

# QUARTERLY MANAGEMENT STATEMENT FOR THE PERIOD ENDING SEPTEMBER 30, 2016

Encouraging Data for MP0250 in Oncology and New Phase 2 DME-Data for Abicipar in Ophthalmology Presented at Leading Scientific Conferences

R&D, Partnerships & Team Milestones:

- Abicipar: Phase 3 trials in wet AMD (wet age related macular degeneration) progress as scheduled
- Abicipar: Allergan presented phase 2 data in DME (diabetic macular edema) at AAO conference in Chicago on October 15 with data showing long duration of action in this indication and supporting progression to phase 3
- MP0250: Additional, encouraging data on phase 1 trial for MP0250, a multi-DARPin<sup>®</sup>\* drug candidate in oncology targeting VEGF and HGF, presented at ESMO Conference
- MP0250: First regulatory submission for phase 2 in Multiple Myeloma planned for 4Q 2016 with first safety data expected in 2017 and efficacy data in 2018
- MP0250: Commitment to run additional phase 2 trial for a solid tumor indication
- MP0274: First regulatory submission for phase 1 with MP0274, a multi-DARPin<sup>®</sup> drug candidate for the treatment of HER2-positive solid tumor indications, planned for 1Q 2017
- Immunology: Janssen returned full rights of the development-stage DARPin<sup>®</sup> drug candidate as the partner strategically decided to deprioritize pulmonary R&D

**Financial Highlights:** 

- Ongoing strong financial position with CHF 185.7 million in cash and short-term time deposits as of September 30, 2016
- Net cash used from operating activities of CHF 27.5 million over the first three quarters of 2016, reflecting the ongoing scale-up of R&D activities and the growth of the company's pipeline
- Operating loss of CHF 13.1 million and net loss of CHF 14.8 million in the first nine months of 2016
- Talent base with 103 full-time employees, up 21% year-over-year, reflecting the further build-up of clinical development expertise

**Zurich-Schlieren, October 27, 2016.** Molecular Partners AG (SIX: MOLN), a clinical-stage biopharmaceutical company that is developing a new class of therapies, known as DARPin<sup>®</sup> therapies, today announced its Quarterly Management Statement for the period ending September 30, 2016 and key financial highlights for the third quarter 2016. "We are very pleased with the development and progression of our broad and novel pipeline, based on our innovative DARPin<sup>®</sup> technology platform, and the ongoing strength of our financial position," said Dr. Christian Zahnd, Chief Executive Officer of Molecular Partners. "We look forward to starting two phase 2 trials for our lead oncology asset MP0250 and initiating the phase 1 trial with MP0274. We are also pleased to see Allergan progressing the phase 3 trials for Abicipar fully in line with our expectations."

# Abicipar phase 3 trials in wet AMD progress according to plan

The company's strategic partner Allergan is currently enrolling patients in a phase 3 trial for wet age-related macular degeneration (wet AMD) using an updated formulation of abicipar. Enrollment is progressing well and topline results are expected in 2018.

#### Additional phase 2 data supports abicipar progression into phase 3 for DME

Allergan presented phase 2 clinical trial data evaluating abicipar for diabetic macular edema (DME) at 2016 American Academy of Ophthalmology Annual Meeting (AAO) in Chicago. Abicipar for DME met its study end points and the efficacy of abicipar was shown in all three treatment groups. Over the 28 week trial period, abicipar with a 2 mg dose (and injected every 8 weeks, respectively every 12 weeks, following three monthly loading doses) demonstrated functional (BCVA) and anatomical (CRT) effects comparable with ranibizumab (Lucentis<sup>®</sup>) which was injected every 4 weeks into each eye. Overall, the safety profile of abicipar is acceptable. Intraocular inflammation occurred in 7, 5 and 4 patients in the three treatment groups respectively. The first two groups were treated with a 1 mg dose, respective a 2 mg dose of abicipar at an 8 weeks injection interval. The third group was treated with a 2 mg dose of abicipar every 12 weeks. The adverse events observed were mostly mild to moderate in severity, and resolved with treatment. These data show the long duration of abicipar and support its progression to phase 3 for DME.

The objective of this study was to assess the safety, efficacy, systemic pharmacokinetics, and immunogenicity profile of abicipar in patients with decreased vision due to centrally-involved DME compared to Lucentis<sup>®</sup> which is the standard of care.

#### Additional phase 1 data presented confirming potential of MP0250

On October 9, 2016, the company presented completed phase 1 dose escalation interim results of MP0250 at the Conference of the European Society of Medical Oncology (ESMO) in Copenhagen.

