



## Molecular Partners Reports H1 2023 Corporate Highlights and Financials

August 24, 2023

*Phase 1/2a clinical trial of tetraspecific T cell engager candidate MP0533 initiated in patients with relapsed/refractory AML and MDS/AML; dosing ongoing in the 4th dose cohort; initial data expected in Q4 2023*

*Positive MP0317 data of ongoing Phase 1 clinical trial presented at ASCO confirm proposed MOA and indicates favorable safety profile in patients with advanced solid tumors, supporting future combination studies with potential partners; presently finalizing recruitment of weekly dosing regimen*

*Preclinical data supporting the Radio DARPIn Therapy platform presented at leading conferences TAT12, AACR and SNMMI in H1 2023*

*Funded well into 2026 with cash of CHF 218 million as of June 30, 2023, Molecular Partners expects total operating expenses of CHF 65 - 75 million in 2023 (previously estimated at CHF 70 - 80 million)*

ZURICH-SCHLIEREN, Switzerland and CONCORD, Mass., Aug. 24, 2023 (GLOBE NEWSWIRE) -- **Ad hoc announcement pursuant to Art. 53 LR: [Molecular Partners AG](#)** (SIX: MOLN; NASDAQ: MOLN), a clinical-stage biopharmaceutical company developing a new class of custom-built protein drugs known as DARPIn therapeutics ("Molecular Partners" or the "Company"), today announced corporate highlights and unaudited financial results for the first half-year of 2023.

"Throughout the first half of the year, our team has worked tirelessly to advance both our clinical programs and our platform, and I am extremely proud of what they have accomplished. We delivered compelling Phase 1 clinical data of MP0317 in patients with a range of different advanced solid tumors, initiated the first-in-human clinical trial of MP0533, a tetraspecific T cell engager DARPIn candidate for the treatment of AML, and deepened the evidence base for the Radio DARPIn Therapy platform," said Patrick Amstutz, Ph.D., Molecular Partners' Chief Executive Officer. "We are well-capitalized to advance these programs and continue leveraging our fundamental DARPIn expertise to enter new areas with unique DARPIn-based therapeutic approaches. I look forward to the second half of the year and beyond as we turn our attention toward MP0533, poised to generate clinical data which may represent a profound opportunity for patients suffering from AML, both initially in this relapsed setting, but also in combination and potentially as front line therapy in the future."

### Research & Development Highlights

#### Oncology

##### MP0533

In January 2023, the first patient was dosed in the Phase 1/2a clinical trial of MP0533, a novel tetraspecific T cell engager for the treatment of relapsed/refractory acute myeloid leukemia ("AML") and myelodysplastic syndrome (MDS)/AML. Recruiting and dose-escalation are ongoing with seven sites open across Europe, presently dosing patients in the fourth cohort. Preliminary results from this clinical trial are expected in Q4 2023 and additional data in H1 2024.

The clonal heterogeneity and lack of single AML-specific target antigens represent major challenges for the development of targeted immune therapies for AML. Molecular Partners designed MP0533, a tetraspecific CD3-engaging DARPIn, which simultaneously targets CD33, CD123 and CD70. This unique mode-of-action is designed to enable avidity-driven T cell mediated killing of leukemic stem cells and malignant blast cells, which co-express at least two of the three target antigens, while preserving a therapeutic window that minimizes damage to healthy cells.

MP0533's clinical development is supported by a comprehensive preclinical data that was presented at the Annual Meeting of the American Society of Hematology (ASH) in December 2022.

##### MP0317

In early June 2023, Molecular Partners presented additional positive results from the ongoing Phase 1 clinical trial of MP0317, a CD40 agonist designed to activate immune cells specifically within the tumor microenvironment by anchoring to fibroblast activation protein (FAP), which is highly expressed within tumors. These data were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting 2023.

MP0317 is designed to resolve the historical limitations of systemic CD40 agonists through the activation of the immune stimulator CD40 only when simultaneously bound to FAP. This design is intended to reduce systemic toxicities seen with prior CD40 agonists and focus CD40's proven immunostimulatory properties on tumor tissue.

Biomarker data of paired tumor biopsies confirmed that MP0317 achieved tumor-localized CD40 activation. The detection of MP0317 in tumors positively correlated with immune activation when comparing high vs. low doses of MP0317, including a statistically significant CD40-mediated increase of antigen-presenting cells and interferon  $\gamma$  signature. MP0317 also demonstrated a favorable safety profile when administered in 3-weekly (Q3W) and weekly (Q1W) regimens, including the highest tested dose of 10mg/kg (Q3W). Dosing at the highest planned regime (Q1W) is ongoing. Additional data are expected to become available in H2 2023, with final data from this Phase 1 clinical trial anticipated in H1 2024. Data presented at ASCO 2023 build on the initial clinical data from the program presented at the Society for Immunotherapy of Cancer (SITC) annual meeting in November 2022 and support Molecular Partners' strategy to pursue future combination studies of MP0317 with potential partners.

