



COMUNICATO STAMPA

MolMed: Board of Directors approved Full Year 2017 Results

Key strategic and operating targets for 2017 successfully achieved:

- *Market access and reimbursement for Zalmoxis® in two main European markets, Italy and Germany;*
- *Positive preclinical results on CAR T CD44v6 project in terms of efficacy on solid and liquid tumours and safety;*
- *New commercial agreements signed with Rocket Pharma and Collectis for GMP manufacturing and development;*
- *Bresso facility authorization process progressed as planned*

Financial results improved significantly:

- *Revenues from sales equal to Euro 23 million, increased by 18.0% compared to 2016, also thanks to the agreements on Zalmoxis®;*
- *Operating Result and Net Result increased notably, respectively by 40.0% and 38.8% compared to 2016;*
- *Net Financial Position equal to Euro 18.1 million (Euro 19.7 million at December 31st 2016).*

Milan (Italy), March 2018 – The Board of Directors of MolMed S.p.A. (MLMD.MI) a medical biotechnology company focusing on research, development, manufacturing, and clinical validation of innovative therapies to treat cancer, met today under the chairmanship of Professor Claudio Bordignon, reviewed and approved the draft Financial Statements for the Full Year 2017.

Riccardo Palmisano, CEO of MolMed, commented: “2017 marked the achievement of important operating and strategic milestones as well as a progression in the enhancement of MolMed’s value, which, since 2015 is also reflected in the financial results. The procedure to access the European market for Zalmoxis® was completed within the expected timeframe and with rewarding results respect to the reference field. Access to two of the main European markets, Italy and Germany lead us to confirm the validity of our state-of-the-art therapy. The preclinical data on our CAR T CD44v6 reported in the course of 2017 provide an excellent basis to face the challenges that lie ahead. In 2018, supported by the extremely positive data not only on the potential

efficacy of the therapy, but also on its safety profile, we aim to request approval from regulatory authorities for the first clinical trial. Along with the positive progress of our proprietary pipeline, development and manufacturing for third parties also moved forward. In fact, in 2017 the Company finalized two important strategic agreements, with Rocket Pharma and Collectis, enriching its collaborations both from a quantitative and qualitative standpoint. Moreover, in light of the progress made on the Bresso facility, in 2018, following completion of the authorization process by AIFA, we will be able to count on a much larger production capacity to be dedicated, both to production of Zalmoxis® and to development and manufacturing of third party therapies, strengthening, in this manner, our dual business model, based on GMP Services for third parties, but primarily on R&D of proprietary products, which in 2017 started contributing to the growth of turnover”.

Key financial results as of December, 31st 2017

<i>(amounts in Euro thousand)</i>				
	Year 2017	Year 2016	Variation	
	(a)	(b)	(a-b)	%
Operating Revenues	23,987	22,825	1,162	5.1%
Revenues from sales	23,000	19,484	3,516	18.0%
Other revenue	987	3,341	(2,354)	(70.5%)
Operating costs	32,135	36,411	(4,276)	(11.7%)
Operating result	(8,148)	(13,586)	5,438	40.0%
Net financial income & charges	(349)	(290)	(59)	(20.3%)
Result for the period	(8,497)	(13,876)	5,379	38.8%

Operating Revenues for the year 2017, equal to Euro 23.987 thousand, increased by +5.1% compared to the previous year (Euro 22,825 thousand in 2016). Specifically, Revenues from sales, equal to Euro 23,000 thousand, increased by 18% compared to 2016 (Euro 19,484 thousand), as a result of:

- Revenues from development and manufacturing activities equal to Euro 20,500 thousand, up 5.2% compared to the previous year;
- Revenues from Zalmoxis® equal to Euro 2,500 thousand, which include the first milestone related to the exclusive agreement with exclusive license agreement for the commercialization of Zalmoxis® in certain Asian countries, and the upfront from the exclusive license and distribution agreement with Dompé farmaceutici for distributing and selling Zalmoxis® in all member countries of the current European Economic Area (EEA), with an option right for Australia, Switzerland and Turkey.

This increase in Revenues from sales is partially offset by the reduced weight of the Other Revenue amount, mainly including R&D public grants, equal to Euro 987 thousand in 2017, compared to Euro 3,341 thousand in 2016 (including a tax credit income of Euro 1,517 thousand).

