



Molecular Partners Reports Corporate Highlights and H1 2022 Financials

August 25, 2022

- Continued development of MP0317, with initial clinical data from Phase 1 study expected in the second half of 2022
- Initiation of Phase 1 study for MP0533 expected by year end
- Continued progression of proprietary DARPin-conjugated radioligand therapeutics; innate immune cell engagers; next-generation T-cell engagers; and antiviral DARPins
- MP0310 Phase 1 enrollment complete; no additional studies currently planned
- In January 2022, Molecular Partners received a payment of CHF 150 million from Novartis to license ensovibep
- Novartis is responsible for further development, manufacturing, and commercialization activities. An application for Emergency Use Authorization (EUA) was submitted to the U.S. Food and Drug Administration (FDA) by Novartis for ensovibep
- Cash position of CHF 285.1 million as of June 30, 2022, anticipated to support operations into 2026

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Aug. 25, 2022 (GLOBE NEWSWIRE) -- **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 protein drugs known as DARPin therapeutics, today announced its corporate highlights and unaudited financial results for the first half-year of 2022.

"In the first half of this year, we have delivered a major clinical success with ensovibep, leading to its licensure by our partner Novartis and a position of financial strength to execute on the next phase of our strategy at full speed," said Patrick Amstutz, Ph.D., CEO of Molecular Partners. "Programs like ensovibep and our trispecific T-cell engager for AML, MP0533, represent our strategic focus: highly differentiated approaches to major diseases that leverage the strengths of the DARPin class. Using our leading platform, we are focused on advancing and growing our pipeline to meaningfully impact treatment for patients."

Research & Development Highlights:

MP0317 (FAP x CD40):

- Phase 1 open-label dose escalation study continues in patients with solid tumors known to express FAP. Initial clinical data from this study expected to be presented at a conference in the second half of 2022
- Preclinical data published in *Cancer Immunology Research* supporting MP0317's potential to deliver tumor-localized immune activation while avoiding systemic toxicity seen with other CD40-targeting agents

MP0533 (CD3 x CD33 x CD70 x CD123)

- Lead candidate, MP0533, selected, following continued promising preclinical data supporting its unique design and mechanism. It is expected to reach clinical development by year end
- New *in vivo* data from the MP0533 program were presented at the European Hematology Association Congress in June 2022

DARPin-Radioligand Therapies

- Novartis partnered program ongoing
- Proprietary programs now advancing

Ensovibep COVID-19 antiviral program

- In January 2022, Novartis exercised its option to in-license ensovibep and is now solely responsible for further development, manufacturing, and commercialization activities. Upon exercise of the option, Molecular Partners received a payment of CHF 150 million, which was in addition to the initial upfront payment of CHF 60 million, from Novartis
- Novartis submitted an application for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) in February 2022, following positive, topline results from the primary analysis of the Phase 2 EMPATHY clinical trial. As previously announced, the FDA has asked that Phase 3 data be provided for their review. Novartis is currently engaged in developing a Phase 3 protocol

- The primary analysis from Phase 2 of the EMPATHY clinical trial was presented at the 2022 European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in April 2022
- Key preclinical data documenting the unique design and mechanism of action of ensovibep were published in *Nature Biotechnology* in July 2022, in a paper titled "The trispecific DARPIn ensovibep inhibits diverse SARS-CoV-2 variants"

MP0310 (FAP x 4-1BB)

- Amgen has returned the global rights for MP0310 following a strategic pipeline review. The last patient has been dosed in the Phase 1 study, and the study data are currently being collected and reviewed. The results of the full analysis will inform further business development activity. No additional internal investment in the program is currently planned

Abicipar for wet age-related macular degeneration

- Evaluation of business development opportunities for pivotal-stage asset continues, informed by correspondence with the FDA and discussions with potential partners

Oncology: MP0533 approaching Phase 1 initiation; Phase 1 trials of MP0317 and MP0310; Development of a DARPIn-based radioligand program

MP0533, Molecular Partners' novel acute myeloid leukemia (AML) candidate, is a DARPIn designed to engage CD3 on T cells while binding up to three tumor-associated antigens (CD33, CD70, and CD123) on AML cells. Preclinical studies have shown that MP0533 T cell activation and tumor killing increased significantly with the number of tumor-associated antigens present. This 'avidity-dependent' mechanism, enabled by the DARPIn platform, can lead to preferential targeting of AML cells which, unlike healthy cells, generally express two or more of these antigens. Once bound, the AML cells are marked for termination by nearby T cells. Half-life extension of MP0533 is ensured by its HSA (human serum albumin)-binding DARPIns, making the drug compatible with weekly dosing. MP0533 is on track to begin clinical development before the end of 2022.

