Development Strategy Update

2023-2025

molecure

Fate can be altered

29 June 2023

Experienced company leadership

Marcin Szumowski
Chairman of the Board & CEO

Sławomir Broniarek
Chief Financial Officer

Nicolas Beuzen
Business Development Director

R&D leaders

Samson Fung
Chief Medical Officer

Zbigniew Zasłona
Chief Scientific Officer

Barbara Dymek
R&D Operations Director

Development Strategy Update for 2023-2025

2 assets in clinical trials

Progress in the development of current programs and **expansion** of new early stage projects

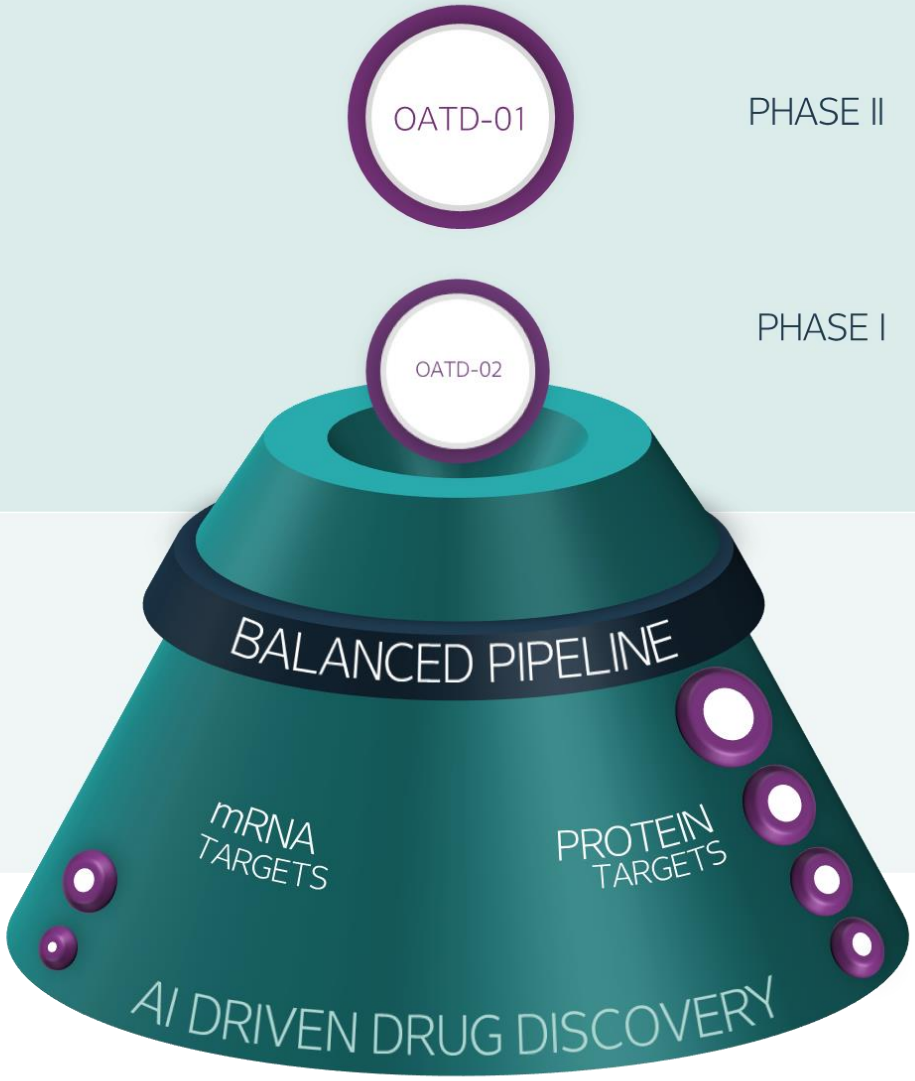
AI inv**aids** biotechnology

Main strategic BD goal:

Expected partnering for at least one of clinical programs and one major partnering transaction for mRNA platform

Development areas as a foundation for future growth

- Clinical progression of two most advanced assets, OATD-01 and OATD-02
- Machine learning and Generative Artificial Intelligence (GenAI)-driven drug discovery platform for small molecule drugs modulating the function of mRNA and previously unexplored proteins
- Current balanced pipeline fueled by exploratory stage programs



Strategic goals for 2023-2025

1. Clinical development of OATD-01 to demonstrate therapeutic efficacy (a Phase II clinical proof-of-concept) in patients with pulmonary sarcoidosis (final report in mid-2025).

