

# Molecular Partners Reports Corporate Highlights from Q4 2020 and Key Financials for FY2020

February 5, 2021

## Research & Development Highlights:

### Virology:

- Initiated and rapidly advanced COVID-19 antiviral program into the clinic; secured collaboration with Novartis for co-development of multi-specific candidates MP0420 (ensovibep) and MP0423, including options for global commercialization; terms included potential total cash consideration of CHF 215 million, comprised of an upfront payment, equity purchase, and milestone, as well as 22% royalty on sales in commercial territories
- Announced positive safety data from first dose cohort of ongoing phase 1 COVID-19 study which is on track to report data from all cohorts in Q1 2021
- Announced intention to explore broader virology portfolio with focus on major global viral threats where unique therapeutic
  profile of DARPin® antivirals could make major impact
- Published new research in February 2021 showing ensovibep and MP0423 remain active against the major known mutations of SARS-CoV-2 including those present in variants first identified in the United Kingdom (UK), and South Africa (SA)

## Oncology:

- First-in-human data from ongoing phase 1 study of MP0310/AMG 506 demonstrate biological activity, including successful localized tumor engagement and saturation of tumor antigen at higher doses; optimization of dosing schedule ongoing in 2021
- Achieved proof-of-biology and mechanism in clinical studies of MP0250 and MP0274, which have no further studies planned

### Research:

- Advanced CD3/T cell engager therapeutics platform to demonstrate both highly selective, potent/efficacious and targeted T cell engagement, context-dependent T cell engagement, and 'slow release' T cell engagement, giving multiple new levels of control over this powerful immunomodulatory mechanism
- Validated peptide MHC (pMHC) therapeutics platform, with data demonstrating high potency, specificity and extended systemic half-life of research candidates, and the capacity to rapidly generate multiple candidates in parallel

## **Financial and Team Highlights:**

- Strong financial position with CHF 173.7 million in cash (including short-term deposits) as of December 31, 2020
- Net cash used in operating activities of CHF 29.0 million in 2020
- Operating loss of CHF 58.3 million and net loss of CHF 62.8 million in 2020
- Company funded into 2023, excluding any potential payments from R&D partnerships
- Talent base of 145 full-time employees at year-end 2020
- Gwen Fyfe has worked closely with the Board of Directors and has informed the team of her intent not to stand for re-election at upcoming Annual General Meeting on 21 April 2021

**Zurich-Schlieren, Switzerland, February 05, 2021.** Molecular Partners AG (SIX: MOLN), a clinical-stage biotech company that is developing a new class of custom-built proteins known as DARPin® therapeutics, today announced its unaudited financial results for 2020 and corporate highlights for the fourth quarter of 2020.

"In 2020, our pipeline grew and evolved in several key ways, including clinical proof of biological activity for our first localized immune agonist program, important platform advances for the design of new immunomodulatory DARPin® candidates, and of course the rapid progression to the clinic of our COVID-19 program, specifically designed to deliver differentiated therapeutics that answer the need of an evolving global viral pandemic," said Patrick Amstutz, Ph.D., chief executive officer of Molecular Partners. "We have significantly expanded the horizons of possibility for DARPin® molecules in 2020, and look forward to executing on multiple parallel clinical programs with very diverse targets in the year ahead."

## Antiviral program: Rapid development progress for highly differentiated anti-COVID-19 multi-DARPin® candidates with unique advantages

In October 2020, the Company announced further supportive preclinical data from in vivo assessments of its two DARPin® candidates targeting SARS-CoV-2. These candidates showed robust activity in an aggressive viral challenge hamster model, supporting potential efficacy as therapeutic options in patients with late-stage disease. In a highly susceptible COVID-19 challenge model developed by expert virologists at Freie Universität Berlin, hamsters were first infected with SARS-CoV-2 and then administered either select doses of anti-COVID-19 DARPin® candidates or placebo, at either 0, 6, or 24 hours. In the five-day experiment, all animals treated with DARPin® molecules recovered and survived, while 83% of animals in the placebo group had to be euthanized due to severe disease progression.

