



molecule

Fate can be altered

October 3, 2023

Presenting Team

Marcin Szumowski
Chairman of the Board & CEO



Zbigniew Zastona
Chief Scientific Officer



Samson Fung
Chief Medical Officer



Sławomir Broniarek
Chief Financial Officer



Summary | Molecule on the path of continued growth

OATD-01: FDA approval for Ph2 clinical trial, EMA and MHRA submission completed

OATD-02: start of a Ph1 clinical trial in patients and first patient in roll-over study

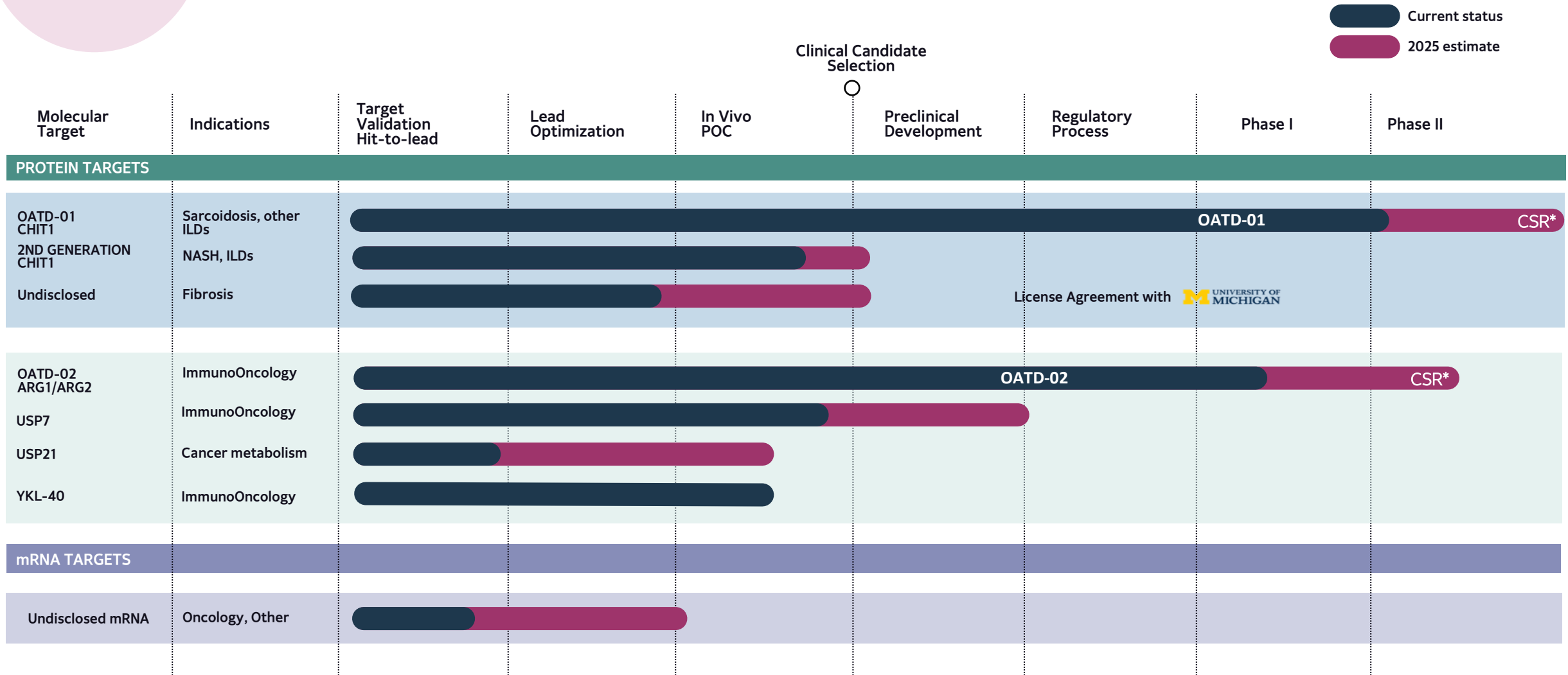
Update of strategy for 2023-2025

Approx. PLN 50 m raised in SPO

Further development of mRNA platform

Progress in early stage projects

Balanced pipeline as a trigger for commercialization





OATD-01: Disease modifying potential in sarcoidosis

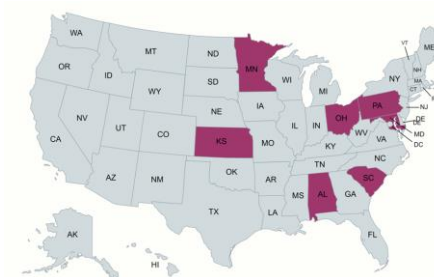
OATD-01 | Phase 2 in sarcoidosis

Double-blind, randomized, placebo-controlled multi-center study to assess the safety and efficacy of an oral inhibitor of CHIT1 (OATD-01) in patients with active pulmonary sarcoidosis.