MP0317 binds both the fibroblast activation protein (FAP) and the immunostimulatory protein CD40. It also contains an HSA-binding DARPIn for half-life extension. It is designed to enable tumor-localized immune activation with fewer side effects compared to other CD40-targeting agents. The ongoing Phase 1 trial of MP0317 is expected to enroll up to 30 patients, dosed once every 3 weeks, across six dosing cohorts and up to 15 patients are then expected to be enrolled in a dose expansion cohort. Further, the Company plans to test a weekly dosing regimen to provide potential options for future combinations with either immunotherapy, radiation, or chemotherapy. In addition to evaluating safety, tolerability, and pharmacokinetics of a monotherapy, the study plans to gather a variety of biomarker data to support the establishment of combination therapies with MP0317 in specific indications.

MP0310 is designed to deliver tumor-localized activation of the immunostimulatory 4-1BB protein. A Phase 1 study of this candidate as a treatment for solid tumors has concluded patient enrollment and is expected to yield a full dataset in the second half of 2022. Following Amgen's return of global rights to MP0310 to the Company, the Phase 1 dataset will inform potential further business development activity.

Thanks to their small size and their high specificity and affinity, DARPIns represent ideal delivery vectors for therapeutic radionuclides to efficiently target cancer cells with minimal systemic side effects. Molecular Partners is developing new DARPIn-based radioligand therapy (**DARPIn-RLT**) candidates internally, and in collaboration with Novartis. DARPIn-RLTs have the potential to selectively deliver targeted radionuclides deeply into the tumor, with long tumor retention, causing direct tumor cell killing. In the Novartis partnership, the two companies plan to combine DARPIns' unique properties, including small size and high affinity and specificity, with the RLT capabilities and expertise of Novartis. Under the terms of the agreement, Molecular Partners will collaborate with Novartis to discover DARPIns that target specific tumor-associated antigens. Both parties will collaborate on the discovery and optimization of therapeutic DARPIn-RLT candidates for further development.

Ensovibep for COVID-19: In partnership with Novartis

Pursuant to the Company's Option and Equity Rights Agreement executed in October 2020 with Novartis, Novartis exercised its option to in-license ensovibep in January 2022, triggering a milestone payment of CHF 150 million to Molecular Partners. Novartis is now responsible for further development, manufacturing, distribution, and commercialization activities.

Ensovibep is an investigational treatment, designed specifically to inhibit SARS-CoV-2, the virus that causes COVID-19. It is made up of five DARPIn domains, three domains that bind to the SARS-CoV-2 spike protein, and two domains that are intended to extend half-life. It is the first clinical-stage trispecific antiviral candidate for COVID-19.

As announced in January 2022, Phase 2 of the EMPATHY clinical trial – a randomized, placebo-controlled study which enrolled 407 symptomatic patients infected with SARS-CoV-2 – met its primary endpoint with a statistically significant reduction in viral load over eight days in the ensovibep arms, compared to placebo. The secondary endpoint of hospitalization and/or emergency room (ER) visits related to COVID-19, or death was met by showing an overall 78% reduction in relative risk of events across all ensovibep arms, compared to placebo. Following discussions with the FDA, the Agency has asked that Phase 3 data be provided for their review. Novartis is currently engaged in developing a Phase 3 study protocol.

Based on the strong clinical performance of ensovibep, Molecular Partners is assessing further viral disease areas where DARPIns may offer advantages over existing antivirals or where no effective treatments exist.

Ophthalmology

In August 2021, Molecular Partners regained global development and commercial rights to abicipar for the treatment of neovascular age-related macular degeneration (nAMD) and Diabetic Macular Edema (DME). Abicipar went through two positive Phase 3 studies, CEDAR and SEQUOIA, which supported the non-inferior efficacy of its quarterly dosing regimen compared to monthly ranibizumab.

