Molecure

Clinical progression ahead in FY23

Molecure is entering FY23 with two active clinical programmes. OATD-01, the company's lead proprietary asset, is in development for the treatment of sarcoidosis, but management expects to expand into new indications if the data are supportive. The first patient is due to be dosed in the Phase II trial for this asset in H223. Molecure also recently reported the first dosing in the Phase I trial for OATD-02, a novel drug for the treatment of solid tumours; an update for this study is expected in Q423. The company reported a 22.3% y-o-y increase in operating expenses for FY22, due to higher costs of external services and personnel expenses during the year. With a net cash position of PLN54.0m at end FY22, management anticipates a cash runway into early FY24 (at least 12 months).

OATD-01 expected to enter Phase II in H223

OATD-01 is a novel chitotriosidase 1 (CHIT1) inhibitor under development as the first disease-modifying drug for the treatment of pulmonary sarcoidosis. Following supportive advice from the EMA and FDA, Molecure is preparing for a Phase II trial and expects the first patient to be dosed in H223. Results from this trial may enable the expansion of the drug into additional indications such as idiopathic pulmonary fibrosis (IPF) as well as non-alcoholic steatohepatitis (NASH), provided the data continue to be positive. Given the larger market size in these indications, this could significantly increase the commercial impact of OATD-01, in our view.

Clinical trials underway for OATD-02

In March 2023, Molecure announced an important milestone with the commencement of the Phase I trial for OATD-2, the company's second asset. To our knowledge, OATD-02 is the first and only inhibitor of arginases 1 and 2, therapeutic targets validated in preclinical studies for a variety of tumours. The Phase I trial is an open-label, multi-centre, first-in-human, dose-escalation study to assess the safety, tolerability and preliminary efficacy of OATD-02 in patients with advanced and/or metastatic solid tumours. We view the initiation of this trial as a key milestone for the company; an update from this study is now expected in Q423.

Cash runway for at least 12 months

Operating expenses for FY22 amounted to PLN18.63m, up 22.3% y-o-y from PLN15.2m in FY21, attributable to higher personnel expenses and external services as the company's pipeline advances. This resulted in net loss of PLN15.26m for the period, versus PLN13.64m in FY21. With a net cash position of PLN54.0m at end FY22, management expects a cash runway into early FY24.

Historical figures

Year end	Revenue (PLNm)	PBT (PLNm)	EPS* (PLN)	DPS (PLN)	P/E (x)	Yield (%)
12/20	124.9	73.7	4.64	0.0	3.08	N/A
12/21	1.5	(13.6)	(0.98)	0.0	N/A	N/A
12/22	1.6	(15.3)	(1.09)	0.0	N/A	N/A

Source: Company accounts. Note: *EPS are diluted.

Price	PLN25.5
Market cap	PLN359m

Share price graph

Share details

Code	MOC
Listing	Warsaw Stock Exchange
Shares in issue	14.06m
Cash (PLNm) at 31 December 2022	66

Business description

Molecure is a clinical-stage biotechnology company. It uses its medicinal chemistry and biology capabilities to discover and develop first-in-class small molecule drug candidates that directly modulate underexplored protein targets and the function of RNA to treat multiple incurable diseases.

Bull

- Two assets in clinical development (OATD-02 in Phase I; OATD-01 in preparation for Phase II).
- OATD-01 has potential for disease-modifying action in interstitial lung disease.
- Pipeline supported by preclinical assets and technology platform.

Bear

- Delays or disruptions to timelines could affect management's estimated cash runway.
- Unvalidated mechanisms of action increase development risk.
- Additional funding needed to complete Phase II development.

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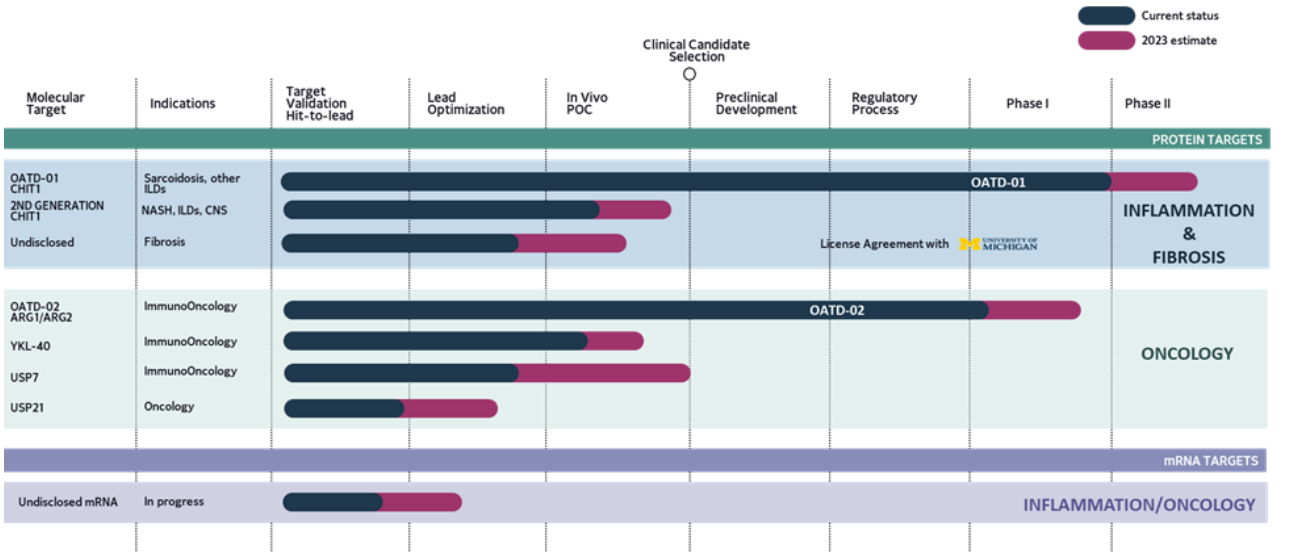
Looking to expand clinical potential across 2023–25