Treatment goals

- Stop disease progression and organ damage
 - Quantification of the change in granulomatous inflammation
- Improve symptoms
 - Boost lung function/ prevent lung dysfunction
 - Forced Vital Capacity (FVC) and radiographic sarcoidosis
- Improve Quality of Life (QoL)



Each patient treated for 12 weeks

~90 male and female patients with active pulmonary sarcoidosis

20-30 outpatient sites in the EU and US

OATD-01 | current status

Approval from the U.S. FDA

U.S. Central Bioethics Commission approval and process of obtaining clinical trial approvals from Local Bioethics Commissions

Site initiations process ongoing in US

Grant application to PARP (FENG program) for a total amount of PLN 16m submitted

Ph2 Clinical Trial

Clinical trial in Europe:

- CTA to EMA filed (filing accepted)
- application submitted to Medicines and Healthcare products Regulatory Agency (MHRA) in UK (filing accepted)

Branding activities started (WASOG participation, establishing FSR collaboration, study design poster at ERS, social media campaign in US and EU ready to launch).



THE KITE STUDY

FDA's green light paved the way for Molecure to initiate the study in the United States becoming only the second Polish biotech company ever to do so

OATD-02: A first in class dual
arginase inhibitor for cancer
applications



OATD-02 | Phase I FIH clinical trial



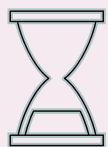
Design: Open-label single-arm dose-escalation monotherapy study (Bayesian design, 2.5-30mg)



Patient population (30-40 pts):
Relapsed/refractory advanced and/or metastatic solid tumors



