

# MolMed: Board of Directors approved 2018 Full Year financial results.

Financial results significantly improved compared to 2017, with a net loss of the period reduced by more than 50%:

- Revenues from sales equal to Euro 28.5 million, increased by 23.7% compared to Euro 23.0 million of 2017;
- Operating Result and Net Result, respectively equal to a loss of Euro 3.9 million and Euro 4.1 million, reduced by 52.6% and 51.5% compared to a loss of Euro 8.1 million and Euro 8.5 million of 2017;
- Net Financial Position equal to Euro 16.5 million compared to Euro 18.1 million as of December 31st 2017.

Milan (Italy), March 18<sup>th</sup>, 2019 - The Board of Directors of MolMed S.p.A. (MLMD.MI), a biotechnology company focused on research, development, production and clinical validation of gene and cell therapies for the treatment of cancer and rare diseases, met today under the chairmanship of Carlo Incerti, reviewed and approved the draft Financial Statements for the Full Year 2018.

Riccardo Palmisano, MolMed's CEO commented on the results for the year and the evolution of the business: "The results for the 2018 financial year confirm the trend observed throughout the year and show a clear improvement when compared to those of 2017, with Operating revenues of nearly 30 million Euro and Operating losses reduced by 50%, mainly as a consequence of the increase in Operating revenues and focused management of priorities and costs. Despite the unexpected and premature termination of Zalmoxis licensing and commercialization agreement with Dompé, 2018 was characterized by a series of very positive events for the future development of the Company: on the side of proprietary products we successfully negotiated the price and reimbursement of the same Zalmoxis with the German authorities; we submitted to the Regulatory Authorities the dossier for the authorization of the first clinical phase I/II study on hematological tumors (AML and MM) with the CAR-T CD44v6 and above all we signed agreements with AbCheck and with Glycostem to expand our pipeline of CARs, both autologous and allogeneic. With regard to third party GMP services, whose turnover increased by 18.2% when compared to prior year, we successfully managed the transfer of Tiget / Telethon products to Orchard, which entrusted us with the development of two additional products of their pipeline. Most importantly, we signed a new contract with GSK to develop its new cell & gene product line in the oncology field, and a five-year Master Service Agreement for a rare disease project with Boston Children's Hospital. On these excellent bases we are preparing for a 2019 in which the priorities will be the identification of a new commercial partner for Zalmoxis, the beginning of the phase I / II clinical study



on hematological tumors (AML and MM) for the CAR-T CD44v6 and the parallel completion of the dossier to start the phase I / II clinical study on solid tumors, the development of the new CAR pipeline, with the publication of the first pre-clinical data, and a double-digit growth in the turnover of the development and manufacturing activities for third parties".

# Key financial results as of December, 31st 2018

(amounts in Euro thousand)	FY 2018	FY 2017	Variation	
	(a)	(b)	(a-b)	%
Operating Revenues	29,880	23,987	5,893	24.6%
Revenues	28,447	23,000	5,447	23.7%
Other revenues	1,443	987	456	46.2%
Operating costs	(33,745)	(32,135)	(1,610)	5.0%
Operating result	(3,865)	(8, 148)	4,283	(52.6%)
Net financial income & charges	(258)	(349)	91	(26.1%)
Result for the period	(4,123)	(8, 497)	4,374	(51.5%)

**Operating revenues** are equal to Euro 29,880 thousands and increased by Euro 5,893 thousands or by 24.6%, when compared to previous year. Specifically, Revenues from sales, equal to Euro 28,447 thousands, increased by Euro 5,447 thousands or by 23.7%, compared to 2017, when they were equal to Euro 23,000 thousands.

# Revenues from sales include:

- revenues from development and manufacturing activities for third parties, totaling Euro 24,224 thousands, from Euro 20,500 thousands as of December 31<sup>st</sup> 2017, with an increase of Euro 3,724 thousands or by 18.2%;
- revenue from the product Zalmoxis<sup>®</sup>, equal to Euro 4,223 thousands, of which Euro 4,000 as milestone related to the agreement with Dompé, signed on July, 26<sup>th</sup> 2017, on Zalmoxis<sup>®</sup> license and commercialization, and from its mutual termination, on November 12<sup>th</sup> 2018; and Euro 223 thousands from the sale of the product under AIFA funding scheme.

**Other Revenue**, totaling Euro 1,433 thousands from Euro 987 thousands as of December 31st 2017, with an increase of Euro 446 thousands or by 45.2%, mainly thanks to the tax credit income accounted for pursuant to "Decree of May 27th 2015 implementing the tax credit for research and development activities".