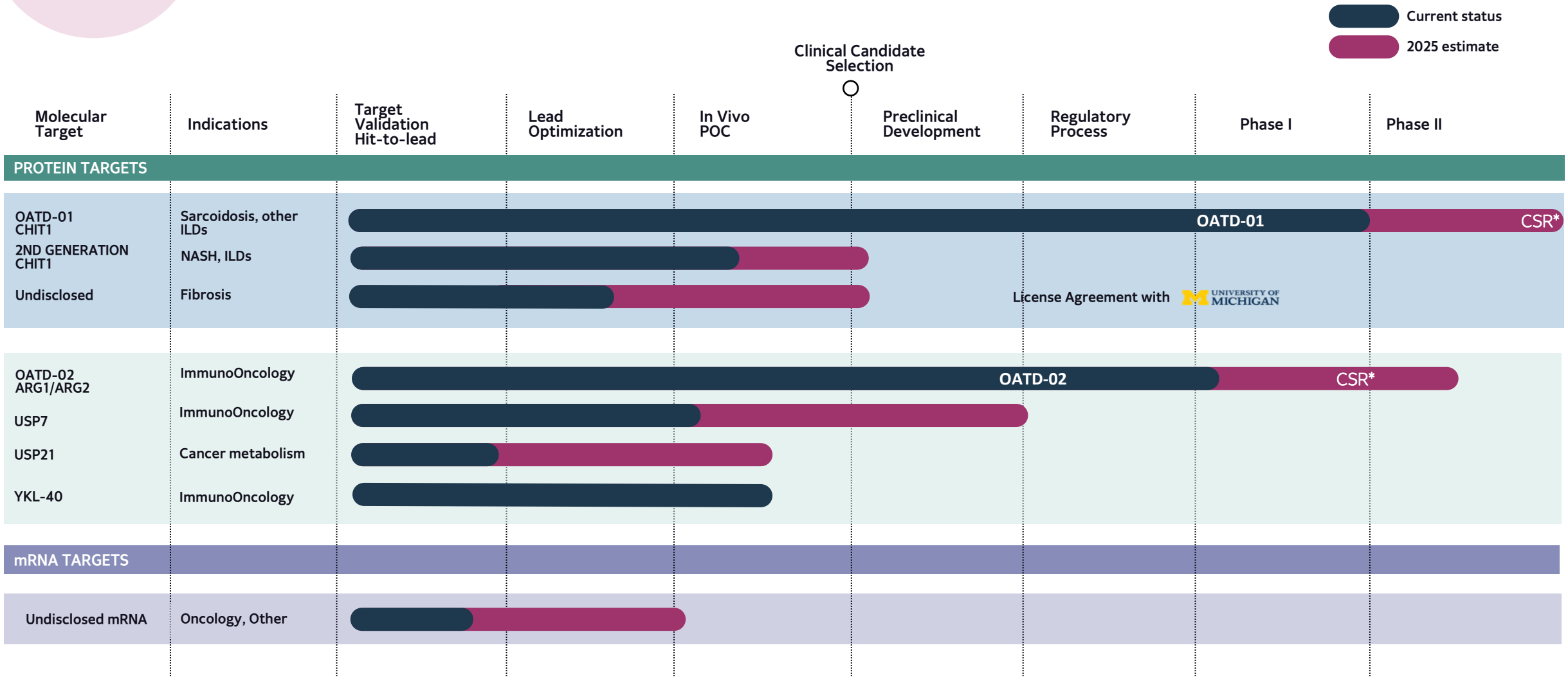
2. Determining the safety, tolerability and maximum tolerated dose (MTD) and the Phase II recommended dose (P2RD) in the ongoing Phase I clinical trial of OATD-02 in oncology patients and continuation of expansion studies in hematological indications and in combination therapies targeting solid tumors.