Location: 3 sites in Poland:
Warsaw, Otwock, Bydgoszcz

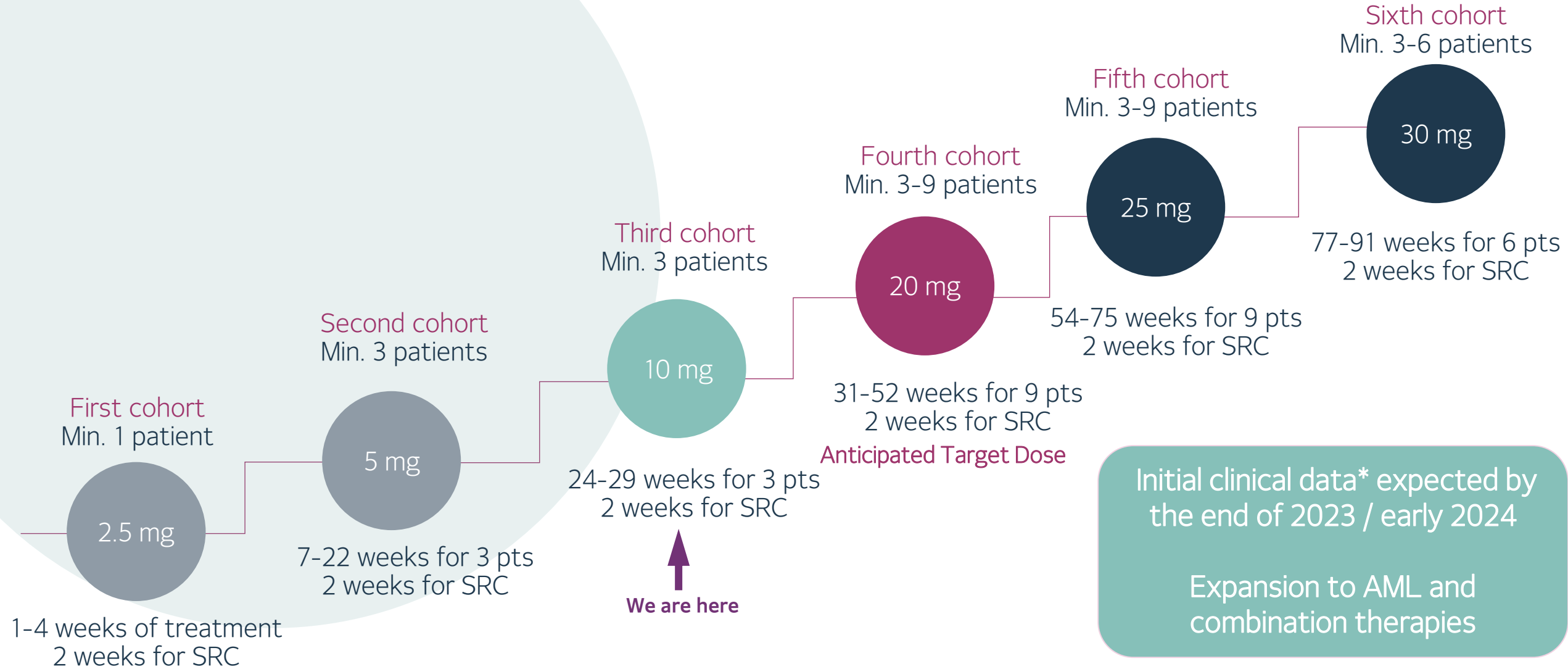


Study Duration: Approx. 1.5 years
(Q1 2023 - H2 2024)

OATD-02 | Addressing cancers with unmet need:

- Pancreatic ductal cancer (advanced, inoperable)
- Metastatic colorectal cancer
- Serous Ovarian Cancer
- Renal Cell Cancer

OATD-02 | administered to the third cohort of patients



*Statistically significant data to estimate MTD and parameters such as safety and efficacy

OATD-02 | roll-over study as an opportunity for patients to continue treatment

All patients to complete the first-in-human study without major safety issues and with clinical benefit (no progression per RECIST 1.1) will be given an option to continue treatment in a subsequent clinical trial.

- **Regulatory approval:** June 2023
- **First patient:** enrolled at the lowest dose (2.5 mg) in August 2023
- **Location:** Warsaw, Otwock, Bydgoszcz
- **Dose level:** the same as in FIH study



- **Duration of treatment:** at least 3 months (until cancer progression)
- **Health patient's monitoring:** every 2 months
- **Efficacy monitoring:** every 3 months (per institutional standards)

Purpose:

evaluation of the safety and OATD-02 antitumor activity in patients with selected advanced and/or metastatic solid tumors who have completed the OATD-02 -C-01 first-in-human study

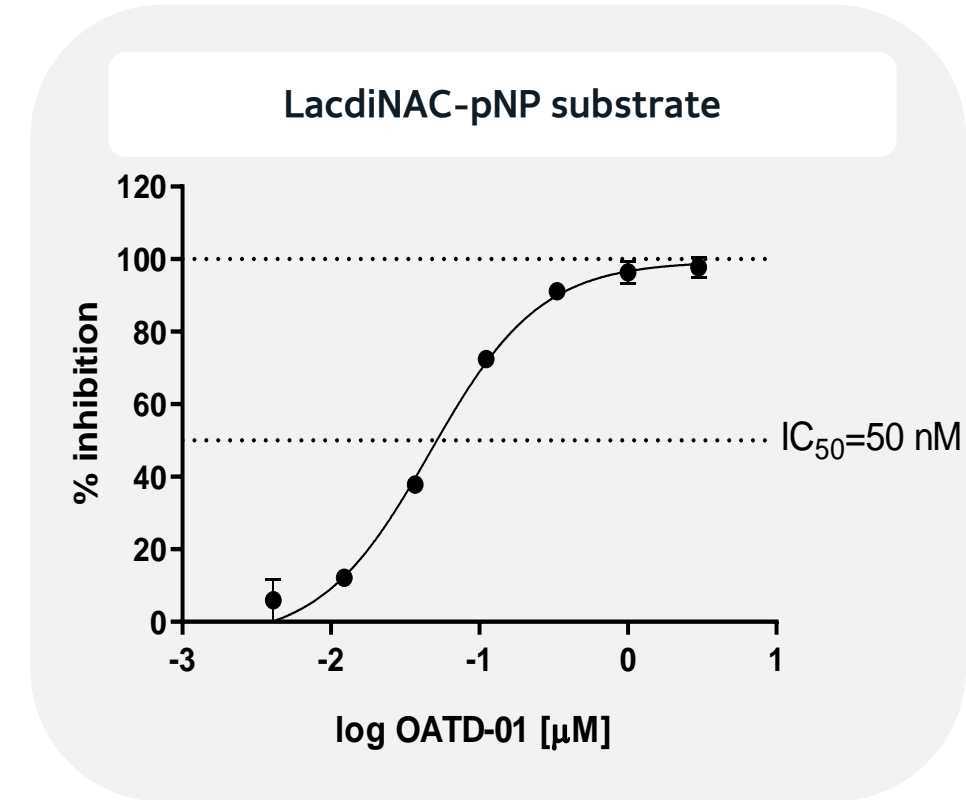
OATD-01 and OATD-02: to
learn more about mechanism
of action (MoA)