These data, based on the enrollment of a total of 24 patients, are an important milestone in the development of DARPin<sup>®</sup> proteins as anticancer agents and expand the results that had been published in November 2015. MP0250, used as single agent, is the first DARPin<sup>®</sup> drug candidate to be studied in humans as systemic treatment. MP0250 was well tolerated at the higher dose levels (up to the maximally tolerated dose of 8 mg/kg administered every 2 weeks). This is an important milestone because it proves that DARPin<sup>®</sup> proteins do not negatively impact the immune system of humans and can be engineered to have a systemic half-life of around two weeks. The drug is well tolerated and the side effect profile is consistent with profound inhibition of the VEGF pathway. MP0250 has the potential to become a new therapeutic in treating various tumor types.

# Update on phase 2 strategy for MP0250: Initiation for two phase 2 trials planned for 2017

The first phase 2 study will examine MP0250 in combination with bortezomib (Velcade<sup>®</sup>) and dexamethasone in patients with multiple myeloma who have failed standard therapies. The first regulatory submission for such study is planned for 4Q 2016 with first safety data expected in 2017 and efficacy data in 2018.

Based on the encouraging data from phase 1 in solid tumors, Molecular Partners committed to run an additional phase 2 trial for a solid tumor indication. Study details will be disclosed in H1 2017.

# First regulatory submission for MP0274 scheduled for 1Q 2017

The company plans the first regulatory submission for the envisaged phase 1 trial of MP0274, a proprietary, single-pathway DARPin<sup>®</sup> drug candidate for the treatment of HER2-positive solid tumor indications, for 1Q 2017.

# Full rights to a multi-DARPin<sup>®</sup> drug candidate in immunology regained from Janssen

In October 2016, Molecular Partners regained the full rights to a multi-DARPin<sup>®</sup> drug candidate targeting both IL-13 and IL-17 with long systemic half-life and potential use in pulmonary indications following the discontinuation of a Collaboration and License Agreement entered into with Janssen in 2011. Under the collaboration, Molecular Partners and Janssen and generated a multi-DARPin<sup>®</sup> drug candidate that is ready to enter into preclinical development. The research and development costs of this drug candidate were supported by Janssen. The termination of the collaboration with Janssen in immunology is the result of a strategic decision not related to the DARPin<sup>®</sup> drug candidate and Molecular Partners is now evaluating if the program will be re-partnered or added to its proprietary pipeline.

#### Financial highlights: Ongoing strong cash position, increased development expenses

Molecular Partners' financial development for the first nine months of 2016 continued in line with management's expectations and reflects the increase in development expenses and the ongoing investments to further expand the company's proprietary pipeline. In the first nine months of 2016, Molecular Partners recognized total revenues of CHF 19.2 million (1Q-3Q 2015: CHF 21.1 million) and incurred total expenses of CHF 26.8 million (1Q-3Q 2015: CHF 17.7 million). This led to an operating loss of CHF 13.1 million for the first three quarters 2016 (1Q-3Q 2015: Operating loss of CHF 1.7 million). The company recognized a net financing expense of CHF 1.7 million for the first nine months 2016, mainly driven by adverse FX effects on its USD and EUR cash positions (1Q-3Q 2015: Net financing income of CHF 0.2 million). This resulted in a 1Q-3Q 2016 net loss of CHF 14.8 million (1Q-3Q 2015: Net loss of CHF 1.5 million).

<b>Key Financials</b> (CHF million, except per share, FTE data)	3Q 2016	3Q 2015	change	1Q-3Q 2016	1Q-3Q 2015	change
Total revenues	5.7	9.9	-4.2	19.2	21.1	-1.9
R&D expenses	-8.7	-5.9	-2.8	-26.8	-17.7	-9.1
G&A expenses	-1.6	-1.8	0.2	-5.5	-5.1	-0.4
Operating profit (loss)	-4.6	2.2	-6.8	-13.1	-1.7	-11.4
Net finance income (expenses)	-0.5	3.3	-3.8	-1.7	0.2	-1.9
Net profit (loss)	-5.1	5.5	-10.6	-14.8	-1.5	-13.3
Basic net profit (loss) per share (in CHF)	-0.25	0.28	-0.53	-0.73	-0.08	-0.65
Diluted net profit (loss) per share (in CHF)	-0.25	0.25	-0.50	-0.73	-0.08	-0.65
Net cash from (used in) operating activities	-10.0	43.3	-53.3	-27.5	34.1	-61.6
Net increase (decrease) in cash & cash equiv.	-20.1	45.4	-65.5	-38.7	32.6	-71.3
Cash balance (incl. time deposits) as of Sep 30	185.7	221.0	-35.3			
Total shareholders' equity at Sep 30	136.7	149.4	-12.7			
Number of total FTE as of Sep 30	103.4	85.6	17.8			
- thereof in R&D	93.4	77.4	16.0			
- thereof in G&A	10.0	8.2	1.8			

#### Key figures as of September 30, 2016

The cash and short term time deposits came down by CHF 10.6 million since June 30, 2016 to CHF 185.7 million as of September 30, 2016 (June 30, 2016: CHF 196.3 million) and continue on a very solid level with a cash runway of multiple years. The total shareholders' equity position decreased to CHF 136.7 million as of September 30, 2016 (June 30, 2016: CHF 141.4 million).

