



PRESS RELEASE

## ***MolMed: the Board of Directors approves first-half 2020 financial results***

*The economic, financial position and performance are significantly and constantly improving:*

- *Operating revenues amounting to 20.7 million Euro increased by 27% compared to 16.4 million Euro in the first half of 2019;*
- *EBITDA amounted to a positive 4.2 million Euro compared to a negative 0.2 million Euro in the first half 2019;*
- *Net profit for the period at 2.4 million Euro compared to a net loss of 1.9 million Euro in the first half of 2019;*
- *Cash balance at 14.4 million Euro compared to 9.9 million Euro at December 31<sup>st</sup>, 2019.*

Milan (Italy), July 27<sup>th</sup>, 2020 – The Board of Directors of MolMed S.p.A. (MLMD.MI) (the “Company”), a biotechnology company focused on research, development, manufacturing and clinical validation of cell and gene therapies for the treatment of tumors and rare diseases, at today's meeting, chaired by Mr. Carlo Incerti, examined and approved first-half 2020 financial results.

**Riccardo Palmisano**, MolMed's Chief Executive Officer, commented the financial results of first half of 2020 and the Company's business development: *“We are proud of the results obtained during the first half of 2020, a period that was, moreover, made extremely complex by the very serious, unforeseeable epidemic that struck the whole world, seeing one of the very first outbreaks in Lombardy and Milan, the area in which our Company operates. By reorganizing the work and relying on the competences and sense of belonging of our people, we were, however, able to guarantee both the safety of our employees and the service to our customers and patients. We think that a growth of Operating revenues of 27% over the same period of last year and, above all, net profit of 2.4 million Euro are the best proof of the success of both the strategic choices made and the operative excellence of MolMed. During the same period, we entered into two new service agreements with new international customers listed on the Nasdaq and in July, we extended the collaboration with our main client, Orchard Therapeutics (Nasdaq: ORTX), a confirmation of the quality of GMP services offered by the Company”.*

## Performance and financial highlights for the first half of 2020

(amounts Euro thousand)

	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019	Change	Change %
Revenues from development and manufacturing activities	20,358	16,313	4,045	24.8%
Other revenue	379	63	316	501.6%
<b>Total operating revenues</b>	<b>20,737</b>	<b>16,376</b>	<b>4,361</b>	<b>26.6%</b>
Total operating costs (amortization and depreciation excluded)	(16,580)	(16,596)	16	(0.1%)
<b>EBITDA</b>	<b>4,157</b>	<b>(220)</b>	<b>4,377</b>	<b>(1989.5%)</b>
Amortization	(1,499)	(1,477)	(22)	1.5%
Devaluation	-	(200)	200	(100.0%)
<b>Total amortization and deprecitaion</b>	<b>(1,499)</b>	<b>(1,677)</b>	<b>178</b>	<b>(10.6%)</b>
<b>EBIT</b>	<b>2,658</b>	<b>(1,897)</b>	<b>4,555</b>	<b>(240.1%)</b>
<b>Net financial income (charges)</b>	<b>(131)</b>	<b>(25)</b>	<b>(106)</b>	<b>424.0%</b>
<b>Pre-tax result</b>	<b>2,527</b>	<b>(1,922)</b>	<b>4,449</b>	<b>(231.5%)</b>
Income taxes	(137)	-	(137)	100.0%
<b>Profit (loss) for the period</b>	<b>2,390</b>	<b>(1,922)</b>	<b>4,312</b>	<b>(224.3%)</b>

In the first half of 2020, **operating revenues** continued their positive trend, growing by 4,361 thousand Euro or 26.6% when compared to the prior-year period. This change was mainly due to the increase in sales revenues from development and manufacturing activities on behalf of third parties that, thanks to the expansion in the customer base and the increase in work performed on behalf of existing customers, increased by 4,045 thousand Euro (or 24.8%) from 16,313 thousand Euro, in the first half of 2019, to 20,358 thousand Euro, in the first half of 2020.