OATD-01 MoA | new preclinical data and other activities

Molecule is still building knowledge on the role of CHIT1 in cellular metabolism as well as explaining the therapeutic effects of OATD-01.

- We are in possession of data compiled in cooperation with other institutions:
 - ✓ translational and omics data in NASH showing reversed disease-specific metabolic changes caused by administration of OATD-01;
 - ✓ new translational data from patients with NASH showing CHIT1 upregulation.
- Two manuscripts in preparation – one review, one mechanistic (with Luke O'Neill as a co-author).



OATD-01 by inhibiting Chit1 regulates protein glycosylation

New member of the Molecule Scientific Advisory Board

Luke O'Neill – advisor on immunometabolism regulation caused by OATD-01

- professor of Biochemistry in the School of Biochemistry and Immunology, Trinity Biomedical Sciences Institute at Trinity College Dublin
- world expert on innate immunity and inflammation listed by Thomson Reuters/ Clarivate in the top 1% of immunologists in the world, based on citations per paper
- co-founder of Sitryx Ltd (which aims to develop new medicines for inflammatory diseases) and Inflazome (recently acquired by Roche)
- awarded the Royal Dublin Society / Irish Times Boyle Medal for scientific excellence, the Royal Irish Academy Gold Medal for Life Sciences, The Society for Leukocyte Biology (SLB) Dolph O. Adams award, the European Federation of Immunology Societies Medal, the Milstein Award of the International Cytokine and Interferon Society and the Landsteiner Award from the Austrian Academy of Sciences
- member of the Royal Irish Academy, EMBO (European Molecular Biology Organisation) and a Fellow of the Royal Society