Further in October, the Company signed a collaboration with Novartis for the co-development of ensovibep and MP0423 as well as options for global commercialization. This collaboration combines the innovative protein drug development expertise of Molecular Partners with Novartis' expertise in clinical development, manufacturing, regulatory affairs & commercialization to accelerate global development of both candidates.

Under the terms of the collaboration agreement, Molecular Partners received a cash payment of CHF 20 million (~\$22 million USD). As part of the transaction, Novartis also agreed to acquire CHF 40 million (~\$44 million USD) worth of ordinary shares at a price of CHF 23 (~\$25 USD) per share. As a result, Novartis now holds approximately 6% of the outstanding shares of Molecular Partners. Molecular Partners is eligible to receive a future milestone payment of CHF 150 million (~\$165 million USD), upon Novartis exercising the option to both therapeutic candidates, additional clinical milestones of CHF 5 million associated with MP0423, and 22% royalty on sales in commercial countries. Molecular Partners has agreed to forgo royalties in lower income countries, and is aligned with Novartis' plans to ensure affordability based on countries' needs and capabilities.

In November 2020, the Company dosed the first cohort of healthy volunteers in a Phase 1, randomized, double-blind, placebo-controlled, first-in-human single ascending dose study to evaluate the safety, tolerability, and pharmacokinetics of intravenously administered ensovibep in up to 24 healthy volunteers divided into three dose cohorts, with each cohort stratified 3:1 in favor of ensovibep. We expect to report initial data in Q1 2021. Multiple characteristics of DARPin® therapeutics make them ideally suited for antiviral therapies, particularly at time of global need. They also offer logistical advantages that other potential therapeutics in development may not possess, including (i) sub-picomolar potency, allowing investigation of subcutaneous administration as both early intervention and potential prophylaxis; (ii) highly scalable microbial manufacturing, allowing for up to 4 production runs on the same fermenter, per month; and (iii) high temperature stability (>80°C) which may allow for avoidance of cumbersome cold chain storage. Molecular Partners is actively exploring opportunities to develop DARPin® therapeutics against other viral infections with significant unmet global need.

Another important characteristic of DARPin® molecules as a class, and specifically against SARS-CoV-2, is the advantage of cooperative binding: multiple DARPin® domains, bound to each other on a single chain, collaboratively interacting with the target protein. In the example of SARS-CoV-2, this cooperative binding allows for much stronger target engagement and inhibition. Moreover, with the rise of new mutations and viral variants, cooperative binding allows DARPin® candidates to maintain a high level of potency even if one or two of the three binding domains lose some of their individual binding strength. As described in recent results, ensovibep and MP0423 continue to inhibit SARS-CoV-2 infections in vitro in the presence of multiple mutations, including those present in the B.1.1.7 P.1 and B.1.351 variants, first identified in UK, Brazil and SA, respectively.

### Oncology: Clinical biomarkers provide support for MP0310/AMG 506 (targeting FAP x 4-1BB)

Initial clinical data from the ongoing phase 1 dose escalation study of MP0310 were presented in December 2020 at the Company's virtual R&D day and support preclinical observations. At the time of analysis, 19 of the 22 patients were available for evaluation. Of these, 50% of patients achieved stable disease (SD). To date, this study has reported no dose-limiting toxicities and no serious adverse events (SAEs) of special interest. Tumor biopsies show tumor-localized immune response consistent with the predicted MoA of MP0310. The PK profile appears to be dose dependent additional dosing regimens are currently being explored.

Additionally, biopsy data showed significant increases in activation across multiple immune cell types, while inflammatory markers in the peripheral blood were unchanged. Grade 2/3 infusion-related responses (IRRs) were observed in 12 patients and were manageable.