3. Identifying 1-2 advanced lead compounds (candidates for preclinical development) as part of reinforcing our balanced pipeline.

4. Accelerated development of a breakthrough platform for the discovery of small molecules targeting mRNA, a future breakthrough technology enabling treatment of many uncurable diseases due to undruggable disease-relevant protein targets.

5. Reducing time, cost and increasing the efficiency of early-stage drug discovery and development.

Balanced pipeline as a trigger for commercialization



OATD-01: Disease modifying potential in sarcoidosis

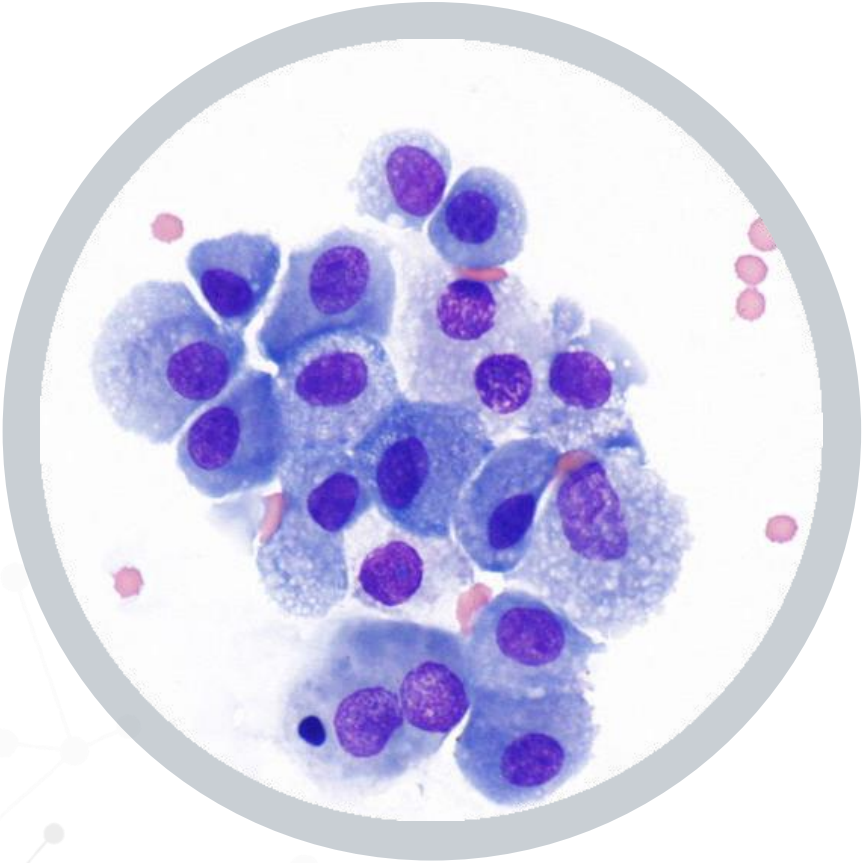
29.06.2023

OATD-01 | a macrophage modifier

CHIT1 plays a key role in macrophages biology

OATD-01 is a potent Chitotriosidase (CHIT1) inhibitor

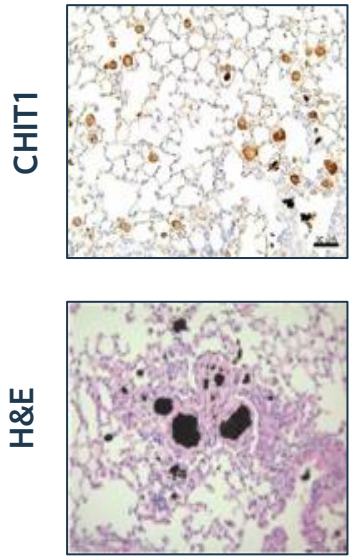
OATD-01 enters Phase II PoC in sarcoidosis this year, MoA could transform treatment of inflammatory & fibrotic diseases



