2014, mainly due to lower funding of research scholarships and entertainment costs.

<i>(amounts in Euro thousand)</i>	<b>2014</b>	<b>2013</b>
Printed and promotional materials	1	1
Stationery	18	6
Entertainment costs	17	31
Membership fees	31	29
Donations	52	75
Books and magazines	3	9
Other costs	5	17
<b>Total other operating costs</b>	<b>127</b>	<b>168</b>

### *Note 26 – Bad debt provision*

At December 31, 2014, this item amounted to zero. At December 31, 2013, it amounted to 500 thousand Euro and referred to the write-down of a current asset following the termination of an agreement. Then, the Company, considering that negotiations were at an early stage at the reporting date and only limited information was available, as well as backed by its legal consultants, had deemed a 50% write-down as reasonable. In 2014, the negotiations over the termination of the agreement resulted in a favorable outcome for the Company.

### *Note 27 – Amortization, depreciation and impairment*

Amortization, depreciation and impairment totaled 411 thousand Euro in 2014, down by 138 thousand Euro compared to the prior-year period, due to the end of the amortization/ depreciation period for some assets. Investments of 4,734 thousand Euro in 2014 were mainly due to the secondary offices in Bresso, to routine replacement of laboratory equipment and the purchase of new machinery to be used in the TK manufacturing process, as well as to maintenance and improvement work on the GMP facility.

At December 31, 2013, this item included a 38 thousand Euro impairment loss represented by the residual value of discontinued laboratory equipment.

<i>(amounts in Euro thousand)</i>	<b>2014</b>	<b>2013</b>
Amortization of intangible assets	75	104
Depreciation of tangible assets	336	407
Bad debt provision	-	38
<b>Total amortization, depreciation &amp; write-downs</b>	<b>411</b>	<b>549</b>

### Note 28 – Financial income and charges

This item is broken down as follows:

<i>(amounts in Euro thousand)</i>	<b>2014</b>	<b>2013</b>
<b>FINANCIAL INCOME:</b>		
Interest and other financial income	51	97
Gains on securities	-	0
Exchange gains	19	25
<b>Total financial income</b>	<b>70</b>	<b>122</b>
<b>FINANCIAL CHARGES:</b>		
Losses on securities	0	(40)
Exchange losses	(176)	(35)
Finance lease interest expense	(2)	(7)
Other interest expense	(150)	(215)
Other charges	(117)	(70)
<b>Total financial charges</b>	<b>(445)</b>	<b>(367)</b>
<b>Total financial income (charges)</b>	<b>(375)</b>	<b>(245)</b>

The Company's financial activities were negative to the tune of 375 thousand Euro, showing a negative change of 130 thousand Euro on the year 2013.

Financial income of 70 thousand Euro (122 thousand Euro at December 31, 2013) mainly arose from the management of the Company's cash resources. The decrease was mainly due to the progressive reduction of available financial resources due to the cash absorbed by ordinary operations, as well as to the net decrease of market return rates.

Financial charges of 445 thousand Euro in 2014 increased on the previous year and were mainly due to the non-recourse factoring of VAT receivables completed in the second quarter of 2013 and 2014.

### Note 29 – Income taxes

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

Taking account of 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, 2014 the tax losses to be carried forward totaled 151,617 thousand Euro and the theoretical deferred tax assets totaled 42,337 thousand Euro. 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.

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



<i>(importi in migliaia di Euro)</i>	December 31, 2014			December 31, 2013		
	Temporary differences amount	Rate	Tax effect	Temporary differences amount	Rate	Tax effect
Directors' fees	22	27.50%	6	-	27.50%	-
Maintenance in exceeds	151	27.50%	42	189	27.50%	52
Other temporary differences	130	27.50%	36	4	27.50%	1
Upfront & milestone revenues difference	479	27.50%	132	479	27.50%	132
Tax losses carried forward as per Article 84, par. 2 TUIR (start up losses)	1,552	27.50%	427	1,552	27.50%	427
Tax losses carried forward as per Article 84, par. 1 TUIR	151,617	27.50%	41,699	138,392	27.50%	38,058
<b>Totale imposte anticipate</b>	<b>153,951</b>		<b>42,341</b>	<b>140,616</b>		<b>38,669</b>
Merger deficit	-	31.40%	-	-	31.40%	-
Other temporary difference	1	27.50%	-	14	27.50%	4
<b>Totale imposte differite</b>	<b>1</b>		<b>-</b>	<b>14</b>		<b>4</b>

### *Note 30 – Basic and diluted earnings (loss) per share*

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

<i>(Amounts in Euro)</i>	2014	2013
Basic earnings/(loss) per share	(0.0566)	(0.0821)
Diluted 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 2014 and 2013 – 13,003 thousand Euro and 18,169 thousand Euro, respectively – and on the weighted average number of ordinary shares outstanding in the relevant periods – 237,375,358 and 228,938,886, respectively.

## 6. Other notes

### Note 31 – Net financial position

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

<i>(amounts Euro thousand )</i>	December 31, 2014	December 31, 2013
Cash on hand	10	11
Other cash	11,374	8,551
Cash equivalents	-	-
<b>A. Total cash and cash equivalents</b>	<b>11,384</b>	<b>8,562</b>
<b>B. Current financial receivables and other financial assets</b>	<b>6</b>	<b>1</b>
Finance lease payables	-	(3)
Current financial Debts	-	-
<b>C. Current financial debt</b>	<b>-</b>	<b>(3)</b>
<b>D. Net current financial position (A+B+C)</b>	<b>11,390</b>	<b>8,560</b>
<b>Finance lease payables</b>	<b>-</b>	<b>-</b>
Non current financial Debts	-	(1,032)
<b>E. Non-current financial debt</b>	<b>-</b>	<b>(1,032)</b>
<b>F. Net financial position (D+E)</b>	<b>11,390</b>	<b>7,528</b>

Net financial position was positive to the tune of 11,390 thousand Euro at December 31, 2014 almost fully consisting of cash and cash equivalents (11,384 thousand Euro).