## Oncology: Preclinical data supports mechanism of MP0317 (targeting FAP x CD40)

In 2020, the Company presented preclinical data at research conferences strongly supporting the intended profile and CD40-mediated immune activation capabilities of MP0317. In a mouse model, a mouse-specific version of MP0317 was found to substantially inhibit the progression of FAP-positive tumors without showing any of the toxicities seen with administration of a mouse CD40 antibody. Phase 1 initiation for MP0317 is now anticipated in H2 2021 due to a loss of drug supply associated with fill/finish procedures. New batches of MP0317 will be produced in H1 2021 and the clinical study is anticipated to initiate shortly thereafter.

## Oncology: Novel therapeutic platforms address key challenges facing non-DARPin® approaches

At its virtual R&D Day in December 2020, the Company shared data demonstrating the substantial progress made across the CD3/T cell engager and peptide MHC (pMHC) therapeutics platforms, which both open an array of new opportunities for modulating the immune system to fight disease.

CD3/T cell engagers: The CD3/T cell engager therapeutics platform is designed to avoid the dose-limiting toxicities that T cell engagers have generally produced to-date. The Company has now demonstrated both highly selective T cell activation in the tumor microenvironment, as well as the capacity for 'slow release' activation of T cells in the circulation, giving multiple levels of control over this key immuno-oncologic mechanism to help reduce off-tumor effects, achieve higher dose levels and ultimately enhanced clinical benefit. The multi-domain DARPin® format potentially allows a high level of functional 'tuning' to a target indication. In models of acute myeloid leukemia, multi-DARPin® CD3/T cell engager research candidates have demonstrated high potency, improved selectivity and lower levels of inflammatory cytokine stimulation.

**pMHC platform:** The unique binding surface of DARPin® molecules can be tailored to target pMHC immune complexes, which display the intracellular proteome on the surface of cells and thereby can show specific peptides intimately associated with disease, including with virus-infected cells or tumor cells. pMHCs have proved extremely challenging to target – with high affinity and specificity – for other modalities. The Company's

pMHC platform is now supported by technical proof-of-concept data demonstrating high potency and specificity – resolving several major challenges of classical pMHC-targeted discovery via non-DARPin® approaches.

## **Board Updates**

Gwen Fyfe has informed the Company that she will not stand for re-election at the upcoming Annual General Meeting on 21 April 2021. Gwen Fyfe has been a member of the Board of Directors since 2017. The Board of Directors would like to express their deep gratitude for her invaluable contributions and commitment to Molecular Partners during her years of service. Gwen Fyfe will be available to support the Company on a consultancy basis.

## Financial Highlights: Net result and cash position on previous year's level

In the financial year 2020, Molecular Partners recognized total revenues of CHF 9.3 million (2019: CHF 20.4 million) and incurred total expenses of CHF 67.7 million (2019: CHF 57.1 million). This led to an operating loss of CHF 58.3 million for 2020 (2019: Operating loss of CHF 36.7 million). The net financial loss of CHF 4.4 million recorded in 2020 compared to a net financial income of CHF 0.4 million in 2019. This resulted in a 2020 net loss of CHF 62.8 million (2019: Net loss of CHF 36.3 million).

The net cash used for operating activities in 2020 was CHF 29.0 million (2019: net cash used of CHF 1.2 million). Including time deposits, the cash and cash equivalents position increased by CHF 78.6 million vs. year-end 2019 to CHF 173.7 million as of December 31, 2020 (December 31, 2019: CHF 95.1 million). Total shareholders' equity stood at CHF 107.2 million as of December 31, 2020, an increase of CHF 53.1 million (December 31, 2019: CHF 54.1 million).

#### Key figures as of December 31, 2020

Key Financials (unaudited)	FY 2020	FY 2019	Change
(CHF million, except per share, FTE data)			
Total revenues	9.3	20.4	(11.1)
R&D expenses	(56.1)	(43.5)	(12.6)
SG&A expenses	(11.6)	(13.6)	2.0
Operating result	(58.3)	(36.7)	(21.6)
Net finance result	(4.4)	0.4	(4.8)
Net result	(62.8)	(36.3)	(26.5)
Basic and diluted net result per share (in CHF)	(2.51)	(1.69)	(0.82)
Net cash from (used in) operating activities	(29.0)	(1.2)	(27.8)
Cash & cash equivalents at December 31 (incl. short-term time deposits)	173.7	95.1	78.6
Total shareholders' equity at December 31	107.2	54.1	53.1
Number of total FTE at December 31	145.4	135.2	10.2

As of December 31, 2020, the company employed 145 FTE, up 8% compared to year-end 2019. Approximately 85% of the employees are employed in R&D-related functions.