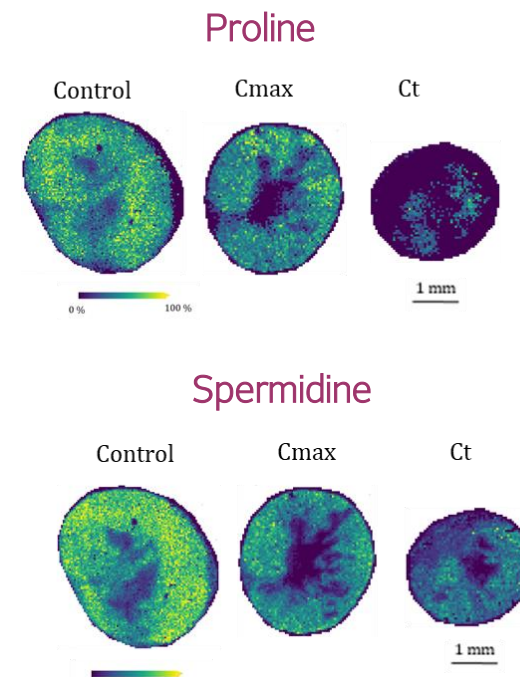
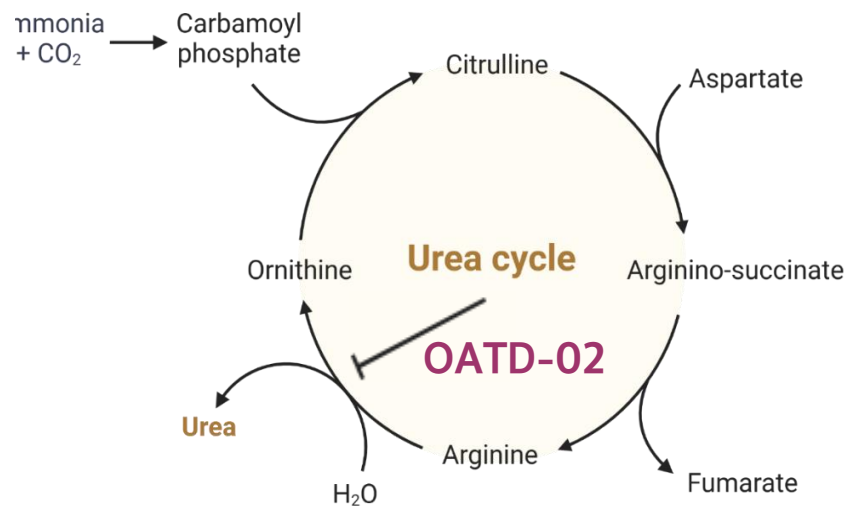
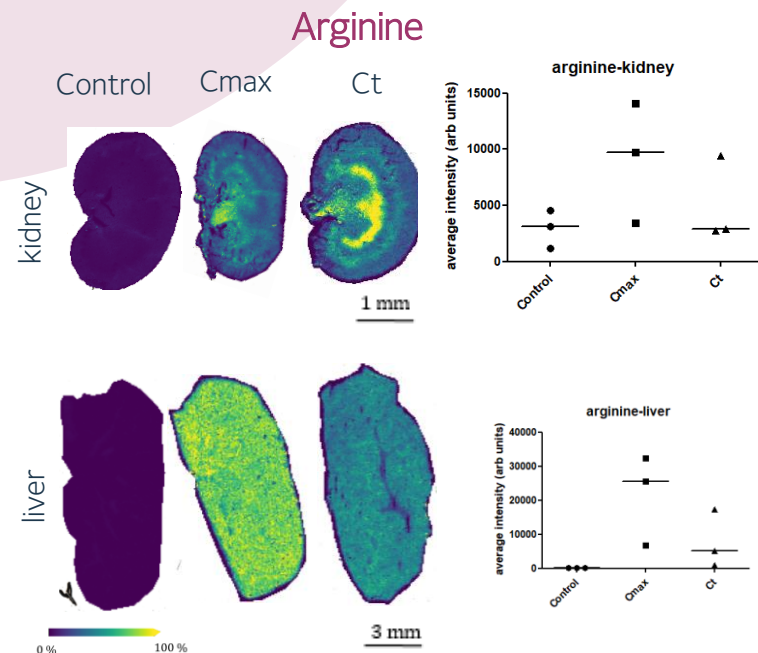


OATD-02 MoA | proof of intracellular activity

- collaboration with a research group from the University of Mannheim to use Mass Spectrometry Imaging (MSI) to assess metabolites

Conclusions:

the metabolic activity of OATD-02 demonstrates significant changes in tissue distribution of important metabolic biomarkers confirming intracellular inhibition of ARG2 activity explaining anti-cancer effects



- Systemic increase of arginine level after OATD-02 administration

- Inhibition of polyamine synthesis in TME illustrates direct inhibition of cancer metabolism

A promising pre-clinical pipeline



USP7 inhibitor | T cell activator with proven anti-cancer potential

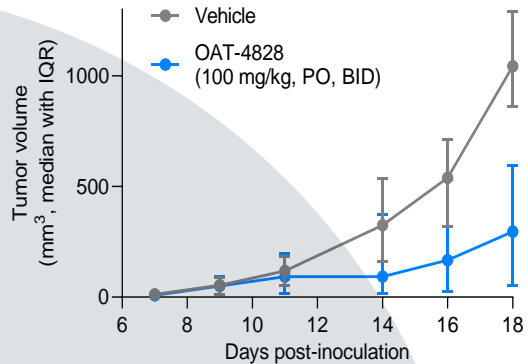
- USP7i exert anticancer effects by activation of cytotoxic T cells in various syngenic models
- We plan to nominate clinical candidate in early 2024