The net financial position was mainly affected by the following items:

- income of 4,969 thousand Euro resulting from the capital increase finalized in the first four months of 2014;
- proceeds of 1,032 thousand Euro from the factoring of the 2013 VAT receivables, as well as of 220 thousand Euro for the relevant price adjustment, after the factor received the amount due from the Inland Revenue;
- 8,593 thousand Euro received from some shareholders parties to the shareholders' agreement as a capital contribution on account of future issues of shares;
- income of 1,506 thousand Euro resulting from the stand-by equity facility (SEF).

Finally, please note that in 2014 the cash flows used in the Company's operations amounted to 13,498 thousand Euro.

### *Note 32 – 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:

<i>(amounts in Euro thousand)</i>	<b>December 31, 2014</b>	<b>December 31, 2013</b>
Guarantees	8,048	6,092
Commitments	-	-
<b>Total guarantees and commitments</b>	<b>8,048</b>	<b>6,092</b>

Guarantees mainly consist of 6,946 thousand Euro of bank guarantees for the refund of VAT receivables, and of 748 thousand Euro for a bank guarantee for the advance received from the Region of Lombardy in relation to the grant for the subsidized ATP 2009 project.

Furthermore, 199 thousand Euro refer to the guarantees issued for the payment of real estate leases, 153 thousand Euro refer to the guarantees issued in favor of Università Vita Salute San Raffaele for commitments undertaken by the Company in relation to the funding of research scholarships.

### *Note 33 – 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 772,178.60 Euro, 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 497,106.24 Euro, 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 provided for 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 December 31, 2014.

Name, Surname and position held		Type of stock options granted	N. stock options 2008	N. stock options expired at December 31, 2013	N. residual options at December 31, 2013	N. stock options expired in 2014	N. residual options at December 31, 2014	Strike price (Euro)
Claudio Bordignon	Board Chairman, Chief Executive Officer	B	750,000	750,000	-	-	-	1.47974
Marina Del Bue	Executive Officer, General Manager B&A	B	450,000	450,000	-	-	-	1.47974
Enrico Cappelli	Chief Financial Officer	A	180,000	180,000	-	-	-	1.47974
Enrico Cappelli	Chief Financial Officer	B	110,000	110,000	-	-	-	1.47974
Holger Neecke	Business Development Director & IR	A	150,000	150,000	-	-	-	1.47974
Holger Neecke	Business Development Director & IR	B	90,000	90,000	-	-	-	1.47974
Marco Dieci	Special Projects Director	A	70,000	70,000	-	-	-	1.47974
Marco Dieci	Special Projects Director	B	60,000	60,000	-	-	-	1.47974
Antonio Lambiase	Clinical Development Director	A	80,000	-	80,000	-	80,000	1.47974
Antonio Lambiase	Clinical Development Director	B	70,000	70,000	-	-	-	1.47974
Paolo Rizzardi	R&D Director	A	70,000	-	70,000	-	70,000	1.47974
Paolo Rizzardi	R&D Director	B	60,000	60,000	-	-	-	1.47974
Daniele Pieraccioni	Intellectual Property Director	B	100,000	100,000	-	-	-	1.47974
Cynthia Giuliani	Human Resources Director	B	70,000	70,000	-	-	-	1.47974
Catia Traversari	Research Director	A	50,000	-	50,000	-	50,000	1.47974
Catia Traversari	Research Director	B	40,000	40,000	-	-	-	1.47974
			<b>2,400,000</b>	<b>2,200,000</b>	<b>200,000</b>	-	<b>200,000</b>	

### **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 1,449,892.95 Euro, 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 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 position held		Options A n.	Options B n.	Total Options	Strike price (Euro)
Claudio Bordinon	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 Rizzardì	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
		<b>3,900,000</b>	<b>2,600,000</b>	<b>6,500,000</b>	

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, the options previously assigned to them under the 2012 Plan expired. In addition, on January 1, 2014, the stock options granted to Mr. Daniele Pieraccioli expired, since as of that date he ceased his employment with MolMed.

Here below is a summary of stock options at December 31, 2014:

#### FROM GENES TO THERAPY

Name, Surname and position held		n. options A 2012 assigned	n. options B 2012 assigned	Tot. Options 2012 assigned	N. stock options expired at December 31, 2014	N. residual options at December 31, 2014	Strike price (Euro)
Claudio Bordignon	Board Chairman, Chief Executive Officer	1,740,000	1,160,000	2,900,000	-	2,900,000	0.45140
Marina Del Bue	Executive Officer, General Manager B&A	630,000	420,000	1,050,000	-	1,050,000	0.45140
Germano Carganico	General Director R&D e Operations	630,000	420,000	1,050,000	-	1,050,000	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	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	0.45140
Antonio Lambiase	Clinical Development Director	150,000	100,000	250,000	-	250,000	0.45140
Paolo Rizzardi	Research & Development Director	150,000	100,000	250,000	-	250,000	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	0.45140
Catia Traversari	Research Director	90,000	60,000	150,000	-	150,000	0.45140
		<b>3,960,000</b>	<b>2,640,000</b>	<b>6,600,000</b>	<b>550,000</b>	<b>6,050,000</b>	

Type A options can be exercised from the date of the approval of the 2014 Financial Statements until December 31, 2020, provided that by December 31, 2014 at least one of the two company products is marketed. In this regard, 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 date	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

On April 24, 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 provided for by the regulations.