Operating Costs, equal to Euro 32,135 thousand, reduced by Euro 4,276 thousand (-11.7%) compared to 2016 (Euro 36,411 thousand), mainly due to reduced *service costs* for Euro 6,052 thousand (-35.9%), as a consequence of:

- (i) decreased *development costs*, totalling Euro 2,348 thousand (from Euro 7,802 thousand in 2016), due to lower development costs for one of the proprietary product and to the termination of the SUPERSIST project in October 2016;

(ii) reduced *licence and patent fee*, equal to Euro 1,004 thousand (Euro 1,614 thousand in previous year as a consequence of the obtainment of the CMA, Conditional Marketing Authorisation for Zalmoxis®).

This decrease was partially offset by an increase in the *purchase of raw material and consumables costs* of Euro 853 thousand (+18.8%), and in the *personnel cost* of Euro 619 thousand (+5.0%), both due to a higher volume of activities compared to the previous year.

As a consequence of this positive trend, the **Operating Result**, negative for Euro 8,148 thousand, shows a change of +40.0% compared to the previous year Operating Result (negative for Euro 13,586 thousand).

Bearing in mind that the Company's operations and the characteristics of the trials performed, research and development costs are fully expensed as incurred.

Net financial income (charges) is negative for Euro 349 thousand, with a small decrease compared to 2016 (negative per Euro 290 thousand), mainly due to the impact of the utilization fees related to the SEF.

Net Result for the year, negative for Euro 8,497 thousand, significantly improved by +38.8% compared to 2016 (negative for Euro 13,876 thousand).

Investments in tangible and intangible assets are equal to Euro 2,098 thousand, substantially in line with 2016 (Euro 2,044 thousand) and, as in the previous year, essentially relating 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 production process of Zalmoxis®, as well as to maintenance and improvement work on the existing GMP facility.

Net Financial Position at December 31st 2017 is positive for Euro 18,111 thousand, in slight decrease compared to December 31st 2016 (positive for Euro 19,702 thousand), and it only consists of cash and cash equivalents and current financial receivables (time deposit), since no financial debt is recognized.

Furthermore the SEF agreement – Stand-by Equity Facility with Société Générale (subscribed on October 2016 and expiring in October 2018) aimed to increase the Company's financial flexibility is still effective. Following the drawdowns of 2016 and 2017, No. 6,488,279 shares are available for future capital increases.

Main 2017 events

February, 27th: signed a collaboration agreement with Rocket Pharma, US biotech company operating in the treatment of rare genetic diseases, for the treatment of Fanconi Anemia: pursuant to this agreement, MolMed will develop and manufacture the lent viral vectors to be used for the ex vivo transduction of hematopoietic stem cells, for clinical trials and in related research and development activities of Rocket Pharma.

April, 28th: signed with Megapharm a license and distribution agreement for Zalmoxis® in Israel.

June, 30th: subscribed with TTY Biopharm an exclusive agreement to commercialise Zalmoxis® in certain Asian territories (Taiwan, Hong Kong, Singapore, Thailand, Philippines, Vietnam and Malaysia).

July, 26th: signed a strategic commercialization and supply agreements for Zalmoxis® in Europe with Dompé. The 15 year exclusive license and distribution agreement grants Dompé the exclusive right and obligation to conduct all activities aimed at promoting, marketing, exploiting, distributing and selling Zalmoxis® in all member countries of the current European Economic Area (EEA) and an option right for Switzerland, Turkey and Australia.

July, 27th: announced with the French biotech Collectis, operating in the development of allogeneic CAR T-cells for clinical use, an agreement to develop and manufacture viral vectors and genetically engineered T-

cells to express UCARTs (Universal Chimeric Antigen Receptor T-cells) that are “off-the-shelf” allogeneic CARs, candidates in the clinic, and are meant to be readily available for large patient populations.

October, 25th: relevant safety data on proprietary immuno-gene therapy project CAR T CD44v6 presented at the 4th International Congress on Stem Cell Transplantation and Cellular Therapies in Berlin. Pre-clinical trial results support the safety profile of CAR T CD44v6 demonstrating the low skin toxicity.

December, 13th: price and reimbursement process for Zalmoxis® in Italy completed, with a reimbursed price from AIFA of Euro 149,000 per infusion, gross of discounts foreseen by law, together with a flat fee per patient (the therapy foresees up to a maximum of 4 infusions).

