



Molecular Partners Reports Corporate Highlights and Key Financials for H1 2021

August 26, 2021

- Significant progress in COVID-19 trials, including positive results from healthy subjects and COVID-19 patients, supporting the launch of ongoing late-stage trials EMPATHY and ACTIV-3

Research & Development:

- Initiated two global Phase 2 and 3 trials of ensovibep (MP0420), to explore safety and efficacy in ambulatory patients with COVID-19 (EMPATHY) in collaboration with Novartis, and hospitalized patients (ACTIV-3) sponsored by the National Institutes of Health (NIH)
- Received FDA Fast Track designation for ensovibep for the treatment of COVID-19 in both hospitalized and ambulatory settings
- Initiated and fully enrolled Phase 2a single arm study of ensovibep in the Netherlands in patients with mildly symptomatic COVID-19, with data expected to be presented in a scientific conference in H2 2021
- Reported that *in vitro* studies indicate that ensovibep maintains potency against all known SARS-CoV-2 variants of concern, including Delta and Lambda
- Presented data further supporting the MP0317, T-cell engager, and Peptide-MHC oncology programs at AACR
- In August, announced receipt of global rights of abicipar pegol for the treatment of neovascular AMD (nAMD) and Diabetic Macular Edema, following termination of license and collaboration agreement by AbbVie Inc.

Leadership & Governance:

- Elected Agnete Fredriksen and Dominik Höchli to the Board of Directors at the Annual General Meeting of April 21, 2021

Financial highlights:

- Successfully completed initial public offering of American Depositary Shares (“ADSs”) on the Nasdaq, raising \$63.8 million (CHF 58.8 million) in gross proceeds to support ongoing operations into H2 2023
- Ongoing strong financial position with CHF 174.3 million in cash and short-term deposits as of June 30, 2021
- Net cash outflow from operating activities of CHF 52.5 million in H1 2021
- FY 2021 expense guidance maintained at CHF 65-75 million

Zurich, Switzerland, August 26, 2021 - Ad hoc announcement pursuant to Art. 53 LR

[Molecular Partners AG](#) (SIX: MOLN, NASDAQ: MOLN), a clinical-stage biotech company developing a new class of custom-built proteins known as DARPin® therapeutics, today announced its corporate highlights and unaudited financial results for the first half-year of 2021.

“Molecular Partners strongly expanded our global clinical presence and collaboration with Novartis in the first half of the year as the evolving COVID-19 pandemic continued to underscore the need for effective antiviral therapeutics. As a now dual-listed company in Switzerland and the United States, our expanded investor base enables us to accelerate our mission to deliver a new class of medicines to people living with cancer and infectious diseases,” said Patrick Amstutz, Ph.D., Chief Executive Officer of Molecular Partners. “To have entered two ongoing, late-stage trials of ensovibep further illustrates our rapid design and development capabilities. In addition to the COVID-19 program we are focused on expanding into new antiviral applications of the DARPin platform while moving towards a new phase for our immuno-oncology programs.”

Antiviral program: Rapid development of trispesific antiviral DARPin® candidate ensovibep in multiple international clinical trials

Molecular Partners advanced in 2021 with strong momentum for the Company’s lead antiviral candidate, ensovibep, which has progressed in the second quarter of 2021 into two ongoing, late-stage global clinical studies, EMPATHY and ACTIV-3, in collaboration with Novartis and the NIH, respectively. Thus far, ensovibep has provided positive Phase 1 data and continued to maintain potency in laboratory studies against all known COVID-19 variants of concern.

In March of 2021, Molecular Partners and its collaboration partner Novartis announced that the National Institutes of Health (NIH) selected ensovibep for inclusion in a global phase 3 randomized, controlled clinical trial as part of NIH’s Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program. The international master protocol ACTIV-3 is designed to evaluate the safety and efficacy of various therapies for the treatment of adults hospitalized with a COVID-19 diagnosis. A sub-study of ACTIV-3 evaluating ensovibep began enrolling hospitalized patients in June 2021 and is currently enrolling patients across seven countries. Topline data from this study are expected in 2022.

In May of 2021, Molecular Partners and its collaboration partner Novartis announced the start of the clinical trial EMPATHY, a global phase 2 - 3 study, to explore the use of ensovibep for the treatment of COVID-19 in patients who are in the early stages of infection, to prevent worsening symptoms and hospitalization. Molecular Partners’ collaboration partner Novartis is conducting the clinical trial for ensovibep, with Molecular Partners as sponsor. EMPATHY is currently enrolling patients across five countries. Topline interim data for the first 400 patients are expected towards the end of second half of 2021 with complete data expected in 2022.