Validated translational potential

Mechanism of action explains efficacy in various models

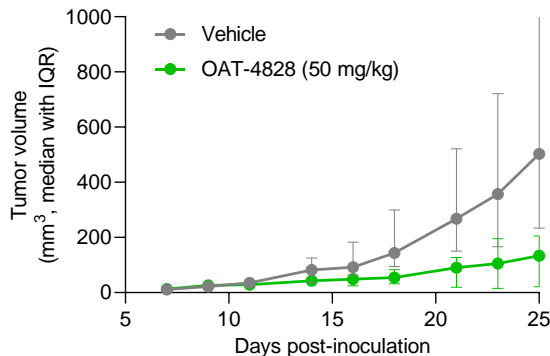
Significant efficacy as monotherapy and in combinations

B16F10 melanoma



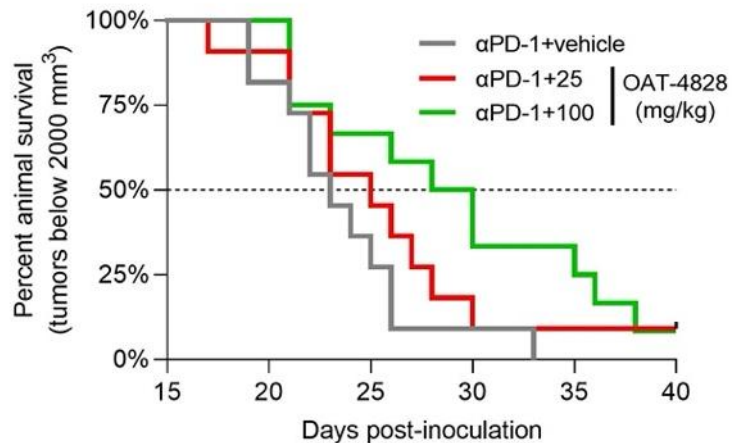
TGI 72% (100 mg/kg)

E0771 breast



TGI 62% (50 mg/kg)

Survival analysis (combo)



molecule

New candidates for preclinical development

USP21 – oncology (cancer metabolism)

- Hit molecule found as a starting point for the development of a first-in-class inhibitor of USP21
- Extensive biological studies **validated role of USP21 in cancer metabolism**: USP21 enhances proliferation and migration of cancer cells - we have identified molecular mechanisms involved in this process **demonstrating regulation of known undruggable proteins by USP21**
- Screening cascade is established to study newly synthesized inhibitors



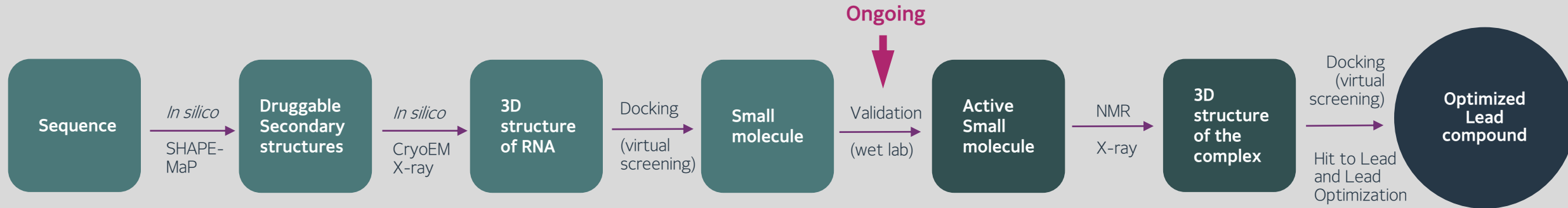
Fibrosis (UoM license)

- The medicinal chemistry team focused on the synthesis of new compounds to create our own IP space of the first in class inhibitor of a molecular pathway driving fibrosis (evaluated in a **phenotypic screen**)
- In February 2023, the Company signed a non-exclusive license agreement with Innovation Partnerships of the University of Michigan, covering know-how in the area of discovering new molecules targeting an undisclosed signaling pathway important in the development of pulmonary fibrosis
- In July 2023, Molecule submitted an application to PARP for funding under the SMART path of the FENG program



mRNA Platform | discovering medicines of the future

Small molecules targeting mRNA to prevent downstream mRNA translation



- Continued development of this novel platform, with a range of biochemical and biophysical techniques being applied to assist structural biology studies of RNA
- In-house investment in both cellular and molecular screening capabilities
- Ongoing collaborations with global leading RNA centers to further leverage the company's expertise and alternative approach to identify compounds interacting with selected mRNA regions
- Currently, mRNA targets with different 3D structures are being explored, and we expect to reach PoC by the end of 2023.