Beside the definition of new commercial agreements, during the year MolMed continued in the development and manufacturing activities for third parties, in particular for GSK, Telethon e Genenta.

In addition, in July 2017 the new Bresso facility was approved by AIFA as a Manufacturing GMP Facility for the execution of quality control tests and for the production of TK cells for clinical studies. Moreover, in July and November 2017, the authorization process for the approval of other GMP Manufacturing areas was started and is currently ongoing.

Main events occurred after December, 31st 2017

January, 15th 2018: price & reimbursement dossier filed in Germany, allowing for prescription and reimbursement in one of the main European markets.

February 8th 2018: Dompé exercises the option right to carry out the market access and commercialization activities for Zalmoxis® in Switzerland, Turkey and Australia.

February 15th 2018: AIFA Determina on reimbursement regime and market price for the proprietary cell therapy Zalmoxis® published in the Official Gazette. Starting from the fifteenth day subsequent to its publication, March 1st, the product has become marketable in Italy.

Business Outlook

In 2018, the Company plans to continue the clinical and industrial development of its main proprietary investigational products.

With the obtainment, in December 2017, of price and reimbursement terms for Italy from AIFA, and access to the German market in January 2018, the Company foresees to gradually advance in the market access of Zalmoxis® in the other main European countries. During 2018, based on the licence agreement, Dompé will continue the interactions with the local European authorities for the definition of price and reimbursement terms, while MolMed will continue the Fase III clinical trial.

With regard to the US market, the Company is working with several KOLs in the field of hematopoietic stem cells transplant in order to define the best strategy to gain an accelerated access approval by the FDA.

With regard to the CAR T CD44v6 project, based on the promising preclinical data collected in 2017, the Company will continue investing in research and development activities, in order to maximize the unique characteristics of the project aiming to start the first clinical in man study, planned in 2018.

As for NGR-hTNF, biological proprietary drug in advanced clinical stage, binding to blood vessels feeding the tumour mass for the treatment of solid tumours, the Company will continue scouting for potential partners for its clinical and industrial development, reserving the option to make further submissions for the market access

to the European authorities in the future.

Furthermore the Company carries on the search aimed at identifying new industrial partners and signing new service contracts.

Finally, in 2018 the new facility in Bresso will be gradually activated in line with the evolution of the existent and future portfolio of collaborations.

The official manager responsible for preparing the Company's financial reports, Andrea Quaglino, 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.*

This press release is available on the Company website <http://www.molmed.com>

About MolMed

MolMed S.p.A. is a biotechnology company focused on research, development, manufacturing and clinical validation of innovative anticancer therapies. MolMed's product portfolio includes proprietary anti-tumor therapies in 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® 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 at the end of 2017 and in Germany at the beginning of 2018. Still focusing on this cell & gene technology, the company is developing a therapy based on Chimeric Antigen Receptor (CAR), specifically the CAR-T CD44v6, an immune gene therapy project, currently in advanced preclinical development, potentially effective for hematological malignancies and several solid epithelial tumors. 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, a GSK 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 framework of innovative anticancer therapies, MolMed's pipeline also includes NGR-hTNF, a therapeutic agent for solid tumors investigated in a broad clinical program, involving more than 1,000 treated patients. 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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Income Statement 2017

<i>(amounts in Euro thousand)</i>	Year 2017	Year 2016
Revenues from sales	23,000	19,484
Other revenues	987	3,341
Total operating revenues	23,987	22,825
Purchases of raw materials and consumables	5,393	4,540
Costs for services	10,807	16,859
Costs for use of third-party assets	1,472	1,417
Personnel costs	12,928	12,309
Other operating costs	186	193
Amortization and depreciation	1,349	1,093
Total operating costs	32,135	36,411
Operating result	(8,148)	(13,586)
Financial income	204	165
Financial charges	(553)	(455)
Net financial income (charges)	(349)	(290)
Pre-tax result	(8,497)	(13,876)
Income taxes	-	-
Profit (loss) for the year	(8,497)	(13,876)