**Operating costs** net of amortization, depreciation and impairment, went from 16,596 thousand Euro, in the first half of 2019, to 16,580 thousand Euro, in the first half of 2020, recording a slight reduction of 16 thousand Euro or 0.1%, due to: (i) a reduction in costs for services of 250 thousand Euro or 4.3%, mainly as a result of fewer costs for license fees, consultancy and research and development of the proprietary pipeline following the decision to suspend research and development on both autologous CAR-T and on allogeneic CAR NK for 1,405 thousand Euro; fewer costs for travel, congresses and other personnel costs for 142 thousand Euro, offset by an increase in external costs for quality controls related to the growth in revenues for 578 thousand Euro, following the greater business and, an increase in legal and consultancy costs linked to the takeover bid for 697 thousand Euro; (ii) an increase in personnel costs of 174 thousand Euro or 2.5%; and (iii) an increase in costs for raw materials of 89 thousand Euro or 2.4%.

**EBITDA** rose by 4,377 thousand Euro, from a negative 220 thousand Euro in the first half of 2019 to 4,157 thousand Euro in the first half of 2020. This was largely attributable to the growth in revenues and margins associated with development and manufacturing on behalf of third parties—an area in which the Company is a global leader, as showed by the international standing of its customers, their loyalty, and the several projects it works on. Furthermore, a revision of proprietary research projects has made it possible to reduce research and development costs, thus contributing to decrease operating costs.

**Amortization, depreciation and impairment** costs amounted to 1,499 thousand Euro, in the first half of 2020, decreasing by 178 thousand Euro compared to the prior-year period (1,677 thousand Euro).



**Income taxes** include regional tax on productive activities (IRAP) of 137 thousand Euro. At June 30<sup>th</sup>, 2020, in view of the previous tax losses of 211,022 thousand Euro—some of which accrued in the first three tax periods and are therefore not subject to the limit of use—no provisions were recognized for IRES.

MolMed recognized a **net profit** for the period amounting to 2,390 thousand Euro. This is a net improvement (+224.3%) compared to prior-year figures when the Company recognized a net loss of 1,922 thousand Euro.

During the first half of 2020, **investments in tangible and intangible assets** were 1,036 thousand Euro: in particular, investments in tangible assets (1,013 thousand Euro) were made to a large extent to fit out new premises dedicated to manufacturing activities at the Bresso facility, including new equipment used in the manufacturing process, for the adjustment and optimization of existing GMP facilities and for routine replacement of laboratory equipment.

At June 30<sup>th</sup>, 2020, the **net financial position** amounted to 6,499 thousand Euro, up by 5,124 thousand Euro from 1,375 thousand Euro at December 31<sup>st</sup>, 2019. MolMed's net financial position is computed in compliance with IFRS 16 "Leases" with finance lease payables recognized as current and non-current financial payable. The period change is due to the non-recourse factoring and collection of VAT credits of 2,601 thousand Euro, the partial use of tax credits for research and development purposes, offsetting INPS contributions and IRPEF withholding taxes, which effectively resulted in lesser financial outlay in the amount of 1,004 thousand Euro, the net liquidity generated by the Company's operations supporting the period business and the change in finance lease payables resulting from the application of IFRS 16. Net of the effects arising from the adoption of IFRS 16, the net financial position would have amounted to 14,429 thousand at June 30<sup>th</sup>, 2020 compared to 9,904 thousand Euro at December 31<sup>st</sup>, 2019.

### **Main events occurred in the first half of 2020**

**February 12<sup>th</sup>, 2020** – MolMed announced it had received AIFA's authorization to manufacture viral vectors to be used in clinical trials based on advanced therapies at new GMP areas of the Bresso facility. The availability of the new premises further boosts the manufacturing capacity that MolMed can offer to existing and prospective customers, enabling it to continue expanding its business of GMP development and manufacturing of gene and cell therapies on behalf of third parties.

**March 6<sup>th</sup>, 2020** – MolMed announced it had entered into a supply and development agreement with Autolus Therapeutics plc (Nasdaq: AUTL), a biopharma company in the clinical stage focusing on the development of "T cell" therapies of the latest generation for cancer treatment. By virtue of this multi-year agreement, MolMed will develop and supply viral vectors for some CAR-T projects of Autolus to be used in clinical trials and potentially available to the market.

**March 18<sup>th</sup>, 2020** – MolMed announced it had entered into a supply and development agreement with a primary US biopharma company (undisclosed for confidentiality reasons), listed on the Nasdaq and engaged in the development of gene and cell therapies for the treatment of rare diseases. Based on this agreement, MolMed will provide GMP development and manufacturing services for one or more pre-clinical and clinical programs involving several therapeutic indications implemented by the customer.