**Summary of the options granted**

The table below shows the options granted and held at December 31, 2014:

Name, Surname and position held	Type of Stock Options assigned	N. of Options assigned	Strike price (Euro)	Options expired at December 31, 2014	Options exercised 2014	Options held December 31, 2014
Claudio Bordignon Board Chairman, Chief Executive Officer	Piano 2008 B	750,000	1.4797	750,000	-	-
	Piano 2012 A	1,740,000	0.4514	-	-	1,740,000
	Piano 2012 B	1,160,000	0.4514	-	-	1,160,000
Marina Del Bue Executive Officer, General Manager B&A	Piano 2008 B	450,000	1.4797	450,000	-	-
	Piano 2012 A	630,000	0.4514	-	-	630,000
	Piano 2012 B	420,000	0.4514	-	-	420,000
Germano Carganico General Director R&D e Operation	Piano 2012 A	630,000	0.4514	-	-	630,000
	Piano 2012 B	420,000	0.4514	-	-	420,000
Enrico Cappelli Chief Financial Officer	Piano 2008 A	180,000	1.4797	180,000	-	-
	Piano 2008 B	110,000	1.4797	110,000	-	-
	Piano 2012 A	90,000	0.4514	90,000	-	-
	Piano 2012 B	60,000	0.4514	60,000	-	-
Andrea Quaglino Chief Financial Officer	Piano 2012 A	60,000	0.7554	-	-	60,000
	Piano 2012 B	40,000	0.7554	-	-	40,000
Holger Neecke Business Development Director & IR	Piano 2008 A	150,000	1.4797	150,000	-	-
	Piano 2008 B	90,000	1.4797	90,000	-	-
	Piano 2012 A	150,000	0.4514	150,000	-	-
	Piano 2012 B	100,000	0.4514	100,000	-	-
Marco Dieci Special Projects Director	Piano 2008 A	70,000	1.4797	70,000	-	-
	Piano 2008 B	60,000	1.4797	60,000	-	-
Marco Manoni Facility Planning & Design Director	Piano 2012 A	90,000	0.4514	-	-	90,000
	Piano 2012 B	60,000	0.4514	-	-	60,000
Antonio Lambiase Clinical Development Director	Piano 2008 A	80,000	1.4797	-	-	80,000
	Piano 2008 B	70,000	1.4797	70,000	-	-
	Piano 2012 A	150,000	0.4514	-	-	150,000
	Piano 2012 B	100,000	0.4514	-	-	100,000
Paolo Rizzardi Research & Development Director	Piano 2008 A	70,000	1.4797	-	-	70,000
	Piano 2008 B	60,000	1.4797	60,000	-	-
	Piano 2012 A	150,000	0.4514	-	-	150,000
	Piano 2012 B	100,000	0.4514	-	-	100,000
Daniele Pieraccioli Intellectual Property Director	Piano 2008 B	100,000	1.4797	100,000	-	-
	Piano 2012 A	90,000	0.4514	90,000	-	-
	Piano 2012 B	60,000	0.4514	60,000	-	-
Cynthia Giuliani Human Resources Director	Piano 2008 B	70,000	1.4797	70,000	-	-
	Piano 2012 A	90,000	0.4514	-	-	90,000
	Piano 2012 B	60,000	0.4514	-	-	60,000
Celia Traversari Research Director	Piano 2008 A	50,000	1.4797	-	-	50,000
	Piano 2008 B	40,000	1.4797	40,000	-	-
	Piano 2012 A	90,000	0.4514	-	-	90,000
	Piano 2012 B	60,000	0.4514	-	-	60,000
<b>Total</b>		<b>9,000,000</b>		<b>2,750,000</b>		<b>6,250,000</b>

**Note 34 – 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.l.), 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 4,131 thousand Euro 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.

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 favorable than the previous terms. Therefore, the Company may have to turn to third parties. In addition, until the termination of the option agreement becomes effective (i.e. March 4, 2016), MolMed may exercise this option on projects of interest.

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 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 (upfront payments, milestones and royalties), based on the product development stages.

MolMed also signed scientific research and cooperation agreements, which are generally associated with in-licensing 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 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 centers.

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 agreement was entered into in early 2010, superseding the previous leases in force up to 2009. The agreement was to run until the end of 2015 and included terms more favorable to 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 favorable 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 a current and savings account with Banca Esperia S.p.A. and a current and savings account with Banca Mediolanum S.p.A. Within this framework, it manages the liquidity which is not temporarily absorbed by the Company's operations. 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 2014:

<i>(amounts in Euro thousand)</i>	Revenues	Financial income	Costs for services	Costs for use of third-party assets	Financial charges
Science Park Raf S.p.A. in liquidazione	-	-	280	840	-
Fondaz. M.te Tabor in liquidazione	-	-	-	-	-
Fondazione Centro S.Raffaele	-	-	-	-	-
Ospedale San Raffaele S.r.l.	111	-	534	-	-
Diagnostica San Raf S.p.A	-	-	11	-	-
HSR Resnati S.p.A.	-	-	12	-	-
Banca Esperia S.p.A.	-	17	-	-	-
Banca Mediolanum S.p.A.	-	-	-	-	-
Alba Servizi Aerotrasporti S.p.A.	-	-	-	2	-
<b>Total</b>	<b>111</b>	<b>17</b>	<b>837</b>	<b>842</b>	<b>-</b>
<b>Financial statements item</b>	<b>11,181</b>	<b>70</b>	<b>11,165</b>	<b>1,236</b>	<b>445</b>
<b>% on financial statements item</b>	<b>1%</b>	<b>24%</b>	<b>7%</b>	<b>68%</b>	<b>0%</b>

Revenues of 111 thousand Euro mainly arise from the services provided by MolMed to Ospedale San Raffaele.

The costs for services, amounting to 837 thousand Euro, relate 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 842 thousand Euro relate to lease payments provided for by the contracts signed with Science Park in liquidation for the premises occupied by the Company within the San Raffaele Science Park.

Financial income and charges relates to income and expenses for the management of bank deposit accounts and investments in securities held with Banca Esperia and Banca Mediolanum.