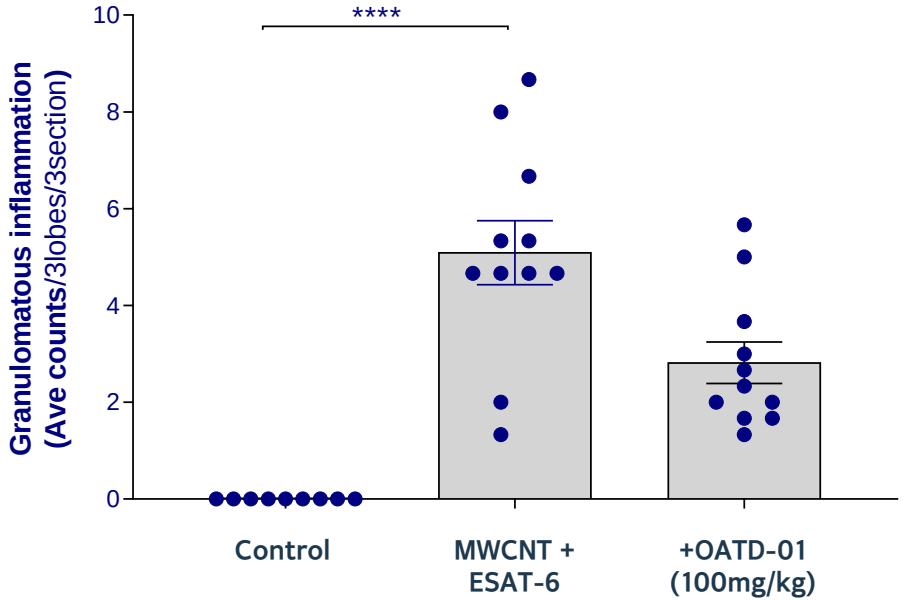
OATD-01 | is efficacious in Multiwalled carbon nanotube-induced granulomatous inflammation model in mice

OATD-01 suppressed development of organized granulomatous structures in lungs and reduced macrophage inflammation protein (CCL4 in the broncho-alveolar lavage fluid - BALf) in the lungs