**Operating Costs**, equal to Euro 33,745 thousands, increased by Euro 1,610 thousands or by 5.0%, compared to 2017 (Euro 32,135 thousands), mainly due to:

• increased Service costs by Euro 910 thousands or by 8.4%, due to higher external development costs by Euro 1,608 thousands, increased maintenance costs by Euro 230 thousands, a decrease of license and patent fee costs by Euro 514 thousands and decreased market access costs by Euro 643 thousands;



• increased Costs from purchases of raw materials and consumables by Euro 474 thousands or by 8.8%, totaling from Euro 5,393 thousands in 2017, Euro 5,867 thousands in 2018, mainly for the development of the pipeline product.

Thanks to Operating revenues more than proportional increased compared to Operating costs, **Operating Result** is equal to a loss of Euro 3,865 thousands, and shows an increase of Euro 4,283 thousands or by 52.6% compared to the loss of the previous year equal to Euro 8,148 thousands.

**Financial result** is negative for Euro 258 thousands, with a decrease of Euro 91 thousands or by 26.1% compared to December 31<sup>st</sup> 2017, negative for Euro 394 thousands. The decrease in loss is mainly due to lower financial charges in 2018 due to lower utilization fees from the *Standby Equity Facility* with Socièté Gènérale.

**Net result of the period**, equal to a loss of Euro 4,123 thousands, shows an increase of Euro 4,374 thousands or by 51.5% compared to the Net Result of 2017 (Euro 8,497 thousands).

**Investments** in tangible and intangible assets are equal to Euro 1,739 thousands, slightly decreased compared to 2017 (Euro 2,098 thousands), and are essentially related to renovation work at the new Bresso facility and, to a lower extent, to routine replacement of laboratory equipment and the purchase of new machinery to be used in the manufacturing processes, as well as to maintenance and improvement work on the existing GMP facility.

**Net Financial Position** on December 31<sup>st</sup> 2018 is positive for Euro 16,466 thousand, decreasing by Euro 1,645 thousands or by 9.1% compared to December 31<sup>st</sup> 2017 (positive for Euro 18,111 thousands), and it only consists of cash and cash equivalents and current financial receivables (corporate bonds), in absence of financial debt

# Main events occurred after December, 31st 2018

**January, 15**<sup>th</sup> **2019**: Transparency Commission of the French National Health Authority (HAS) conveyed a non-favourable opinion concerning the reimbursability of the orphan drug Zalmoxis® in the therapeutic indications granted by EMA (European Medicines Agency). The Commission considered that the submitted phase I and II data are currently not sufficient to justify a reimbursement by healthcare system.

**February**, **4**<sup>th</sup> **2019**: German public health insurance system (GKV) has approved the reimbursement of Zalmoxis® at a price of 130,000 Euros per infusion (ex-factory price excluding VAT). The cost per patient will be based on the approved dosing schedule, which allows from 1 to 4 infusions, until the immune-reconstitution is reached, and on the clinical experience, that shows an average of just over 2 infusions per patient. The agreement, in force as of February 15<sup>th</sup>, 2019, follows the authorization granted in February 2018 and the consequent drug evaluation and price negotiation process regulated by the AMNOG system. Thanks to this agreement, valid for the next 24 months, Zalmoxis® could be prescribed not only in the 2 transplant centers authorized hitherto, but in all the bone marrow transplant centers operating in Germany.

*March, 7<sup>th</sup> 2019*: renewed and extended the collaboration in the oncology field launched in March 2016 with Genenta Science, biotechnology company developing a new generation of hematopoietic stem cell immunogene therapies. Following the collaboration between the two companies, that allowed to successfully develop and validate the analytical manufacturing methods of Genenta's proprietary product Temferon™, MolMed has



been entrusted for the exclusive supply of the drug product to be used in in-human trials.

*March, 13<sup>th</sup> 2019*: renewed and extended to three new therapeutic indications the collaboration, launched in February 2017, with Rocket Pharmaceuticals Ltd. (NASDAQ: RCKT), US company specialized in the development of innovative therapies for the treatment of rare genetic diseases. With the renewal and extension of the development and manufacturing service agreement, initially related to a gene therapy product for the treatment of only Fanconi Anemia, Rocket Pharma will entrust MolMed with the activities related to the production of lentiviral vectors to be used in three new therapeutic indications.

#### **Business outlook**

During 2019, the Company foresees to proceed with the pivotal randomized Phase III trial (TK008) for the treatment of high risk leukemia in association with haploidentical transplant, also with the aim of identifying a new partner to launch the commercial development of Zalmoxis<sup>®</sup> in the shortest possible time or of pursuing direct marketing of the product in some areas of the European Community.