**Equity impact**

(amounts in Euro thousand)

	Other non-current assets	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	-	66	-	-
Fondaz. M.te Tabor in liquidazione	-	110	-	-	59
Fondazione Centro S.Raffaele	-	5	-	-	-
Ospedale San Raffaele S.r.l.	75	-	450	-	90
Diagnostica San Raf S.p.A	-	-	-	-	-
HSR Resnati S.p.A.	-	-	-	-	2
Banca Esperia S.p.A.	-	-	-	-	-
Banca Mediolanum S.p.A.	-	-	-	-	-
Mediobanca S.p.A.	-	-	-	-	-
Gestipark S.Raffaele	-	-	-	-	-
Alba Servizi Aerotrasporti S.p.A.	-	-	-	-	-
<b>Total</b>	<b>86</b>	<b>115</b>	<b>516</b>	<b>-</b>	<b>151</b>
<b>Financial statements item</b>	<b>1,586</b>	<b>4,364</b>	<b>1,734</b>	<b>11,384</b>	<b>9,852</b>
<b>% on financial statements item</b>	<b>5%</b>	<b>3%</b>	<b>30%</b>	<b>0%</b>	<b>2%</b>

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 totaled 4,131 thousand Euro, 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 minimum duration.

Trade receivables and payables reflect the trends in invoicing and payment of services linked to the above-mentioned 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 95 thousand Euro 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 28 thousand Euro allocation made in 2011.

Other receivables and sundry assets consist of a 516 thousand Euro fee agreed for the aforementioned agreement to buy research projects.

Cash and cash equivalents consist of bank deposit accounts.

For information on stock options granted to Directors and Executives with strategic responsibilities, reference should be made to *Note 33*.

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 35 – Significant non-recurring events and transactions**

Pursuant to the Consob Communication of July 28, 2006, it should be noted that during 2014 the Company carried out the above-mentioned capital increases, which qualify as significant non-recurring transactions:

(amounts in Euro thousand)	Equity		Profit (loss) for the year		Cash flow	
	Value	%	Value	%	Value	%
<b>Value</b>	<b>12,082</b>	<b>%</b>	<b>(13,003)</b>	<b>%</b>	<b>(1,859)</b>	<b>%</b>
Capital increase effect 2014	(4,969)	(41%)	-	-	(4,969)	267%
Shareholders' advance payment for share capital increase 2015	(8,593)	(71%)	-	-	(8,593)	-
Capital increase SEF effect	(1,506)	(12%)	-	-	(1,506)	-
Income from capital increase 2014	(45)	(0%)	(45)	0%	(45)	2%
Capital increase costs 2015	306	3%	-	-	306	(16%)
<b>Gross notional value</b>	<b>(2,725)</b>		<b>(13,048)</b>		<b>(16,666)</b>	

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

Pursuant to Consob Communication of July 28, 2006, it should be noted that, during the period, the Company did not enter into any atypical or unusual transactions. The Communication defines as atypical or unusual transactions those transactions that may raise doubts as to the accuracy/completeness of the information in the Financial Statements, the existence of conflicts of interest, the safeguarding of the 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 37 - 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, 2008 (*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 Directors	Fee for presence Board of Directors	Defined Fee Committee	Fee for presence Committee	Variable fee		Non monetary fee	Other fee	Total
									Bonus and other incentives	Partecip. in profit			
<b>DIRECTORS</b>													
Claudio Bordignon	Chairman and CEO	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements	750	12	10					69		841
Romolo Bardin	Director	01.01.2014-14.04.2014	on approval of 2015 Fin.Statements		3	3							6
Maurizio Carfagna	Director	01.01.2014-01.08.2014	on approval of 2015 Fin.Statements		7	4							11
Germano Carganico	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	9							21
Alberto Luigi Carletti	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	10							22
Riccardo Cortese	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	8	5	3					28
Marina del Bue	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	10							22
Gianluigi Fiorendi	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	10	15	12					49
Sabina Grossi	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	9	5	1					27
Khalid Islam	Director	08.09.2014-31.12.2014	on approval of 2015 Fin.Statements		4	2							6
Mario Masciocchi	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	10	15	12					49
Alfredo Messina	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	10							22
Raffaella Ruggiero	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	10	20	14					56
Lorenzo Salieri	Director	01.01.2014-31.12.2014	on approval of 2015 Fin.Statements		12	10							22
				<b>750</b>	<b>146</b>	<b>115</b>	<b>60</b>	<b>42</b>	-	-	<b>69</b>		<b>1160</b>
<b>STATUTORY AUDITORS</b>													
Fabio Scoyni	Chairman of Board	22.04.2013-31.12.2014	on approval of 2015 Fin.Statements		30								30
Enrico Scio	Statutory auditor	22.04.2013-31.12.2014	on approval of 2015 Fin.Statements		20								20
Flavia Daunia Minutillo	Statutory auditor	22.04.2013-31.12.2014	on approval of 2015 Fin.Statements		20								20
				-	<b>70</b>	-	-	-	-	-	-	-	<b>70</b>
<b>GENERAL MANAGERS</b>													
Marina Del Bue		01.01.2014-31.12.2014	Indefinite	356					53		3		412
Germano Carganico		01.01.2014-31.12.2014	Indefinite	350					56		4		410
				<b>706</b>	-	-	-	-	<b>109</b>	-	<b>7</b>	-	<b>822</b>
<b>OTHER MANAGERS WITH STRATEGIC RESPONSIBILITIES</b>													
		01.01.2014-31.12.2014	Indefinite										
No. 6 managers with strategic responsibilities *				<b>657</b>					<b>97</b>		<b>12</b>		<b>766</b>

On April 22, 2013, the Board of Directors decided to grant 750 thousand Euro to the Company's Chairman and CEO Claudio Bordignon by way of annual remuneration until the end of his term of office, and another 750 thousand Euro, 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.