The Company is currently evaluating potential business development opportunities for abicipar. Based on correspondence with the FDA and

discussions with potential partners, the options for resumed development may include the development and commercialization program by a partner, or the formation of a new company focused on abicipar with new investors and a dedicated management team.

Leadership & Governance

Chief Executive Officer Patrick Amstutz was elected as President of the Swiss Biotech Association Board of Directors on May 3, 2022. Switzerland has become one of the global hubs for life sciences and this position will allow Dr. Amstutz the opportunity to provide leadership and influence in the biopharma industry both regionally and globally.

Alexander Zürcher was promoted to Chief Operating Officer, effective as of July 1, 2022. Coinciding with Alexander's promotion, Michael Stumpp, the Company's prior COO, transitioned to the newly formed position of EVP Projects while remaining a member of the Company's Management Board. Renate Gloggner was promoted to EVP People and Community, effective as of July 1, 2022. Both Alexander and Renate were appointed to the Company's Management Board, also effective as of July 1, 2022.

At the Company's 2022 Annual General Meeting held on April 13, 2022, the Company's shareholders approved all motions proposed by the Board of Directors, including the re-election of all members of the Board of Directors for a term of office of one year, as well as of William Burns as Chairman of the Board, the renewal of the authorized share capital for a period of two years until April 13, 2024, and all motions regarding compensation of the Board of Directors and the Management Board.

Expansion of ESG initiative

As an innovative biotechnology company, Molecular Partners' purpose is to find, develop, and bring to market novel therapeutics to improve the lives of patients across the globe. Molecular Partners' company-wide efforts to develop a COVID-19 treatment for the world, ensovibep, exemplify this well. When partnering with Novartis to fight COVID-19, the Company and Novartis agreed to waive profits from ensovibep in developing regions as part of a commitment to corporate social responsibility in a time of urgent global medical need. In oncology, Molecular Partners is focusing the powers of its platform toward finding truly innovative therapeutics for diseases that currently have no sustainable solution, such as in the Company's recent work in AML, a blood cancer with no reliably effective treatment, where the Company is advancing a differentiated potential option for patients through DARPin.

Molecular Partners believes that its growth and constant improvement as a company are closely linked to the well-being and growth of its employees. As a part of that, the Company is focused on programs to support its internal culture, encouraging employees to show initiative, integrity, and to strive to excellence in their work.

Finally, Molecular Partners' believes it is crucial to foster a socially and environmentally aware company culture, which it believes helps its team to better appreciate their contribution to society and the importance of their work. To help accomplish all of this, the Company has engaged external support to help guide its ESG strategy development as the next step toward executing on an ESG plan with practical and best practice metrics.

Creation of Treasury Shares

The Company today reports that it has created 3,500,000 treasury shares with a nominal value of CHF 0.10 each, thereby increasing its registered share capital from CHF 3,229,264.80 to CHF 3,579,264.80. The new shares, created on August 25, 2022 out of the Company's authorized share capital, were subscribed by Molecular Partners Inc., the Company's wholly owned subsidiary, and subsequently transferred at nominal value to the Company, and are expected to be listed on the SIX Swiss Exchange on or around August 26, 2022. With this increase, the Company now holds treasury shares that can be used in the future to raise funds in an efficient manner, including in connection with the Company's at-the-market sales program for American Depositary Shares that the Company established in July 2022.

H1 2022 operational and financial highlights:

- Strong financial position with CHF 285.1 million in cash (including short term deposits) as of June 30, 2022
- Revenue of CHF 184.5 million primarily due to payment received from Novartis upon exercise of option to in-license global rights to ensovibep
- Net cash from operating activities of CHF 151.0 million in H1 2022
- Operating profit of CHF 146.3 million and net profit of CHF 148.6 million in H1 2022
- Company expected to be funded into 2026, excluding any potential payments from R&D partnerships
- The H1 2022 Financial Statements are available on the company's [website](#)