Finance

03.10.2023

SPO (July 2023) | Summary

- High investor interest resulting in several-fold oversubscribed offer: shares were subscribed by 35 investors (new and existing institutional investors participated in the placement).
- Proceeds raised will co-finance the implementation of the Company's strategic plans for 2023-2025, including, in particular, significant progress in the clinical development of two flagship programs (OATD-01 and OATD-02). Additionally, efforts will be intensified in a portfolio of early-stage programs.

Number of shares

2 776 000 shares

Price

18 PLN

Total value

Approx. 50 m PLN

Cost of SPO

0,87m PLN

Financial results

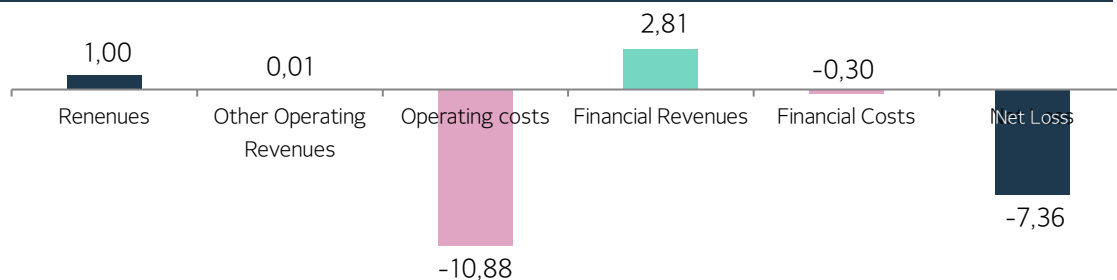
PLN m	H1 2023	H1 2022
Revenue	1,00	1,25
Grants	1,00	1,24
Other	0,01	0,01

Cost incl:	10,88	8,66
General & Adm	6,34	5,97
Early stage programs	4,54	2,16
Commercialisation costs	0,00	0,53

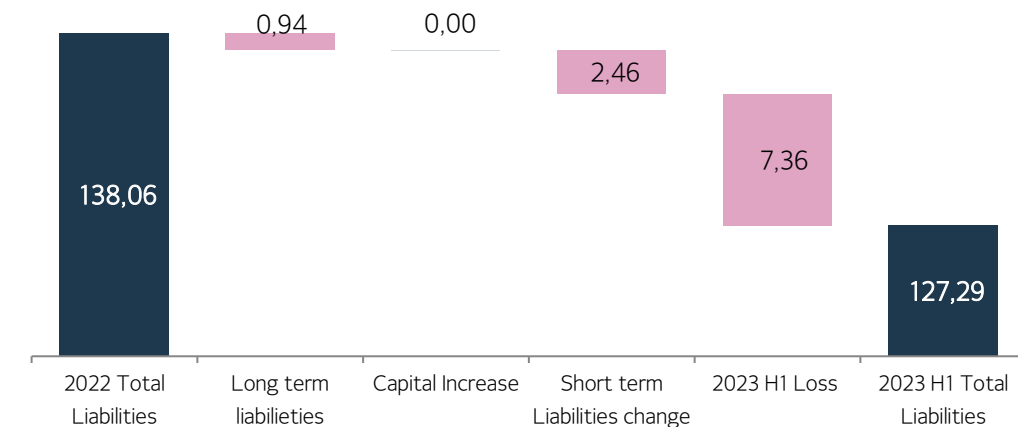
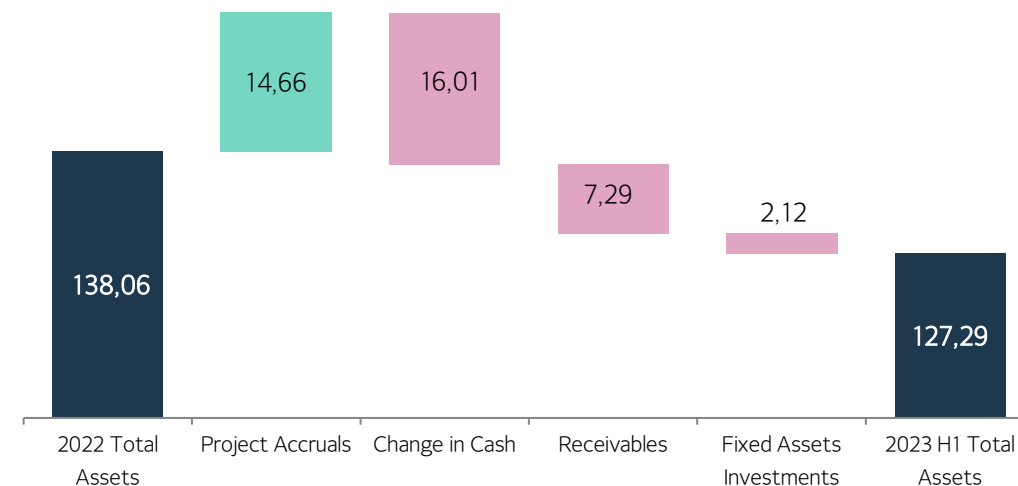
EBIT	-9,88	-7,41
Net Financial income	2,52	0,35