Balance Sheet as of December 31st 2017

<i>(amounts in Euro thousands)</i>	December 31, 2017	December 31, 2016
ASSETS		
Tangible assets	11,860	11,567
Goodwill	77	77
Intangible assets	589	494
Financial assets	210	211
Tax receivables	2,182	1,722
Other assets	1,000	1,500
TOTAL NON-CURRENT ASSETS	15,918	15,571
Inventories	1,754	1,067
Trade receivables and other commercial assets	4,896	5,015
Tax receivables	1,079	2,392
Other receivables and sundry assets	1,326	3,154
Other financial assets	5,006	1
Cash and cash equivalents	13,105	19,701
TOTAL CURRENT ASSETS	27,166	31,330
TOTAL ASSETS	43,084	46,901
LIABILITIES AND SHAREHOLDERS' EQUITY		
Capital	21,514	20,313
Share premium reserve	58,976	49,347
Other reserves	606	461
Retained earnings (accumulated losses)	(47,966)	(34,096)
Profit (loss) for the year	(8,497)	(13,876)
TOTAL SHAREHOLDERS' EQUITY	24,633	22,149
Liabilities for pensions and employee severance indemnity (TFR)	147	146
Trade payables	1,000	1,800
Other liabilities	3,611	4,700
TOTAL NON-CURRENT LIABILITIES	4,758	6,646
Trade payables	9,766	12,526
Other liabilities	3,927	5,580
TOTAL CURRENT LIABILITIES	13,693	18,106
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	43,084	46,901

Cash Flow Statement 2017

<i>(amounts in Euro thousand)</i>		December 31, December 31,	
		2017	2016
Cash and cash equivalents		19,701	11,770
Opening cash and cash equivalents	A	19,701	11,770
Cash flow from operating activities:			
Profit (loss) for the year		(8,497)	(13,876)
Amortization/Depreciation of intangible/tangible assets		1,349	1,093
Change in liabilities for pensions and employee severance indemnity		-	2
Non-cash costs for stock options		151	43
Decrease in other current assets due to option rights		-	86
Reversal of financial income and charges		349	290
Cash flow from operating activities before changes in working capital		(6,648)	(12,362)
Changes in current assets and liabilities:			
(Increase) decrease in inventories		(687)	(273)
(Increase) decrease in trade and other receivables		3,260	(96)
Increase (decrease) in trade and other payables		(2,760)	(1,033)
Increase (decrease) in other liabilities		(1,319)	626
Total changes in current assets and liabilities		(1,506)	(776)
(Increase) decrease in non-current tax receivables		40	735
Increase (decrease) in other liabilities		(800)	(800)
Increase (decrease) in other financial assets		(1,089)	1,336
Increase (decrease) in other activities		1	1
Interest paid		(471)	(314)
Total cash flow generated (absorbed) by operating activities	B	(10,473)	(12,179)
Cash flow from investing activities:			
Net (investment) divestment in tangible assets		(1,746)	(1,888)
Net (investment) divestment in intangible assets		(211)	(245)
Net (investment) in other financial assets		-	-
(investment) in other financial assets		(5,005)	18,000
Interest received		9	190
Total cash flow generated (absorbed) by investing activities	C	(6,953)	16,056
Cash flow from financing activities:			
Increases in capital and share premium reserve		10,893	4,246
Other Equity movemenets (share increase cost)		(63)	(192)
Total cash flow generated (absorbed) by financing activities	D	10,830	4,054
Cash flow generated (absorbed) during the year	E=B+C+D	(6,596)	7,932
Closing cash and cash equivalents	A+E	13,105	19,701

Net Financial Position as of December 31st 2017

(amounts Euro thousand)

	December 31, 2017	December 31, 2016
Cash on hand	12	13
Other cash	13,093	19,688
Cash equivalents	-	-
A. Total cash and cash equivalents	13,105	19,701
B. Current financial receivables and other financial assets	5,006	1
Finance lease payables	-	-
Current financial Debts	-	-
C. Current financial debt	-	-
D. Net current financial position (A+B+C)	18,111	19,702
Finance lease payables	-	-
Non current financial Debts	-	-
E. Non-current financial debt	-	-
F. Net financial position (D+E)	18,111	19,702

Statement of changes in Equity

(amounts in Euro thousand)

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

(amounts in Euro thousands)

	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at January 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	-	-	-	-	-	4,246
Capital increase expenses capitalized	-	(192)	-	-	-	-	-	(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 thousands)

	Capital	Share premium reserve	Other reserves	Stock option plan reserve	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the year	Total shareholders' equity
Balance at January 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 expenses 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