### Events after the reporting period

**July 9<sup>th</sup>, 2020** – MolMed and Orchard Therapeutics (Nasdaq: ORTX) announced the extension of the collaboration—launched in April 2018—for a period of five years through to June 2025. MolMed will continue to support activities relating to the development and manufacturing of vectors and medicinal products for various experimental gene therapies based on the ex vivo genetic modification of hematopoietic stem cells of Orchard, including OTL-200 for metachromatic leukodystrophy (MLD) and OTL-103 for Wiskott-Aldrich Syndrome (WAS) and for additional programs, including OTL-203 for Mucopolysaccharidosis type I (MPS-I).

**July 24<sup>th</sup>, 2020** - the tender offer was concluded to which no. 423.081.597 MolMed shares, equal to 93,23% of the Company's share capital, were tendered, amounting to an economic value of Euro 223,818,267.25.

### Business outlook

Based on its distinctive expertise in the area of gene and cell therapies, demonstrated by the very high standing of its customers, their loyalty and the high number of undertaken projects, the Company places at the core of its growth strategy the provision of development and manufacturing services on behalf of third parties in the field of viral vectors and genetically engineered cells.

As demonstrated by the agreements executed in the year, the Company is continuing to working on expanding the number of its customers and related projects concerning both viral vectors and genetically modified cells in the fields of oncology and rare diseases, and, at the same time, the quantity and scope of the services offered.

In order to offer better services in terms of quantity and quality to current partners and future potential customers, MolMed plans to expand its investments on manufacturing scale and technology supporting development and manufacturing on behalf of third parties, and to extend manufacturing and support areas.

During the first half of 2020, industrial operations, despite the pandemic emergency, were not subject to any slowdown. However, the decision of some customers to suspend or delay the clinical trials underway, due to the global COVID-19 emergency, may have—in the absence of any future changes—a negative impact on sales revenues from activities on behalf of third parties, especially in the second half of 2020, and may generate lower operating results compared to those that may be expected following the trend recorded in the last few quarters.

As a consequence of the COVID-19 emergency and the impact on the management of patients (requiring intensive care treatment), in addition to some logistic problems related to the management of biological samples, the Company has decided to suspend, for the period from May 1<sup>st</sup> to October 31<sup>st</sup>, 2020, the enrollment of patients suffering from acute myeloid leukemia (AML) and multiple myeloma (MM) for the Phase I/II multicentric clinical trial *“A Phase I-IIa trial to assess the safety and antitumor activity of autologous CD44v6 CAR T-cells in acute myeloid leukemia and multiple myeloma expressing CD44v6”*.

With the beginning of phase 2 of the COVID-19 emergency, the Company completed its risk analysis to fully and orderly resume operations based on best practices and in compliance with national and regional legislative provisions. The Crisis Committee is responsible for managing the activities necessary to ensure business continuity in order for the Company to continue as a going concern within a constantly changing scenario.

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In compliance with the provisions of Article 154-bis, paragraph 2 of Legislative Decree 58/1998, Salvatore Calabrese, the Executive Officer responsible for preparing MolMed S.p.A.'s financial reports, hereby states that the financial disclosure included in this press release is consistent with the entries in accounting books and records.

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

### *Information on MolMed*

MolMed S.p.A. (MLMD.MI) is a biotech company focusing on research, development, manufacturing and clinical validation of innovative gene and cell therapies. MolMed is also the first company in Europe to have obtained authorization for GMP manufacturing of gene and cell therapies, in relation to both its own products and those manufactured on behalf of third parties and/or in partnership with other companies (Strimvelis, Orchard's gene therapy for the treatment of ADA-SCID). As regards GMP development and manufacturing activities on behalf of third parties, MolMed has executed a number of partnership agreements with leading European and American companies. Furthermore, MolMed continues the clinical development of its proprietary product CAR-T CD44v6 which has received in March 2019 authorization for trials on human subjects for onco-hematological indications (AML and MM), after completion of a broad phase of pre-clinical development. Founded in 1996 as an academic spin-off of Istituto Scientifico San Raffaele, MolMed has been listed on the MTA (Mercato Telematico Azionario) managed by Borsa Italiana since March 2008. Its registered office and one operating facility are located in Milan, at the Biotechnology Department of the San Raffaele Hospital, while the other operating facility is located in the OpenZone scientific park in Bresso.