Net loss/profit	-7,36	-7,06
-----------------	-------	-------

2023 H1 Profit & Loss Breakdown (PLN m)



Assets & Liabilities changes (PLN m)



R&D expenses, CAPEX and employment

PLN m	H1 2023	H1 2022
R&D expenses incl.:	14,66 (19,20*)	8,52 (10,68*)
Clinical phase programs	9,17	3,82
Discovery and preclinical development programs	5,49	4,70
Early programs	4,54	2,16
General and administrative expenses, including business development & IR	6,34	5,97
other CAPEX	2,12	2,04
Total	27,66	18,69

*includ. expenses on early stage programs

Cash position (Sep 2023)
>PLN 85m



107 employees
(incl. 51 PhDs)

- Projects expenses almost doubled after regaining of OATD-01, reflecting the dynamic progress in their advancement
- Other expenses are on the same level

Grants

Submitted to PARP (May-Sep) and NIH (Sep) pending

PARP
mRNA platform
PLN 52/33** m

PARP
OATD-01
PLN 32/16** m

PARP
USP21
PLN 66/47** m

PARP
Undisclosed target*
PLN 63/44** m

NIH
OATD-01+Undisclosed
target*
USD 2,2 m

In total
6 submitted
PLN 221/149 m

*project aiming at an undisclosed signaling pathway crucial for the development of pulmonary fibrosis (licensed from the University of Michigan)

**qualified costs / amount of funding requested

Plans

03.10.2023

Potential news flow in the next few months

Positive decisions on submitted grants

Continued progress in OATD-02 dose escalation

First Patient Dosed in the KITE clinical trial (in the US)

PoC confirmed in the mRNA discovery platform

EMA & MHRA approvals for the KITE study

Maximum Tolerated Dose (MTD) successfully established for OATD-02

2024-2025 Outlook

Potential milestones targeted by 2025

Protein Targets

- Two clinical assets in PhI/II multi center clinical trials in patients
- Two candidates in formal preclinical development, incl. USP7 project (internal pipeline + in-licensing)
- Three new discovery programs in lead-optimization

RNA Platform

- In vitro PoC reached for 2-3 high value mRNA targets
- Drug-like molecules (leads) in RNA-targeting small molecule programs
- First profit-sharing collaboration on external targets

BD/Financial/Operational

- One clinical stage program partnered in a high-value deal
- High value assigned to the AI driven discovery platform

2024

by 2025

- Final reports from OATD-01/02
- Indication expansion for OATD-01/02
- One new clinical stage program (IND)

- 1-2 collaborations on partner - defined mRNA targets

- Significant cumulative revenue from partnering & collaboration agreements
- At least 2 revenue generating collaborations in mRNA platform (including milestone payments)

Molecure SA ("MOC") and its Board and employees make no warranties or assurances regarding the accuracy or completeness of any representations or other materials contained herein.

The information and data contained herein reflect the current conditions and assessments of the market situation as at the time of preparation of the document and are subject to change at any time. All predictions and forward-looking statements express current views, subjective judgments, predictions and assumptions about potential and uncertain future events and are subject to risk and uncertainty.

MOC and the Management Board indicate that there is a possibility of unexpected events (in particular unpredictable ones), so there is no guarantee that the situation will develop in accordance with the presented predictions.

The document is provided for informational purposes only. MOC, its affiliates and its management and employees do not accept any liability for direct, indirect or any loss or damage that may arise in connection with the use of this document or the information or data contained therein.

Warsaw, October 3, 2023