##### Radio-DARPIn Therapy ("RDT") platform

The Company's RDT platform is being developed to provide a unique and innovative delivery system for radioactive payloads. Thanks to their small

size as well as their high specificity and affinity, DARPins represent ideal vectors for efficient delivery of therapeutic radionuclides to solid tumors while overcoming some historic limitations of radioligand therapy approaches.

Notable recent achievements include a variety of preclinical data supporting the ability to reduce kidney uptake of Radio-DARPin conjugates to overcome nephrotoxicity, one of the key limitations of small protein-based radiotherapies. Molecular Partners presented positive preclinical data from its RDT platform in H1 2023 at the 12th International Symposium on Targeted Alpha Therapy (TAT 12), at the Annual Meeting of the American Association for Cancer Research (AACR), and at the Society of Nuclear Medicine & Molecular Imaging (SNMMI). Additional work is ongoing to demonstrate the ability of RDT to efficiently deliver high amounts of radioactivity to the tumor, leading to effective tumor eradication. More details on these efforts will be presented in the coming months and into 2024.

Molecular Partners continued to progress its RDT platform and portfolio of projects, both in-house and in partnership with Novartis. The tumor-associated protein Delta-like ligand 3 (DLL3) has been selected as one of the first targets of Molecular Partners' proprietary RDT program.

## Virology

As a furtherance of the clinical achievements with ensovibep for COVID-19 in collaboration with Novartis, Molecular Partners and Novartis signed a non-binding letter of intent in January 2023 to negotiate a Research Framework Agreement with a primary focus on emerging infectious global health threats.

## Ophthalmology

### *Abicipar*

In November 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 completed two positive Phase 3 clinical trials, CEDAR and SEQUOIA, which supported the non-inferior efficacy of its quarterly dosing regimen compared to monthly ranibizumab. The Company continues to evaluate potential business opportunities for abicipar outside of internal development at Molecular Partners.

## Corporate and Management Highlights

On April 4, 2023, Molecular Partners shareholders approved [all motions proposed](#) by the Board of Directors at the Annual General meeting.

On August 24, 2023, Nicolas Leupin, M.D. PhD notified Molecular Partners AG of his intent to resign from Molecular Partners in his capacity as Chief Medical Officer, for personal reasons. Dr. Leupin joined Molecular Partners in 2019. Nicolas will remain with Molecular Partners in an advisory capacity to assist with the continued development of MP0533 and its clinical operations. Upon this transition, Philippe Legenne, M.D., MBA, MHS, VP Medical Strategy and Development, will take over activities from Nicolas and serve as acting CMO.

Dr. Legenne joined Molecular Partners in early 2020. Over this time, he has led the clinical development strategy and execution across the Molecular Partners portfolio. Prior to joining Molecular Partners, Philippe held positions of increasing responsibility at JNJ, GSK, and Novartis, both in the United States and Europe. In his most recent role prior to Molecular Partners, Philippe led the EU medical organization for the oncology portfolio at Amgen. He received his medical degree from the Université de Lille (France), an MBA from ESSEC Business School (Paris) and a Master's degree in health economics from Université Paris Dauphine-PSL.

"I would like to thank Nicolas for his time and dedication to Molecular Partners over the last four years. He has been instrumental in building the clinical team we have today. I wish him the best for his time off with his family and his future endeavours," said Patrick Amstutz, CEO of Molecular Partners. "I am grateful that Philippe is stepping into the role of acting CMO. He has worked closely with Nicolas over the past years to establish our key opinion leader network and initiate our clinical sites. Philippe and the team will continue our activities seamlessly with MP0533, as well as the other DARPin programs moving towards clinical development."

## ESG

In 2022, Molecular Partners published its environmental, social and governance ("ESG") priorities and progress. Currently, the Company is creating a baseline status evaluation as the next step toward implementing an ESG plan with clear metrics that detail its progress across priority areas: board oversight of ESG and corporate sustainability; human capital management and Diversity, Equity and Inclusion (DEI); product service and safety; access to medicine; and business ethics.

In its continued commitment to corporate sustainability, MP is continuously refining its ESG strategy to align with the expansion of the pipeline, the future growth of the company and the values and principles of its employees and shareholders. Elsewhere, Molecular Partners offers generous benefits spanning from health to retirement planning to its employees, and fosters diversity and inclusion as a key element of its recruitment process.