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### **Annexes**

- Income statement for the first half of 2020
- Statement of financial position at June 30<sup>th</sup>, 2020
- Statement of cash flows for the first half of 2020
- Net financial position at June 30<sup>th</sup>, 2020
- Statement of changes in net equity at June 30<sup>th</sup>, 2020

## Income statement for the first half of 2020

<i>(amounts in Euro thousand)</i>	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019
Revenues	20,358	16,313
Other revenue	379	63
<b>Total operating revenues</b>	<b>20,737</b>	<b>16,376</b>
Purchases of raw materials and consumables	(3,795)	(3,706)
Costs for services	(5,616)	(5,866)
Costs for use of third-party assets	(43)	(70)
Personnel costs	(7,044)	(6,870)
Other operating costs	(82)	(84)
Amortization and depreciation	(1,499)	(1,677)
<b>Total operating costs</b>	<b>(18,079)</b>	<b>(18,273)</b>
<b>Operating result</b>	<b>2,658</b>	<b>(1,897)</b>
Financial income	3	51
Financial charges	(134)	(76)
<b>Net financial income (charges)</b>	<b>(131)</b>	<b>(25)</b>
<b>Pre-tax result</b>	<b>2,527</b>	<b>(1,922)</b>
Income taxes	(137)	-
<b>Profit (loss) for the period</b>	<b>2,390</b>	<b>(1,922)</b>

<i>(amounts in Euro)</i>	1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019
Basic earnings/(loss) per share	0.0052	(0.0041)
Diluted earnings/(loss) per share	0.0052	(0.0041)

\* The calculation of basic earnings (loss) per share is based on the net profit/loss of the first half of 2020 and 2019, amounting to a profit of 2,390 thousand Euro and a loss of 1,922 thousand Euro, respectively, and on the weighted average of the ordinary shares outstanding in the two periods equal to no. 463,450,672.

## Statement of financial position at June 30<sup>th</sup>, 2020

(amounts in Euro thousand)

	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019
<b>ASSETS</b>		
Tangible assets	18,387	18,971
Intangible assets	377	423
Financial assets	206	206
Tax receivables	-	2,601
<b>TOTAL NON-CURRENT ASSETS</b>	<b>18,970</b>	<b>22,201</b>
Inventories	2,644	1,830
Trade receivables and other commercial assets	10,636	9,911
Tax receivables	2,667	2,528
Other receivables and sundry assets	651	542
Cash and cash equivalents	14,429	9,904
<b>TOTAL CURRENT ASSETS</b>	<b>31,027</b>	<b>24,715</b>
<b>TOTAL ASSETS</b>	<b>49,997</b>	<b>46,916</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Capital	21,819	21,819
Share premium reserve	61,754	61,754
Other reserves	217	217
Retained earnings (accumulated losses)	(60,617)	(60,190)
Profit (loss) for the period/year	2,390	(427)
<b>TOTAL SHAREHOLDERS' EQUITY</b>	<b>25,563</b>	<b>23,173</b>
Liabilities for pensions and employee severance indemnity (TFR)	129	150
Financial debts	6,726	7,325
Other liabilities	1,812	2,944
<b>TOTAL NON-CURRENT LIABILITIES</b>	<b>8,667</b>	<b>10,419</b>
Provision risk	256	611
Trade payables	10,297	8,230
Financial debts	1,204	1,204
Tax payables	137	87
Other liabilities	3,872	3,192
<b>TOTAL CURRENT LIABILITIES</b>	<b>15,766</b>	<b>13,324</b>
<b>TOTAL LIABILITIES &amp; SHAREHOLDERS' EQUITY</b>	<b>49,997</b>	<b>46,916</b>

## Statement of cash flows for the first half of 2020

(amounts in Euro thousand)