With reference to the CAR-T CD44v6 project, the Company plans to start clinical trials on humans with the commencement of the first clinical study of Phase I / II in hematological tumors (AML and MM) within the first half of 2019. In this regard, the authorization process for the clinical trial, which began in the first half of 2018, and started in Italy with the submission of the documentation to AIFA on 10 October 2018, currently under evaluation, is expected to proceed also in other European countries. Preparatory studies are also being completed to submit the application for authorization to human testing of the same CAR-T CD44v6 on solid tumors.

The business plan also foresees to continue the activities for the development the proprietary pipeline to continue, already started in the second quarter of 2018 with the agreements with Glycostem and AbCheck, aimed at developing new autologous and allogeneic CARs through the inclusion of new therapeutic targets and the introduction of innovative technological platforms, also through the search for new partnerships and opportunities aimed at strengthening internal pre-clinical research capabilities.

Lastly, in 2019 the gradual activation of the new Bresso facility is expected to continue, in line with the evolution of the portfolio of existing collaborations, which is continuously being strengthened. Also on the basis of the new areas available, business development activities will be increased with the aim of extending ongoing collaborations and signing new alliances for the development and manufacturing of cell & gene therapy products for third parties.

The Board of Directors also agreed to call the Ordinary Shareholders' Meeting of Molecular Medicine S.p.A. to be held on **April 30, 2019 at 10.00 AM on single call**, at "Sala Ascolto", Zambon OpenZone, via Meucci 3, Bresso (Milan), Italy, to discuss and pass a resolution on the following:

- approval of the statutory financial statements for the fiscal year ended December 31, 2018. Related and consequential resolutions
- 2. report on remuneration first section: resolution pursuant to article 123-*ter* of Italian Legislative Decree 58/98
- 3. appointment of the members of the Board of Directors, upon determination of their number; possible appointment of the Chairman; determination of term and remuneration. Related resolutions.



4. aappointment of the members of the Board of statutory auditors and determination of their remuneration. Related resolutions.

Notice of ordinary shareholders' meeting will be available to the public on March 19<sup>th</sup> 2019 on the Company's website (www.molmed.com) and on regulated information system 1Info-Storage (www.1info.it); in addition, it will be published in the national newspaper "II Giornale" on the same date.

The Board of Director report about the items on Shareholders' Meeting Agenda will be made available to the public on March 19<sup>th</sup> 2019 at the Company's registered office, on the Company's website (www.molmed.com) and on regulated information system 1Info-Storage (www.1info.it).

The further documentation of the Shareholders' meeting will be made available to the public, according to the methods envisaged by current regulations and in the terms indicated in the notice convening the meeting.

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The official manager responsible for preparing the Company's financial reports, Salvatore Calabrese, herewith attests, pursuant to Article 154-bis, paragraph 2 of the Legislative Decree 58/1998 ("Testo Unico della Finanza"), that the accounting disclosure contained in this press release matches documentary evidence, corporate books, and accounting records.

In this press release, use is made of "alternative performance indicators" which are not provided for under European IFRS, and whose significance and content - in line with Recommendation CESR/05-178b published on November 3, 2005 - are illustrated below:

- Operating Result: defined as the difference between sales revenues and other income and costs for materials, costs of services received, costs for use of third-party assets, personnel costs and amortization, depreciation & write downs. It represents the profit before financial flows and taxes;
- Net Financial Position: is the algebraic sum of cash, cash equivalents, financial receivables and other financial assets, and current and non-current financial debt.

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## About MolMed

MolMed S.p.A. is a clinical stage biotech company focused on research, development, manufacturing and clinical validation of innovative therapies. MolMed's product portfolio includes proprietary anti-tumor therapies in both clinical and preclinical development: Zalmoxis® (TK) is a cell therapy based on donor T cells genetically engineered to enable bone marrow transplants from partially compatible donors for patients with high-risk hematological malignancies, eliminating post-transplant immunosuppression prophylaxis and inducing a rapid immune reconstitution. Zalmoxis®, that received orphan drug designation and is currently in Phase III in a high-risk population of acute leukemia patients, but has already obtained a Conditional Marketing Authorization by the European Commission in the second half of 2016 as well as reimbursement conditions in Italy and in Germany at the beginning of 2018. Still focusing on this cell & gene technology, the Company is developing a new therapeutic platform based on Chimeric Antigen Receptor (CAR), both autologous and allogeneic; the