Molecure currently has two active and ongoing clinical programmes (Exhibit 1): OATD-01 in sarcoidosis, for which Phase II trials are expected to commence in H223, and OATD-02 in solid tumours, for which the first patient was dosed in the Phase I trial in March 2023 and updates are expected in Q423. In the interest of enriching, expanding and diversifying this clinical pipeline, management has communicated four strategic objectives to focus on for the period 2023–25:

- Continue to demonstrate clinical proof-of-concept in the development of OATD-01 for patients suffering from pulmonary sarcoidosis.
- In the Phase I trial, determine the maximum tolerated dose of OATD-02 for oncology patients, and continue to explore the possibility of this treatment in combination with other anti-cancer therapies.
- Identify one or two advanced lead compounds (candidates for pre-clinical development) within this expanding pipeline. Through the initiation of new research projects, based on in-house research, in-licensing and collaborations, Molecure aims to have a balanced project portfolio with high clinical and market potential.
- Continue to develop a platform for the discovery of small molecules that modulate the function of mRNA in order to address a multitude of deadly diseases. As a proof-of-concept, in 2023 the company plans to confirm binding of at least one of these small molecules to an RNA fragment and observe the desired modulation of function (in vitro). Molecure believes that achieving this milestone would increase the chances of establishing a partnership. By 2025, the company hopes to have signed a partnering agreement in the mRNA platform space.

Exhibit 1: Molecure's clinical development pipeline



Source: Molecure 2022 financial report

Management has stated that, based on the current pipeline, it plans to launch or continue three independent Phase I and Phase II clinical programmes in the coming years, and expects to commercialise two of these by end-2025. In our opinion, while these goals are ambitious, they could represent significant growth for the company, provided that a partnership agreement to license the further development and sale of any drug candidates is attained.

Financials

In FY22, Molecure recorded total revenue (including other operational revenue) growth of 12.2% y-o-y to PLN1.64m (US$0.39m), which primarily consisted of domestic research grants. Total operating expenses stood at PLN18.63m, 22.3% y-o-y higher than PLN15.22m in FY21, attributed to the continued advancement of the clinical development pipeline, higher personnel expenses and increased costs of external services. Third-party services, accounting for 32% of the total operating expenses, were significantly up by 49.5% y-o-y to PLN6.03m in FY22 due to increased clinical activities related to OATD-01 (first patient dosed in FY22) and OATD-02 (nearing start of Phase II in H223). The company will be running two parallel clinical studies (OATD-01 Phase II and OATD-02 Phase I) by end H223, which might result in further escalation in operating expenditure. Salaries (33% of operating expenses) increased by 58.4% y-o-y to PLN6.22m. The company reported a net loss of PLN15.26m in FY22 versus PLN13.64m in FY21.

While the cash outflow from operating activities stood at PLN10.21m in FY22 (PLN13.50m in FY21), the cash outflow from investing activities was materially higher at PLN33.59m (PLN18.82m in FY21) largely due to the ramp up pre-clinical work progressing toward the clinic. Notably, Molecure capitalises parts of its R&D expenditure, which stood at PLN30.31m in FY22, versus PLN16.38m in FY21.

As of the end of FY22, the company reported a cash position of PLN65.62m (US$15.29m), from PLN102.04m at end-FY21, reflecting PLN36.42m in total cash outflows during the year. Considering the increased future cash burn related to two clinical trials, management expects current resources to fund the company's operations into early 2024 (at least 12 months). Management is also exploring potential sources of non-dilutive funding through various mechanisms including alternative R&D grants and collaborative agreements (cost/profit sharing; milestones). For example, in February 2023, the company submitted a funding application to the Medical Research Agency for the project 'Development and advancement of the first-in-class approach in treating idiopathic pulmonary fibrosis targeting a novel signalling pathway with high translational potential' as a part of a competition for the development of targeted or personalised medicine based on nucleic acid and small molecule therapeutic products (ABM/2022/6). Furthermore, if the company can demonstrate the utility of its RNA platform, we see this as a potential source of future revenues, through licensing deals or usage agreements.

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