		1 <sup>st</sup> half 2020	1 <sup>st</sup> half 2019
<b>Opening cash and cash equivalents</b>	<b>A</b>	<b>9,904</b>	<b>15,507</b>
<b>Cash flow from operating activities:</b>			
Profit (loss) for the period		2,390	(1,922)
Amortization of assets		1,499	1,477
IFRS16 effects		(599)	(626)
Amortization pro-quota Bresso		(167)	(167)
Write down of fixed asset and assets items		-	200
Non monetary costs		125	-
Reversal of non monetary financial income and charges		84	(65)
<b>Cash flow from operating activities before changes in working capital</b>		<b>3,332</b>	<b>(1,103)</b>
<b>Changes in current assets and liabilities:</b>			
(Increase) decrease in inventories		(814)	(385)
(Increase) decrease in trade and other receivables		(974)	(3,130)
Increase (decrease) in trade and other payables		2,117	259
Increase (decrease) in other liabilities		(681)	429
<b>Total changes in current assets and liabilities</b>		<b>(351)</b>	<b>(2,827)</b>
(Increase) decrease in non-current tax receivables		2,601	1,969
Increase (decrease) in non current trade liabilities		-	(200)
Increase (decrease) in other liabilities and TFR paid		(21)	(200)
<b>Total cash flow generated (absorbed) by operating activities</b>	<b>B</b>	<b>5,561</b>	<b>(2,361)</b>
<b>Cash flow from investing activities:</b>			
Net (investment) divestment in tangible assets		(1,013)	(547)
Net (investment) divestment in intangible assets		(23)	(72)
<b>Total cash flow generated (absorbed) by investing activities</b>	<b>C</b>	<b>(1,036)</b>	<b>(619)</b>
<b>Total cash flow generated (absorbed) by financing activities</b>	<b>D</b>	<b>-</b>	<b>-</b>
<b>Cash flow generated (absorbed) during the period</b>	<b>E=B+C+D</b>	<b>4,525</b>	<b>(2,980)</b>
<b>Closing cash and cash equivalents</b>	<b>A+E</b>	<b>14,429</b>	<b>12,527</b>

## Net financial position at June 30<sup>th</sup>, 2020

<i>(amounts Euro thousand)</i>	June 30 <sup>th</sup> , 2020	December 31 <sup>st</sup> , 2019
Cash on hand	2	3
Other cash	14,427	9,901
<b>A. Total cash and cash equivalents</b>	<b>14,429</b>	<b>9,904</b>
<b>B. Current financial receivables and other financial assets</b>	<b>-</b>	<b>-</b>
Liabilities to financial leasing entities (IFRS16)	(1,204)	(1,204)
<b>C. Current financial debt</b>	<b>(1,204)</b>	<b>(1,204)</b>
<b>D. Net current financial position (A+B+C)</b>	<b>13,225</b>	<b>8,700</b>
Liabilities to financial leasing entities (IFRS16)	(6,726)	(7,325)
<b>E. Non-current financial debt</b>	<b>(6,726)</b>	<b>(7,325)</b>
<b>F. Net financial position (D+E)</b>	<b>6,499</b>	<b>1,375</b>
G. IFRS16 effects - current	1,204	1,204
H. IFRS16 effects - non current	6,726	7,325
<b>I. I. Net financial position - NO IFRS 16 effects</b>	<b>14,429</b>	<b>9,904</b>

## Statement of changes in net equity at June 30<sup>th</sup>, 2020

<i>(amounts in Euro thousand)</i>	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
<b>Balance at January, 1<sup>st</sup> 2019</b>	21,819	61,754	223	(11)	(56,067)	(4,123)	23,595
Allocation of prior year result	-	-	-	-	(4,123)	4,123	-
Profit (loss) for the period	-	-	-	-	-	(1,922)	(1,922)
<b>Balance at June, 30<sup>th</sup> 2019</b>	<b>21,819</b>	<b>61,754</b>	<b>223</b>	<b>(11)</b>	<b>(60,190)</b>	<b>(1,922)</b>	<b>21,673</b>
<i>(amounts in Euro thousand)</i>							
<i>(amounts in Euro thousand)</i>	Capital	Share premium reserve	Other reserves	Actuarial valuation reserve	Retained earnings (accumulated losses)	Profit (loss) for the period	Total shareholders' equity
<b>Balance at January, 1<sup>st</sup> 2020</b>	21,819	61,754	223	(6)	(60,190)	(427)	23,173
Allocation of prior year result	-	-	-	-	(427)	427	-
Profit (loss) for the period	-	-	-	-	-	2,390	2,390
<b>Balance at June, 30<sup>th</sup> 2020</b>	<b>21,819</b>	<b>61,754</b>	<b>223</b>	<b>(6)</b>	<b>(60,617)</b>	<b>2,390</b>	<b>25,563</b>