## H1 2023 Operational and Financial Highlights

- Strong financial position with CHF 218.2 million in cash (including short term deposits) as of June 30, 2023
- Net cash used in operating activities of CHF 29.8 million in H1 2023
- Operating loss of CHF 31.0 million and net loss of CHF 30.8 million in H1 2023
- Company expected to be funded well into 2026, excluding any potential payments from R&D partnerships

The H1 2023 Financial Statements are available on the company's [website](#).

Key figures as of June 30, 2023 (unaudited) (CHF million, except per share, FTE data)	H1 2023	H1 2022	Change
<b>Total revenues and other income</b>	<b>3.5</b>	<b>184.5</b>	<b>(181.0)</b>

R&D expenses	(24.3)	(27.0)	2.7
SG&A expenses	(10.2)	(11.2)	1.0
<b>Operating result</b>	<b>(31.0)</b>	<b>146.3</b>	<b>(177.3)</b>
<b>Net result</b>	<b>(30.8)</b>	<b>148.6</b>	<b>(179.4)</b>
Basic net result per share (in CHF)	(0.94)	4.59	(5.53)
<b>Net cash from (used in) operating activities</b>	<b>(29.8)</b>	<b>151.0</b>	<b>(180.8)</b>
<b>Cash balance (incl. time deposits) as of June 30</b>	<b>218.2</b>	<b>285.1</b>	<b>(66.9)</b>
<b>Total shareholders' equity as of June 30</b>	<b>206.0</b>	<b>265.9</b>	<b>(59.9)</b>
<b>Number of total FTE as of June 30</b>	<b>168.5</b>	<b>164.0</b>	<b>4.5</b>

## Business Outlook and Priorities

Molecular Partners' strategic focus on areas of maximum differentiation by virtue of DARPin's unique capabilities remains steady, with funding to support portfolio development forecasted well into 2026. With two existing clinical programs and new areas of growth in the Radio DARPin Therapy and antiviral portfolios, Molecular Partners is well positioned to generate value through developmental milestones, new candidates and potential partnerships.

## Financial Outlook 2023

For 2023, at constant exchange rates, the Company expects total expenses of CHF 65 - 75 million (previously estimated at CHF 70 - 80 million), of which approximately CHF 9.0 million will be non-cash effective costs for share-based payments, IFRS pension accounting and depreciation. This guidance does not include any potential receipts from R&D partnerships.

With CHF 218.2 million in cash and short-term time deposits and no debt as of June 30, 2023, the Company expects to be funded well into 2026, excluding any potential receipts from R&D partners.

The Company's balance sheet continued to be debt-free in 2023. As of June 30, 2023, the Company employed 168.5 FTE (full time equivalents), up 3% year-on-year. About 84% of the employees are employed in R&D-related functions.

## Documentation

The results presentation, this press release, and the H1 2023 report will be made available on [www.molecularpartners.com](http://www.molecularpartners.com) after 10:00pm (CET) on August 24, 2023.

## H1 2023 Conference Call & Audio Webcast

Molecular Partners will hold a conference call and audio webcast on August 25, 2023, 2:00pm CET (8:00am EDT). To register for the H1 2023 conference call, please dial the following numbers approximately 10 minutes before the start of the presentation:

Switzerland / Europe:	+41 43 210 5163
USA:	+1 800 715 9871
UK:	+44 800 260 6466
Conference ID:	8671406

## Financial calendar

August 24, 2023	Half-year results 2023 (unaudited)
October 26, 2023	Interim Management Statement Q3 2023

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 (designed ankyrin repeat protein) 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 oncology and virology and has compounds in various stages of clinical and preclinical development across multiple therapeutic areas. [www.molecularpartners.com](http://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, and Molecular Partners' expected business and financial outlook, including expenses and cash utilization for 2023 and its expectation of its current cash runway. 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 impact of any health pandemic, macroeconomic factors and other global 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, 2022, filed with Securities and Exchange Commission (SEC) on March 9, 2023 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](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.

**For further details, please contact:**

Seth Lewis, Head of Investor Relations & Strategy

Concord, Massachusetts, U.S.

[seth.lewis@molecularpartners.com](mailto:seth.lewis@molecularpartners.com)

Tel: +1 781 420 2361

Antonio Ligi, Head of Communications

Zurich-Schlieren, Switzerland

[antonio.ligi@molecularpartners.com](mailto:antonio.ligi@molecularpartners.com)

Tel: +41 44 755 57 53