In April of 2021, the first patient was dosed in a Phase 2a clinical trial of ensovibep in a single arm, open label study in the Netherlands that enrolled patients with mild symptomatic COVID-19, and is designed to evaluate the dynamics of viral clearance, pharmacokinetics and tolerability of ensovibep. This study enrolled a total of 12 patients in two dose cohorts, with data expected to be presented in a scientific conference in H2 2021. Initial results show a steady decline of viral loads in treated patients, validating the follow-up methods implemented in the Company's ongoing late-stage trials, EMPATHY and ACTIV-3.

In March 2021, Molecular Partners reported positive initial Phase 1 results in healthy volunteers. Ensovibep, administered intravenously (I.V.), was seen to be safe and well tolerated, with no serious or severe adverse events reported. These preliminary results also confirmed extended exposure to ensovibep in serum, with a half-life of 2-3 weeks, as was expected from preclinical experiments. These data confirmed the systemic administration of ensovibep to be safe and well tolerated and supported the initiation of later stage trials. Following I.V. administration, ensovibep was also evaluated for safety and half-life when administered in bolus, and is presently being evaluated in subcutaneous (S.C.) administration in healthy subjects.

DARPin® molecules offer a differentiated approach to treating COVID-19 through a 'cocktail in a molecule' mechanism; a single molecule that can engage three domains of the SARS-CoV-2 virus simultaneously to inhibit viral entry into cells. This allows for a potentially broader efficacy and reduces the likelihood for the development of viral drug resistance which can result from selection pressure on any single molecular target. In addition, DARPin® candidates are produced through rapid, high-yield microbial fermentation for potential speed and logistical advantages over mammalian cell production employed for antibodies.

Based on the success seen to-date of ensovibep's unique approach to neutralizing the virus, Molecular Partners is also evaluating the next generation of opportunities to develop antivirals against other infectious diseases with global unmet need.

Immuno-oncology programs: Clinical work for AMG 506 / MP0310 (FAP x 4-1BB) ongoing; new supportive data published across acute myeloid leukemia and MP0317 (FAP x CD40) programs as well as novel technology platforms

Following the positive initial results of MP0310, clinical work advanced into weekly administration of MP0310 in the Phase 1 study, to identify a dosing regimen to obtain sustained 4-1bb activation. Molecular Partners expects to obtain data from this trial within 2021, allowing for its partner, Amgen, to evaluate potential future development of MP0310 in combination with Amgen's oncology assets, including BITE® molecules.

In April of 2021, Molecular Partners presented four posters highlighting research across its immuno-oncology programs at the American Association for Cancer Research (AACR) virtual Annual Meeting. Molecular Partners' novel multi-specific DARPin® candidates are designed to activate the immune system to fight cancer while reducing damage to healthy cells. These candidates use multiple novel DARPin® technologies potentially applicable against a wide range of tumor types. The preclinical data shared include first results from the Company's acute myeloid leukemia (AML) CD3 T-cell engager program, initial results from the CD3 prodrug program, and new data from the MP0317 and peptide-MHC programs.

With respect to MP0317, a multi-specific DARPin® product candidate targeting both FAP and CD40 to enable tumor-localized immune activation, new preclinical data showed activation of B-cells and myeloid cells in *ex vivo* human tumor samples. This demonstrated that physiological presence of FAP, expressed in the connective tissue of a broad range of solid tumors, is mandatory and sufficient for MP0317 to induce immune activation. Furthermore, the data presented at AACR shows that MP0317 led to a range of pro-inflammatory activities, including macrophage repolarization and reversion of T-cell suppression only in the presence of FAP. In both assays the killing effect was comparable to that achieved by an anti-CD40 antibody. The Company believes these data support MP0317's potential to deliver tumor-localized CD40-mediated immune cell activation while avoiding systemic toxicity seen with other agents. MP0317 is anticipated to begin clinical trials in the second half of 2021.

In preclinical studies, the Company's AML research candidates demonstrated substantial activity against different populations of AML cells *in vitro* and *ex vivo*, without significant damage to healthy cells. The candidate is further designed to bind with increased avidity as the number of relevant antigens presented increases, further strengthening its preference for tumor cells. The candidate is a single molecule designed to target three different cancer antigens simultaneously (CD70, CD33, and CD123). This multi-specific DARPin® T-cell engager candidate is designed to deliver a highly potent and specific anti-tumor response to AML cells, with a reduced effect on healthy normal cells, and with the potential to counteract target escape mechanisms expected due to tumor heterogeneity. The AML DARPin candidate demonstrated potent induction of T-cell mediated cytotoxicity against AML cell lines and primary AML calls. In an *ex vivo* assay using fresh blood from healthy donors, the candidate induced profoundly less inflammatory cytokine production and reduction in platelet counts than T-cell engager candidates in development by other parties. Molecular Partners believes this candidate shows a unique avidity-driven ability to kill a broader population of AML cells while decreasing the risk of toxicity.