Key figures as of June 30, 2022 (unaudited) (CHF million, except per share, FTE data)	H1 2022	H1 2021	Change
Total revenues and other income	184.5	4.4	180.1
R&D expenses	(27.0)	(31.6)	4.5
SG&A expenses	(11.2)	(7.6)	(3.6)
Operating result	146.3	(34.8)	181.1
Net result	148.6	(33.6)	182.2
Basic net result per share (in CHF)	4.59	(1.13)	5.72
Net cash from (used in) operating activities	151.0	(52.5)	203.5
Cash balance (incl. time deposits) as of June 30	285.1	174.3	110.8

Total shareholders' equity as of June 30	265.9	134.6	131.3
Number of total FTE as of June 30	164.0	158.3	5.7

Business Outlook and Priorities

With expected funding into 2026 and several programs across infectious diseases, immuno-oncology, and ophthalmology, Molecular Partners is well-resourced to continue expanding the capabilities of its DARPin platform and the breadth and differentiation of its DARPin therapeutic candidates.

Initial data for the Phase 1 open-label dose escalation study of MP0317 (FAP x CD40) are expected in the second half of 2022 and MP0533 (CD3 x CD33 x CD70 x CD123) for AML are expected to reach clinical development in the second half of 2022.

Financial outlook 2022

For the full year 2022, at constant exchange rates, the Company expects total expenses of CHF 70 - 80 million, of which approximately CHF 9 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation. This cash flow guidance does not include any potential receipts from R&D partnerships.

With CHF 285.1 million in cash and short-term time deposits and no debt as of June 30, 2022, the Company expects to be funded into 2026, excluding any potential receipts from R&D partners.

Documentation

The results presentation, this press release, and the half-year 2022 report will be made available on www.molecularpartners.com after 10pm CET on August 25, 2022.

Half year 2022 conference call & audio webcast - August 26, 2022 - 2pm CET, 8am ET

The half year 2022 results presentation will be [webcast live](#) and made available on the Company's website under the investor section. The replay will be available for 90 days following the presentation.

In order to register for the H1 2022 conference call on Friday, August 26, 2pm CET / 8am ET, please dial the following numbers approximately 10 minutes before the start of the presentation:

Switzerland	0800 246787
USA	18666525200
Full list of dial-in numbers	Linked here
Conference ID	Please ask to be joined into the Molecular Partners call

Financial calendar

October 27, 2022	Interim Management Statement Q3 2022
March 9, 2023	Full-year results 2022

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 other currently available protein therapeutics. DARPin therapeutics have been clinically validated through to registration via the development of abicipar, Molecular Partners' most advanced DARPin drug candidate. 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.

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](#)

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, 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, or any potential business development opportunities for product candidates, Molecular Partners' position of financial strength and ability to execute on the next phase of its strategy, and Molecular Partners' expected expenses and cash utilization for 2022 and its expectation that its current cash resources will be sufficient to fund its operations and capital expenditure requirements into 2026. These statements may be identified by words such as "believe", "expect", "may", "plan", "potential", "will", "would" and similar expressions, and are based on Molecular Partners' 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 Molecular Partners' expectations include its plans to develop and potentially commercialize its product candidates; Molecular Partners' reliance on third party partners and collaborators over which it may not always have full control; Molecular Partners' ongoing and planned clinical trials and preclinical studies for its

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 Molecular Partners' ability to obtain and maintain regulatory approvals for its product candidates; the extent of clinical trials potentially required for Molecular Partners' product candidates; the clinical utility and ability to achieve market acceptance of Molecular Partners' product candidates; the potential impact of the COVID-19 pandemic or other geopolitical events on Molecular Partners' preclinical studies, clinical trials or operations, or the operations of third parties on which it relies; Molecular Partners' plans and development of any new indications for its product candidates; Molecular Partners' commercialization, marketing and manufacturing capabilities and strategy; Molecular Partners' intellectual property position; Molecular Partners' ability to identify and in-license additional product candidates; and other risks and uncertainties that are described in the Risk Factors section of Molecular Partners' Annual Report on Form 20-F for the fiscal year ended December 31, 2021 filed with Securities and Exchange Commission (SEC) on March 15, 2022 and other filings Molecular Partners makes with the SEC. These documents are available on the Investors page of Molecular Partners' website at 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.

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