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 and Chief Executive Officer 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 38 – 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 2014 and 2013 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 2014	Fees for 2013
Audit	Deloitte & Touche S.p.A.	79 (3)	60 (1)
Certification services	Deloitte & Touche S.p.A.	53 (4)	2 (2)
<b>Total</b>		<b>132</b>	<b>62</b>

(1) Audit of Statutory Financial Statements and limited audit of the half-year report and control activities on accounting procedures and reporting of operating events

(2) Activities relating to the preparation of *Modello Unico* and *Modello 770* tax returns

(3) Audit of Statutory Financial Statements, limited audit of the half-year report, limited audit of September 30, Report and control activities on accounting procedures and reporting of operating events

(4) Activities related to the signing *Modello Unico* and the *Modello 770* and the issuance of the opinion 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 39 – 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. The available liquidity arising from stock exchange listing was invested in current account deposits, government and corporate bonds. Their yield depends on the trend 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 the exposure to interest rate risk can be determined through a sensitivity analysis, in accordance with IFRS 7. This analysis shows the effects of a given assumed change in the levels of the relevant variables on financial charges and income and, at times, directly on equity. The sensitivity analysis was carried out on the basis of the following assumptions:

- the analysis was performed by applying reasonably possible changes of the relevant risk variables to the figures of the Financial Statements at December 31, 2014 and 2013, 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.

<i>(amounts in Euro thousand)</i>	2014		2013	
	effect on financial income		effect on the fair value reserve	
Shift compared to zero-coupon	+1%	-1%	+1%	-1%
Effect	114	(114)	-	-

### 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

## FROM GENES TO THERAPY

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 33](#).

### 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, 2014.

Class of financial instruments	Measurement criteria for financial instruments in the Statutory Financial Statements					
	Financial instruments at fair value through		Financial instruments at amortized	Book value at December 31, 2014	Fair value at December 31, 2014	of which fair value reserve
	profit or loss	equity				
(1)	(2)	(3)				
<b>Assets</b>						
Cash and cash equivalents	-	-	11,384	11,384	11,384	-
Financial assets	-	-	6	6	6	-
Trade receivables	-	-	4,364	4,364	4,364	-
<b>Liabilities</b>						
Trade payables	-	-	9,852	9,852	9,852	-
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, 2014	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)
<b>Assets</b>						
Cash and cash equivalents	34	-	-	-	-	34
Financial assets	-	-	-	-	-	-
Trade receivables	-	-	-	-	-	-
<b>Liabilities</b>						
Trade payables	-	-	-	-	-	-
Finance lease payables	(2)	-	-	-	-	(2)
Other financial debts	(150)	-	-	-	-	(150)
<b>IAS 39 categories - total</b>	<b>(118)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(118)</b>

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, 2014 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, 2014, it recorded a positive net financial position of 11,390 thousand Euro, mainly consisting of cash and cash equivalents. 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 aimed at improving the management of financial resources and reducing liquidity risk:

- keeping an adequate level of cash and cash equivalents;
- constant monitoring of the financial flows generated by the Company's operations and of the net financial position, so that any necessary actions can be taken forthwith;
- monitoring of prospective liquidity conditions related to corporate planning.

For 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 40 – Significant events after the reporting period*

For further information on significant events after the reporting period, reference should be made to paragraph *15.1 Significant events after the reporting period*.

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

During the Board of Directors’ meeting of November 12, 2012, based on the amendments to Articles 70 and 71 of the Issuers’ Regulations introduced by Consob resolution 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 Chief Executive Officer, 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 2014.
- Measurement of the adequacy of the administrative and accounting procedures used for the preparation of the Financial Statements at December 31, 2014 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, 2014:
  - 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, 24 2015

[Signed by]

Claudio Bordignon  
Chairman of the Board of Directors and  
Executive Officer

[Signed by]

Andrea Quaglino  
Executive Officer responsible for preparing  
Company financial reports

*Report of the external auditors*



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**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.**

1. We have audited the financial statements of MolMed S.p.A., which comprise the statement of financial position as of December 31, 2014, and the income statement, the statement of comprehensive income, the statement of changes in equity and the statement of cash flow for the year then ended, and a summary of significant accounting policies and other explanatory notes. These financial statements prepared 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° 38/2005 are the responsibility of the Company's Directors. Our responsibility is to express an opinion on these financial statements based on our audit.
2. We conducted our audit in accordance with the Auditing Standards recommended by CONSOB, the Italian Commission for listed Companies and the Stock Exchange. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by the Directors, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

For the opinion on the prior year's financial statements, whose data are presented for comparative purposes, reference should be made to our auditors' report issued on March 18, 2014.

3. In our opinion, the financial statements give a true and fair view of the financial position of MolMed S.p.A. as of December 31, 2014, and of the results of its operations and its 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° 38/2005.

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



4. In order to provide a better understanding of the statutory financial statements, we draw attention to the information provided in the Report on Operations, “Risks associated with funding for research and development activities”, “Capital increase of 5 million Euro completed in April 2014 and capital increase of 50 million Euro completed in April 2015” and “Subsequent events” and in the Notes “Going concern”, regarding the fact that the Company has incurred in current fiscal year losses of Euro 13,003 thousand, due to the business model of biotech companies. At this stage, negative cash flows have been incurred relating to significant costs sustained for the clinical and pharmaceutical development of investigational new drugs, where economic return of such investments in future years remains uncertain. In this framework, the Directors state that, based on the analysis of future cash flows projected by the 2015-2017 business plan, approved on April 9, 2015 based on the most recent available information following the end of the capital increase on the same date, 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 the approval of 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.
5. The Directors of MolMed S.p.A. are responsible for the preparation of the Report on Operations and the Annual Report on corporate governance, published in the Investors/Corporate Governance/Corporate Governance system section of the MolMed S.p.A..Web site, in accordance with the applicable laws and regulations. Our responsibility is to express an opinion on the consistency of the report on operations and of the information reported in compliance with art. 123-bis of Italian Legislative Decree n. 58/1998, paragraph 1, letters c), d), f), l), m) and paragraph 2, letter b) in the annual report on corporate governance, with the financial statements, as required by law. For this purpose, we have performed the procedures required under Auditing Standard n. 001 issued by the Italian Accounting Profession (CNDCEC) and recommended by CONSOB. In our opinion, the Report on Operations and the information reported in compliance with art. 123 bis of Italian Legislative Decree n. 58/1998 paragraph 1, letters c), d), f), l), m) and paragraph 2, letter b) included in the Annual Report on Corporate Governance are consistent with the financial statements of MolMed S.p.A. as of December 31, 2014.