most advanced product, CAR-T CD44v6, is looking forward to receive the authorization to start human clinical trials in onco-hematologic indications (AML and MM), following an extensive pre-clinical phase; the product is potentially effective also in several epithelial solid tumors. With regards to allogeneic CARs, MolMed is developing a pipeline based on NK (Natural Killer) cells, following a research agreement signed in 2018 with Glycostem. MolMed is also the first company in Europe to have obtained the GMP manufacturing authorization for cell & gene therapies for its proprietary products (Zalmoxis®) as well as for third parties and/or in partnership (Strimvelis, an Orchard (Nasdaq: ORTX) gene therapy for the ADA-SCID). With reference to GMP development and manufacturing activities for third parties, MolMed signed numerous partnership agreements with leading European and US companies. In the field of innovative oncological therapies MolMed pipeline also includes NGR-hTFN, a therapeutic agent for the treatment of solid tumors. MolMed, founded in 1996 as an academic spin-off of the San Raffaele Scientific Institute, is listed on the main market (MTA) of the Milan stock exchange managed by Borsa Italiana since March 2008. MolMed is headquartered and based in Milan, at the San Raffaele Biotechnology Department (DIBIT) and has an operating unit at OpenZone in Bresso.

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## **Appendices**

- Income Statement for the year ended December 31st 2018
- Balance Sheet as of December 31st 2018
- Cash Flow Statement for the year ended December 31st 2018
- Net Financial Position as of December 31st 2018
- Statement of changes in Equity



# Income Statement for the year ended December 31st 2018

(amounts in Euro thousand)	Year 2018	Year 2017
Revenues from sales	28,447	23,000
Other revenues	1,433	987
Total operating revenues	29,880	23,987
Purchases of raw materials and consumables	(5,867)	(5,393)
Costs for services	(11,717)	(10,807)
Costs for use of third-party assets	(1,507)	(1,472)
Personnel costs	(12,902)	(12,928)
Other operating costs	(105)	(186)
Amortization and depreciation	(1,647)	(1,349)
Total operating costs	(33,745)	(32,135)
Operating result	(3,865)	(8,148)
Financial income	48	204
Financial charges	(306)	(553)
Net financial income (charges)	(258)	(349)
Pre-tax result	(4,123)	(8,497)
Income taxes	-	_
Profit (loss) for the year	(4,123)	(8,497)
(amounts in Euro)	FY 2018	FY 2017
Basic earnings/(loss) per share	(0.0089)	(0.0194)
Diliuted earnings/(loss) per share	(0.0089)	(0.0194)





# Balance sheet as of December 31th 2018

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





# Cash Flow Statement for the year ended December $31^{st}$ 2018

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





# Net Financial Position as of December 31st 2018

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

# Statement of changes in Equity as of December $31^{th}2018$

(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Fair value valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2016	19,842	45,764	223	416	(12)	(	(13,520)	(20,784)	31,929
Allocation of prior year result	-	-	-	-	-	-	(20,784)	20,784	-
Personnel costs for stock options 2012	-	-	-	14	-	-	-	-	14
Other variations - stock options, Plan 2012	-	-	-	(208)	-	-	208	-	-
Personnel costs for stock options 2016-2021	-	-	-	29	-	-	-	-	29
Capital increase dedicated to SG	471	3,775	-	0	-	-	-	-	4,246
Capital increase expences capitalized	-	- 192	-	0	-	-	-	-	- 192
Profit (loss) for the year	-	-	-	-	(1)	-	-	(13,876)	(13,877)
Balance at December, 31 2016	20,313	49,347	223	251	(13)	-	(34,096)	(13,876)	22,149
(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Fair value valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2017	20,313	49,347	223	251	(13)	(	(34,096)	(13,876)	22,149
Allocation of prior year result	-	-	-	-	-	-	(13,876)	13,876	-
Personnel costs for stock options 2016-2021	-	-	-	151	-	-	-	-	151
Other variations - stock options, Plan 2016-2021	-	-	-	(6)	-	-	6	-	-
Capital increase dedicated to SG	1,201	9,692	-	-	-	-	-	-	10,893
Capital increase expences capitalized	-	(63)	-	-	-	-	-	-	(63)
Profit (loss) for the year	-	-	-	-	-	-	-	(8,497)	(8,497)
Balance at December, 31 2017	21,514	58,976	223	396	(13)	-	(47,966)	(8,497)	24,633
(amounts in Euro thousand)	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Fair value valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at Jaunary 1st 2018	21,514	58,976	223	396	(13)	(	(47,966)	(8,497)	24,633
Allocation of prior year result	-	-	-	-	-	-	(8,497)	8,497	-
Other variations - stock options, Plan 2016-2021	-	-	-	(396)	-	-	396	-	-
Capital increase dedicated to SG	305	2,803	-	-	-	-	-	-	3,108
Capital increase expences capitalized	-	- 25	-	-	-	-	-	-	(25)
Profit (loss) for the year	-		-	-	2	-	-	(4,123)	(4,121)
Balance at December, 31 2017	21,819	61,754	223	-	(11)	-	(56,067)	(4,123)	23,595