Molecular Partners' T-cell engager programs also include a novel prodrug DARPin® technology for tumor-localized release of immune stimulation, through incorporation of a protease-cleavable blocker DARPin® molecule. As CD3-binding T-cell engagers are highly potent and can lead to systemic toxicities, Molecular Partners has developed a DARPin® domain designed to mask the CD3 engager from interacting with T cells, systemically or outside of the tumor, thus reducing toxicity by limiting immune activation to the tumor microenvironment. Molecular Partners' prodrug research candidate, CD3-PDD, has demonstrated *in vitro* and *in vivo* proof-of-concept, being shown to be unable to bind and recruit T-cells in its non-cleaved state in circulation while delivering an anti-tumor effect.

Finally, new data were presented supporting Molecular Partners' peptide-MHC targeting program, which focuses on developing the capability to target cell surface protein complexes indicating disease through display of intracellular peptides. At AACR, the Company presented preclinical results demonstrating rapid and reliable generation of DARPin® proteins against a peptide-MHC complex (pMHC). These DARPin® proteins were then formatted into bispecific T-cell engagers, and engineered to enable potent and specific activation of T cells. Further, the results showed that a pMHC-targeting DARPin® candidate was able to achieve systemic half-life extension.

Ophthalmology

In August, the Company was updated by its collaboration partner, AbbVie Inc. of its termination of the license and collaboration agreement for the investigational drug abicipar pegol for the treatment of nAMD and DME. As such, Molecular Partners will regain the development and commercial rights of abicipar on a worldwide basis.

Financial Highlights: Nasdaq offering extends cash runway into H2 2023

Molecular Partners remains solidly funded to capture upcoming value inflection points. In June 2021, the Company successfully completed an initial public offering of American Depositary Shares on the NASDAQ exchange, raising \$63.8 million (CHF 58.8 million) in gross proceeds. With the U.S. listing, Molecular Partners has broadened its access to capital from the global investment community to support its programs and growing pipeline. In

the first six months of 2021, Molecular Partners recognized total revenues and other income of CHF 4.4 million (H1 2020: CHF 7.5 million) and incurred total operating expenses of CHF 39.2 million (H1 2020: CHF 30.6 million). This led to an operating loss of CHF 34.8 million for the first six months in 2021 (H1 2020: Operating loss of CHF 23.1 million) and a net loss of CHF 33.6 million for H1 2021 (H1 2020: Net loss of CHF 24.7 million).

The net cash outflow from operating activities during the first six months in 2021 was CHF 52.5 million (2020: net cash outflow of CHF 27.9 million). Including time deposits, the cash and cash equivalents position increased by CHF 0.6 million vs. year-end 2020 to CHF 174.3 million as of June 30, 2021 (December 31, 2020: CHF 173.7 million).

Total shareholders' equity stood at CHF 134.6 million as of June 30, 2021, an increase of CHF 27.4 million (December 31, 2020: CHF 107.2 million). As of June 30, 2021, the Company employed 158 FTEs (full time equivalents), up 15 year-on-year. About 80% of the employees are employed in R&D-related functions.

KEY FIGURES AS OF JUNE 30, 2021

Key Financials (unaudited) (CHF million, except per share, FTE data)	H1 2021	H1 2020	Change
Total revenues and other income	4.4	7.5	(3.1)
R&D expenses	(31.6)	(25.1)	(6.5)
SG&A expenses	(7.6)	(5.5)	(2.1)
Operating result	(34.8)	(23.1)	(11.7)
Net result	(33.6)	(24.7)	(8.9)
Basic net result per share (in CHF)	(1.13)	(1.14)	0.01
Net cash from (used in) operating activities	(52.5)	(27.9)	(24.6)
Cash balance (incl. time deposits) as of June 30	174.3	64.4	109.9
Total shareholders' equity as of June 30	134.6	31.0	103.6
Number of total FTE as of June 30	158.3	143.6	14.7

BUSINESS OUTLOOK AND PRIORITIES

In the second half of 2021, Molecular Partners remains focused on the rapid clinical development of ensivibep across two major global studies as well as a further bridging study to evaluate the option of subcutaneous/intramuscular administration. Topline interim data for the first 400 patients from the ongoing EMPATHY trial are expected in the second half of 2021 with full interim data expected in early 2022. Molecular Partners is committed to advancing other antiviral programs and is currently evaluating several potential targets with global unmet need. The Company expects to announce additional antiviral programs in the second half of 2021. In immuno-oncology, Molecular Partners expects to provide results from the MP0310 trial to Amgen, to inform their decision regarding future development of the program. Further, the Company intends to begin clinical studies of MP0317 in the second half of 2021 and expects to present additional research data from its trispesific CD3 T-cell engager for the treatment of AML. Molecular Partners is now working with AbbVie for the receipt of data and materials related to the abicipar program. The Company has formed a special committee to evaluate the program and determine appropriate next steps regarding abicipar.