DELOITTE & TOUCHE S.p.A.

*Signed by*  
Patrizia Arienti  
Partner

Milan, Italy  
April 30, 2015

*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 Article 153 of Legislative Decree 58/1998*

Dear Shareholders,

this Report illustrates the activities carried out by the Board of Statutory Auditors during 2014 and until today, pursuant to Consob Communication DEM/1025564 of April 6, 2001 and subsequent amendments and additions.

During the year ended December 31, 2014, the Board of Statutory Auditors of MolMed S.p.A. (hereinafter the "Company") performed the supervisory activities provided for by the law, also taking account of the principles of conduct recommended by the Italian National Councils of Certified Public Accountants and Bookkeepers.

During 2014, the Board of Statutory Auditors acquired information that is instrumental to perform its general supervisory tasks by participating in the meetings of the Board of Directors and of the board committees (i.e. the Control and Risk Management Committee and the Remuneration Committee), meetings with the Company's top management, interviews with Company's management, meetings with the company in charge of the independent audit, meetings with the Internal audit department, the Supervisory Body pursuant to Law 231, analysis of the information flows acquired from the relevant corporate departments, as well as the appropriate control activities carried out during its meetings or during those held with the Control and Risk Management Committee. The Board of Directors as a whole, together with the members of the Board of Statutory Auditors, provides prior approval of significant or material transactions with related parties. The Board of Statutory Auditors has obtained information from the Directors on the activities undertaken and the most important transactions carried out at least on a quarterly basis.

MolMed is a medical biotechnology company, focused primarily on the research, development and clinical validation of innovative therapies for the treatment of tumors with high unmet medical need. The Company's product portfolio is innovative and diversified. Over the years, MolMed has developed specific skills in genetic and cell therapies, including the use of stem cells for various pathologies or tissues, which make the company one of the major players at the international level. MolMed also carries out specialized activities on behalf of third parties within the scope of this sector, offering high-level skills for the development, realization and validation of investigational therapies, from preclinical to Phase III trials, in addition to the development of innovative control procedures that comply with the requirements of the new advanced cell-based therapies.

1. Based on the information received from the corporate bodies and the outcome of the assessments made by the Board of Statutory Auditors, in carrying out its own supervisory activity, it emerged that the main economic, financial and equity operations carried out by the Company to implement the business plan and, specifically, develop the product portfolio and third-party operations involving genetic cell therapy, essentially comprise the following:

- pursuit of the clinical and pharmaceutical development of two anti-tumor treatments, which are being tested:
- TK, an investigational cell therapy product based on genetically engineered cells allowing for more safe and effective transplant of haemopoietic stem cells (HSCT) even from a partially compatible donor, thus opening to all patients the door for this therapy, which is the only potential curative treatment available, especially for high-risk leukemias. During 2014, the Company continued its investigation by enrolling new patients and filed a request of authorization for market placement with the European regulatory authority (EMA) through a specific procedure (Conditional Marketing Authorization) which is based on the Phase II clinical data. The EMA validated this request on March 26, 2014, thereby starting the case assessment process.

As for the production of TK, the project for the development, in cooperation with a German company, of automatic systems to be used in the production and control process of TK continued in 2014.

- NGR-hTNF, a new biological treatment meant to act on tumor blood vessels. The action of the treatment aims at functional alteration of tumor blood vessels, thus cutting off supplies to the tumor and thus blocking its growth. In early May 2014 Phase III trial of the product was completed: although it did not reach the primary end point concerning the overall survival (OS) of the whole population, there was a statistically significant 40% increase in both the overall survival as well as the disease-free survival in the population of poor-prognosis patients, whose diseases had progressed during or immediately after first-line chemotherapy. The production of the molecule – which is the active ingredient of the investigational drug – and the final drug product are outsourced to specialized companies. Also in 2014, MolMed continued the project to further increase the scale of NGR-hTNF commercial production, pursuing the same outsourcing strategy.
- GMP development and production activities on behalf of third parties. During 2014, the activities provided for by the two major agreements signed with Telethon and GlaxoSmithKline (GSK) continued in order to develop and produce highly innovative investigational gene therapies for a total of seven rare diseases, all caused by the malfunction of a single gene. Furthermore, the Company continued with the production, on behalf of GSK, of a compassionate use investigational gene therapy for patients affected by Adenosine Deaminase Deficiency – Severe Combined Immune Deficiency (ADA-SCID).
- Securing the necessary financial resources to support the Company's development plan. In 2014, a capital increase was approved and successfully completed, as resolved by the Extraordinary Shareholders' Meeting of March 3, 2014. The capital increase concluded on April 4, 2014 with the full subscription of 8,252,092 newly issued ordinary shares for an overall amount of Euro 4,969 thousand.

On July 31, 2014, the Company's Board of Directors agreed to sign a “SEF – Standby Equity Facility” (SEF Agreement) with Société Générale. In particular, under said Agreement, Société Générale committed to subscribe to the Company's capital increase to be carried out in several tranches, with the exclusion of the pre-emption right, pursuant to Article 2441, paragraph 4, second sentence, and Article 2443 of the Italian Civil Code. The capital increase shall be completed no later than July 31, 2016, issuing up to 46,000,000 ordinary shares, i.e. 19.9% of MolMed's shares outstanding as at the date of the Agreement, based on subscription requests made by MolMed to the counterparty according to the terms and conditions of the Agreement.