#### **Business outlook and priorities**

In 2021, Molecular Partners will focus on advancing its immuno-oncology and infectious disease programs. For the **COVID-19 program**, the Company anticipates final data from the ongoing phase 1 study of ensovibep will be available in the first quarter of 2021. The Company also anticipates the initiation of additional clinical studies of ensovibep throughout the first half of 2021, with the goal of achieving clinical proof of concept and potential emergency use authorization within 2021.

In **immuno-oncology**, the Company is planning to investigate an optimized dosing schedule for MP0310/AMG 506 via exploration of weekly administration ahead of potential combination studies with Amgen assets. The Company also expects initiation of a phase 1 study of MP0317, the second immuno-oncology local agonist, in H2 2021.

Additionally, Molecular Partners will continue to advance its immuno-oncology research pipeline, including the significantly advanced peptide MHC (pMHC) and CD3/T Cell targeting platforms, both of which have the potential to open up a range of new targets to DARPin® therapeutics, and plans to publish or present multiple updates across its portfolio at select scientific venues.

### Financial outlook 2021

For the FY 2021, at constant exchange rates, the company expects total P&L expenses of CHF 65-75 million, of which around CHF 7 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciations. In terms of cash outflow the company expects a

gross cash burn of CHF 85-95 million, which includes CHF 20 million payable to Novartis for the manufacturing of commercial supply. This cash flow guidance does not include any potential payments from R&D partnerships.

With CHF 173.7 million cash at hand and no debts as per the end of 2020 the company is funded into 2023, excluding any potential payments from R&D partners.

This guidance is subject to the progress of the pipeline, mainly driven by manufacturing costs, the speed of enrollment of patients in clinical trials and data from research and development projects.

## Investor documentation of FY 2020 results

The results presentation as well as this press release will be made available at <a href="https://www.molecularpartners.com">www.molecularpartners.com</a> after 7:00am (CET) on February 05, 2021.

#### FY 2020 conference call

Molecular Partners will hold a conference call and video webcast on Friday, February 05, 2021, 2:00pm CET (1:00pm GMT, 8:00am EST).

In order to register for the FY 2020 conference call, please dial the following numbers approximately 10 minutes before the start of the presentation:

Switzerland / Europe +41 (0) 58 310 5000
UK +44 (0) 207 107 0613
US +1 (1) 631 570 5613

Participants will have the opportunity to ask questions after the presentation.

#### Video webcast

The FY 2020 results presentation will be <u>webcast live</u> and will be made available on the <u>Company's website</u> under the <u>investor section</u>. The replay will be available for 90 days following the presentation.

## **Financial Calendar**

DateEvent26 February 2021Publication of FY 2020 Annual Report21 April 2021Annual General Meeting12 May 2021Interim Management Statement Q1 202126 August 2021Publication of HY Results 2021 (unaudited)

This calendar is always viewable at this link.

## **About Molecular Partners AG**

Molecular Partners AG is a clinical-stage biotech company developing DARPin® therapeutics, a new class of custom-built protein drugs designed to address challenges current modalities cannot. The Company has formed partnerships with leading pharmaceutical companies to advance DARPin® therapeutics in the areas of ophthalmology, oncology and infectious disease, and has compounds in various stages of clinical and preclinical development across multiple therapeutic areas. <a href="www.molecularpartners.com">www.molecularpartners.com</a>; Follow the Company on Twitter at <a href="@MolecularPrings">@MolecularPrings</a>.

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## Forward-looking statements

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