FINANCIAL OUTLOOK 2021

For the full year 2021, at constant exchange rates, the company continues to expect total expenses of CHF 65-75 million, of which around CHF 7 million will be non-cash effective costs.

In terms of cash outflow the company expects a gross cash utilization of CHF 85-95 million for FY2021, which includes a total of CHF 20 million payable to Novartis for the manufacturing of commercial supply (of which CHF 10.5 million occurred during H1 2021). This cash flow guidance does not include any potential receipts from R&D partnerships.

With CHF 174.3 million cash at hand and no debt as per June 30, 2021 the company expects to be funded into H2 2023, excluding any potential receipts from R&D partners.

DOCUMENTATION

The results presentation, this press release, and the half-year 2021 report will be made available on www.molecularpartners.com after 7:00am (CET) on August 26, 2021.

H1 2021 CONFERENCE CALL & AUDIO WEBCAST

Molecular Partners will hold a conference call and audio webcast on August 26, 2021, 2:00pm CET (1:00pm GMT, 8:00am EST).

In order to register for the H1 2021 conference call, please dial the following numbers approximately 10 minutes before the start of the presentation:

Switzerland / Europe	+41 800 83 6508
USA	+1 844 865 3856
Conference ID	9774461

Participants in the conference call will have the opportunity to ask questions after the presentation.

AUDIO WEBCAST

The H1 2021 results presentation will be webcast live and will be made [available](#) on the Company's website under the investor section. The replay will be available for 90 days following the presentation.

FINANCIAL CALENDAR

October 28, 2021
December 15, 2021

Interim Management Statement Q3 2021
Virtual R&D Day

The latest timing of the above events can always be viewed on the [investor section](#) of the website.

ABOUT DARPin® THERAPEUTICS

DARPin® therapeutics are a new class of custom-built protein therapeutics based on natural binding proteins that open a new dimension of multi-functionality and multi-target specificity in drug design. A single DARPin® candidate can engage more than five targets, and its flexible architecture and small size offer benefits over conventional monoclonal antibodies or other currently available protein therapeutics. DARPin® therapeutics have been clinically validated through to the registrational stage. The DARPin® platform is a fast and cost-effective drug discovery engine, producing drug candidates with optimized properties for development and very high production yields. DARPin® is a registered trademark owned by Molecular Partners AG.

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. www.molecularpartners.com; Find us on Twitter - [@MolecularPrtnrs](#)

FOR FURTHER DETAILS, PLEASE CONTACT:

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding the clinical development of Molecular Partners' current or future product candidates, including timing for the potential submission of emergency use authorization for ensovibep, expectations regarding timing for reporting data from ongoing clinical trials or the initiation of future clinical trials, the potential therapeutic and clinical benefits of Molecular Partners' product candidates, the selection and development of future antiviral or other programs, and Molecular Partners' expected expenses and cash utilization for 2021 and that its current cash resources will be sufficient to fund its operations and capital expenditure requirements into H2 2023. These statements may be identified by words such as "anticipate", "believe", "could", "expect", "intend", "may", "plan", "potential", "will", "would" and similar expressions, although not all forward-looking statements may contain these identifying words, and are based on Molecular Partners AG's current beliefs and expectations. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Some of the key factors that could cause actual results to differ from our expectations include our plans to develop and potentially commercialize our product candidates; our reliance on third party partners and collaborators over which we may not always have full control; our ongoing and planned clinical trials and preclinical studies for our product candidates, including the timing of such trials and studies; the risk that the results of preclinical studies and clinical trials may not be predictive of future results in connection with future clinical trials; the timing of and our ability to obtain and maintain regulatory approvals for our product candidates; the extent of clinical trials potentially required for our product candidates; the clinical utility and ability to achieve market acceptance of our product candidates; the potential impact of the COVID19 pandemic on our operations or clinical trials; our plans and development of any new indications for our product candidates; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position; our ability to identify and in-license additional product candidates; the adequacy of our cash resources and our anticipated cash utilization; and other risks and uncertainties that are described in the Risk Factors section of Molecular Partners' Registration Statement on Form F-1 filed with Securities and Exchange Commission (SEC) on June 14, 2021 and other filings Molecular Partners makes with the SEC. These documents are available on the Investors page of Molecular Partners' website at

<http://www.molecularpartners.com>. Any forward-looking statements speak only as of the date of this press release and are based on information available to Molecular Partners as of the date of this release, and Molecular Partners assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.