On September 23, 2014, the Board of Directors executed the SEF Agreement and exercised the powers assigned to it pursuant to Article 2443 of the Italian Civil Code by the Extraordinary Shareholders' Meeting held on September 8, 2014 and submitted to SG a request to subscribe to the first tranche of the reserved capital increase. SG confirmed the subscription of 3,080,670 ordinary shares, i.e. a 1.32% investment in MolMed's share capital, for an aggregate amount equal to Euro 1,505,524. The transaction concluded on September 29, 2014.

Furthermore, on February 23, 2014 and in view of the power assigned to it by the Extraordinary Shareholders' Meeting of March 3, 2014 to increase the Company's capital for a total maximum amount of Euro 50,000,000 including the relevant share premium, in one or more tranches by and no later than December 31, 2016 through the issue of ordinary shares, to be offered with pre-emption rights to the Company's shareholders pursuant to Article 2441, paragraph 1 of the Italian Civil Code, the Board of Directors resolved to increase the Company's capital up to a maximum amount of Euro 50 million.

The transaction was concluded in the months of March and April 2015 with the subscription of the entire proposed capital increase.

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

The Board of Statutory Auditors has confirmed that the transactions referred to above comply with the law, the company by-laws and the principles of good management, having ensured that they were not manifestly imprudent or risky, or potentially in 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 are subject to the transparency procedures set forth in the relevant provisions.

2. The Board of Statutory Auditors did not ascertain, during the year 2014 or after the reporting period, any atypical and/or unusual corporate transactions carried out with third parties or with related parties. Information on transactions carried out with related parties in the year 2014, along with a description of the characteristics and economic effects of such transactions, is found in the Report on Operations (point 10.3), in the Notes (no. 34), in the Statement of Financial Position and in the Income Statement. During the year 2014, the Board of Statutory Auditors, also through joint meetings with the Control and Risk Management Committee, verified whether the Company has implemented actions aimed at ensuring both the procedural and substantial 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 n. 17221 of March 12, 2010 and subsequent amendments. The Board of Statutory Auditors verified that the procedure adopted by the Company complies with the principles indicated by Consob and that it was actually carried out.
3. Taking into account the Company's structure and size, and the lack of atypical and/or unusual transactions, the Board of Statutory Auditors considers that the information on the Company's transactions with related parties, shown in the 3 notes to MolMed's 2014 financial statements is considered adequate.
4. On April 30, 2015 the external auditors Deloitte & Touche issued their report pursuant to Articles 14 and 16 of Legislative Decree 39/2010, in which the firm certifies that the Financial Statements at December 31, 2014 comply with the criteria used for their preparation, that 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 also certify that the Report on Operations and the information – as set out in paragraph 1, letters c), d), f), l), m) and paragraph 2, letter b) of Article 123-bis of the Consolidated Law on Finance – included in the report on corporate governance and ownership structure are in line with MolMed S.p.A.'s financial statements at December 31, 2014. Finally, the external auditors «focused on the Directors' analysis included in the Report on Operations in the sections "Risks associated with funding research and development activities", "Capital increase of Euro 5,000,000 concluded in April 2014 and capital increase of Euro 50 million concluded in April 2015", and "Significant events after the reporting period" and the Notes in the section "Going concern," regarding the fact that during the year the Company incurred a loss of Euro 13,003 thousand and that this situation is typical of the business model of biotech companies during the development of new products, the economic return on which is uncertain by its very nature and in any case expected for future years. Against this background, the Directors note that, on the basis the analysis of the future cash flows provided for by the 2015-2017 business plan, approved on April 9, 2015 based on the most recent available information following the capital increase concluded on that date, the available financial and equity resources will guarantee adequate funding to continue the Company's operations in the foreseeable future and for 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».
5. During the year, no complaints of the type referred to under Article 2408 of the Italian Civil Code, notifications or reports were submitted to the Board of Statutory Auditors.

6. During 2014, the Company assigned to the external auditors Deloitte & Touche a task other than the auditing of the financial statements, whose fee, excluding VAT, is indicated below:

Task	Fee
on the issue price of the shares involved in the capital increase, excluding pre-emption rights	53,620

7. During 2014, the Company did not confer any duties on subjects connected to Deloitte & Touche on the basis of continuing relations and/or to companies belonging to the Deloitte & Touche network.
8. During the year 2014, the Board of Statutory Auditors did not issue to the Board of Directors, pursuant to Article 2389, paragraph 3, of the Italian Civil Code, any opinion on the fees paid to the Directors with key responsibilities.
9. During the year 2014, the Company's Board of Directors held 10 meetings, all of which were attended by the Board of Statutory Auditors.

The Control and Risk Management Committee met 12 times. The Remuneration Committee met 2 times. The Board of Statutory Auditors always took part in all the meetings of both Committees with at least one representative. The Board of Statutory Auditors held 17 meetings, 12 of which jointly with the Internal Control Committee. In addition, it took part in the Company's Shareholders' Meetings held on March 3, 2014, April 8, 2014 and September 8, 2014.

10. The Board of Statutory Auditors obtained information on and monitored compliance with the principles of good management, within the scope of its responsibilities, by constantly taking part in 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 the Supervisory body. With regard to the decision-making processes of the Board of Directors, the Board of Statutory Auditors has verified, in part 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 of outside professionals.

The Board of Statutory Auditors carefully monitored the company's financial position, encouraging the Board of Directors to consider the most appropriate initiatives to take in order to strengthen it and taking into account the actions taken to this end and concluded as part of the Company's business plan.

11. The Board of Statutory Auditors has obtained information on, and monitored the adequacy of, the Company's organizational structure through contact with 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.

As at December 31, 2014, MolMed S.p.A.'s organizational structure was broken down into four main operating divisions: Research, Drug development, Operations and Clinical development.

These structures report to the two Director Generals who, in their turn, report to the Chairman and to the Chief Executive Officer.