The third quarter 2015 had been positively impacted by the USD 15 million milestone payment received from the company's strategic partner Allergan for the start of the phase 3 trials for abicipar in wet AMD as well as the USD 35 million in accelerated milestone payments tied to the research collaboration also paid by Allergan in 3Q 2015.

As of September 30, 2016, the company employed 103 FTEs, with 90% of employees in R&D (September 30, 2015: 86 FTEs). The increase of 21% of R&D employees year-on-year reflects the strong investments by the company in its research and development capabilities in order to advance its proprietary pipeline.

"Over the course of the first nine months of 2016, Molecular Partners' financial position developed in line with our projections amid the ongoing commitment to increase our research and development expenses and to invest into value creating proprietary pipeline assets," said Andreas Emmenegger, Chief Financial Officer of Molecular Partners. "We will close the full year 2016 with an ongoing strong cash position which provides us with the envisaged financial flexibility going forward."

# **Business Outlook and priorities**

In ophthalmology, Molecular Partners will continue to support its strategic partner Allergan in advancing abicipar through phase 3 trials in patients with wet AMD, and possibly in initiating phase 3 trials of abicipar in patients with DME, the next logical retinal indication.

For the company's proprietary oncology pipeline, plans for the remainder of 2016 include the first regulatory submission of the envisaged phase 2 trial of MP0250 for patients with Multiple Myeloma (MM). First safety data of this trial are expected in 2017 and efficacy data in 2018. With respect to the additional phase 2 trial for a solid tumor indication, the company will disclose further details in H1 2017. Molecular Partners envisages initiating a phase 1 trial of MP0274, a proprietary, single-pathway DARPin<sup>®</sup> drug candidate for the treatment of HER2-positive breast cancer with first regulatory submission expected in 1Q 2017.

The company will continue to advance its immuno-oncology pipeline, an area in which Molecular Partners has demonstrated the potential utility of targeting immune checkpoint modulators (ICMs)

via combination therapy (e.g., joint inhibition of PD-1 and VEGF) or activating agonists while localizing its effects.

# **Financial Outlook 2016**

For the full year 2016, at constant exchange rates, the company expects total expenses of around CHF 50 million, of which around CHF 6 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciations. However, this may change depending on the progress of the pipeline, mainly driven by the speed of enrollment of patients in clinical trials and data from research and development projects. Additionally, the company expects around CHF 2 million of capital expenditures, mainly for laboratory equipment.

No guidance can be provided with regard to net cash flow projections. Timelines and potential milestone payments for existing and potentially new partnerships are not disclosed.

# **Financial Calendar**

Publication of Full-year Results 2016 (unaudited)	February 09, 2017	
Expected Publication of Annual Report 2016	March 29, 2017	
Annual General Meeting	May 11, 2017	

http://investors.molecularpartners.com/financial-calendar-and-events/

# About the DARPin® technology

Molecular Partners is progressing programs in ophthalmology in partnership with Allergan and in oncology with a proprietary pipeline of DARPin<sup>®</sup> drug candidates. The most advanced assets globally is abicipar, a molecule currently in phase 3 which is being advanced by Allergan. Abicipar is being followed by several DARPin<sup>®</sup> molecules for various ophthalmic indications. The most advanced systemic DARPin<sup>®</sup> molecule, MP0250, is in clinical development for solid tumors and is moving to phase 2 for hematological and solid tumors. The second most advanced oncology DARPin<sup>®</sup> drug candidate is MP0274, which has broad anti-HER activity, inhibiting HER1, HER2, and HER3-mediated downstream signaling via Her2 and leading to induction of apoptosis. MP0274 is currently in preclinical development. There is a growing pipeline of immune-oncological treat-ments following the two proprietary lead assets.

#### **About Molecular Partners AG**

Molecular Partners AG is a clinical-stage biopharmaceutical company that is developing a new class of therapies known as DARPin<sup>®</sup> therapies. DARPin<sup>®</sup> therapies are potent, specific, and versatile small proteins, which have the potential to offer benefits over conventional monoclonal antibodies or other currently available protein therapeutics. The DARPin<sup>®</sup> technology has the potential to offer a multi-specific approach to treatment, which enables the DARPin<sup>®</sup> therapies to target multiple pathways, or multiple epitopes on a single target to achieve substantial patient benefit. DARPin<sup>®</sup> therapies have the potential to advance modern medicine and significantly improve the treatment of serious diseases, including cancer and sight-threatening disorders. DARPin<sup>®</sup> is a registered trademark owned by Molecular Partners AG.

Molecular Partners has four compounds in various stages of clinical and preclinical development and several more in the research stage, with a current focus on ophthalmology and oncology. The company establishes research and development partnerships with leading pharmaceutical companies and is backed by established biotech investors.

For more information regarding Molecular Partners AG, go to: www.molecularpartners.com .

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