The aforementioned operating divisions are supported by a system of horizontal departments consisting of the following divisions: Administration, Finance and Control, Human Resources, Business Development and Investor Relations, Intellectual Property, Information Technology.

At December 31, 2014, the Company's total staff consisted of 115 employees and 14 temporary staff members.

The Board of Statutory Auditors expresses a positive judgment on the organizational structure, which appears adequate to implement the measures necessary for the achievement of corporate targets and adequate with respect to the size of the Company, the activities to be performed and the coordination measures to be implemented.

Based on the assumption that people constitute the most important factor for the success of a business, the Company has made a noteworthy effort to improve its styles of management, as well as the motivation and training of personnel. Significant training activities have been undertaken with regard to the governance system adopted, the Organizational Model pursuant to Legislative Decree 231/2001 and liability for crimes involving the misuse of price sensitive information and the manipulation of markets. In addition, specific scientific training programs have been carried out, as well as training on information technology, safety and the protection of personal data.

12. 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 ongoing 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 information 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 help of the Control and Risk Management Committee, defines the guidelines for the internal control system, checks its adequacy, effectiveness and correct operation, all with the aim of ensuring that the main corporate risks (operating, economic, financial and compliance) are adequately highlighted, monitored and managed.
- Executive Director, responsible for overseeing the functioning of the internal control system, has the tasks of identifying the main corporate risks; implementing the guidelines established by the Board of Directors; arranging the design, realization 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 allocated the functions of checking the adequacy and efficiency of the system and, should anomalies be found, putting forward corrective plans. This figure was identified by the Board of Directors in the head of the Internal Audit department. The Internal Audit Manager in operating terms is under the Company's Chairman, reports to the Control and Risk Management Committee and interacts with the Executive Director responsible for internal control.
- Control and Risk Management Committee. Assesses, together with the Executive Officer responsible for preparing company financial reports and the External Auditors, the correct use of accounting standards. At the request of the Executive Director responsible for audit, it expresses views on the identification of the corporate risks and on the design, realization and management of internal control system. It assesses work plans as well as the reports to the Internal Audit Manager and the External Auditors, oversees the effectiveness of the auditing process, assists the Board of Directors in carrying out its tasks regarding corporate internal audit and, in particular: a) in defining the guidelines for audit checks 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 effective operation of the internal control system.
- Internal Audit: it undertakes activities relating to and dependent on internal audit, in other words



services that can verify and improve the effectiveness and efficiency of the internal control system and risk management.

- Executive Officer responsible for preparing company financial reports: their duties are specified in detail by Article 154-bis of Legislative Decree 58/1998.

The "231 Model" completes the picture and governs the internal control system in relation to the contents of Legislative Decree 231/2001 on the administrative liability of organizations for crimes committed by their employees and collaborators.

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

During 2014, the Board acknowledged the overall assessment of the internal control system made by the Internal Audit Manager, who judged the internal control system to be adequate and functional for the purpose of reducing the risk profiles to an acceptable level for the correct operation of corporate processes. The Board of Directors has 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 the Company's financial reports, the management and the External Auditors.

13. The Board of Statutory Auditors has assessed and monitored the adequacy of the administrative-accounting system, as well as its reliability in terms of correctly depicting 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 has acknowledged the declarations made by the Chief Executive Officer, together with the Executive Officer responsible for preparing the Company's financial reports, regarding the adequacy - in relation to the business' characteristics - and the actual application of the administrative and accounting procedures for the preparation of the financial statements for 2014.

The Board of Statutory Auditors has also overseen the process of financial disclosure and has verified, including through information received from the Company's management, the adequacy and effectiveness of the procedure to produce and disclose information to the public.

14. The Board of Statutory Auditors has verified, 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 IAS/IFRS (as well as with relevant rules and regulations). Specifically: i) with regard to the structuring of information by sector of activity and by geographic area required under CONSOB regulations, the Company has identified a single business segment (see "Accounting principles" in the Financial Statements); ii) the information called for under CONSOB Resolution 15519 of July 27, 2006, as well as CONSOB notification DEM/6064293 of July 28, 2006, has been supplied; iii) the information referred to in document no. 2 of February 6, 2009 of the Bank of Italy, CONSOB and Isvap has been supplied; in particular, Directors have indicated 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.

15. The Board of Statutory Auditors has overseen the procedures for correct implementation of the rules of corporate governance provided for under the Code of Self-Discipline prepared by the Corporate Governance Committee of Borsa Italiana in December 2012, adopted by the Company.

MolMed has adopted the criteria set out in the Code of Self-Discipline of Borsa Italiana as far as independent Directors are concerned. Based on the information provided by the Directors themselves, the Board of Directors has checked whether the independence requirements of the three non-executive Directors, who are qualified as independent, existed.

The Board of Statutory Auditors has also checked whether the independence requirements of its own

members, pursuant to Article 148, paragraph 3, of the Consolidated Law on Finance, and those set out in the Code of Self-Discipline of Borsa Italiana exist.

16. 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.
17. The Board of Statutory Auditors, having seen the financial statements at December 31, 2014, has no objections to raise regarding the proposals presented by the Board of Directors on covering the loss for 2014.

On March 19, 2015, Director Riccardo Cortese resigned from his office as independent, non-executive member of MolMed's Board of Directors, effective from April 1, 2015. Following this resignation, the Board decided not to replace him immediately by co-optation, as it deemed it correct to allow the Shareholders' Meeting to decide upon this issue, given the time required to find an appropriate candidate, and the fact that the next Shareholders' Meeting was upcoming.

For this reason, you will be called to resolve also on the designation of a new director replacing the resigning Director, or to decrease the number of members of the Board of Directors from 12 to 11.

Milan, Thursday, April 30, 2015

The Statutory Auditors

Fabio Scoyni (Chairman of the Board of Statutory Auditors)

Flavia Daunia Minutillo (Statutory Auditor)

Enrico Scio (Statutory Auditor)