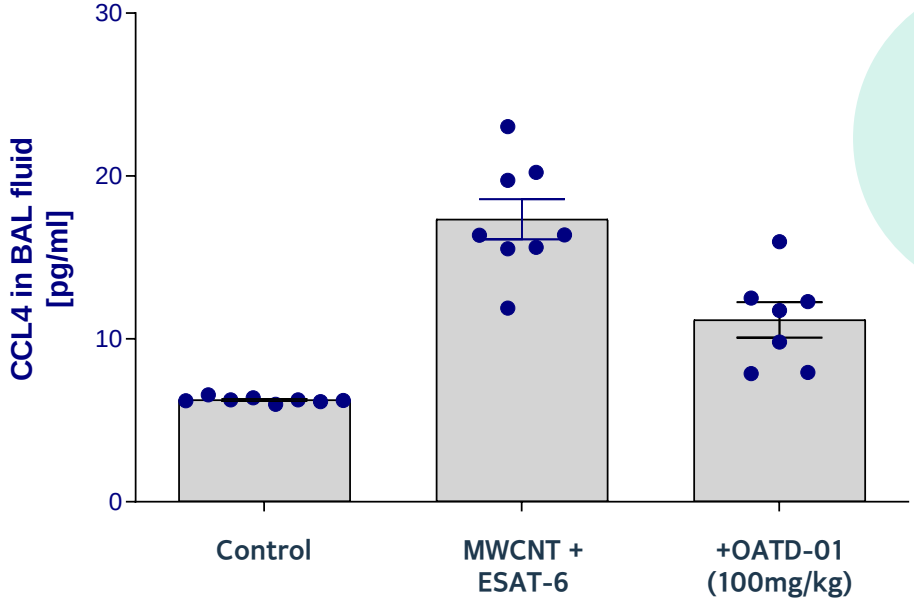
40 days post MWCNT+ESAT-6



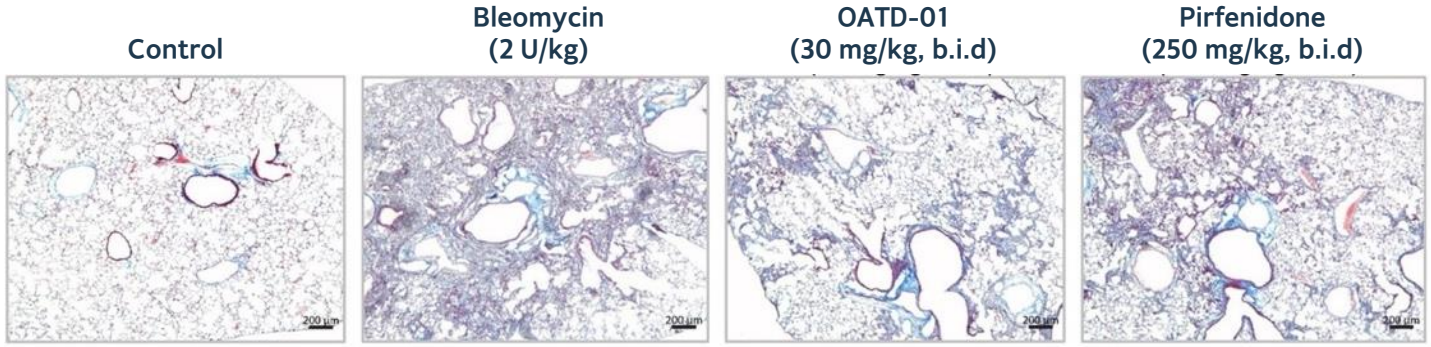
Organized granulomatous structures



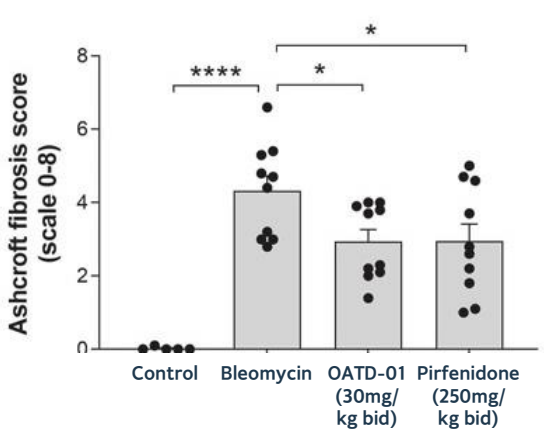
Day 10

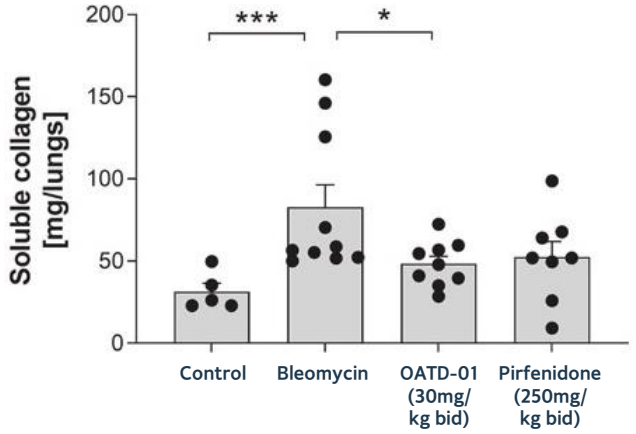


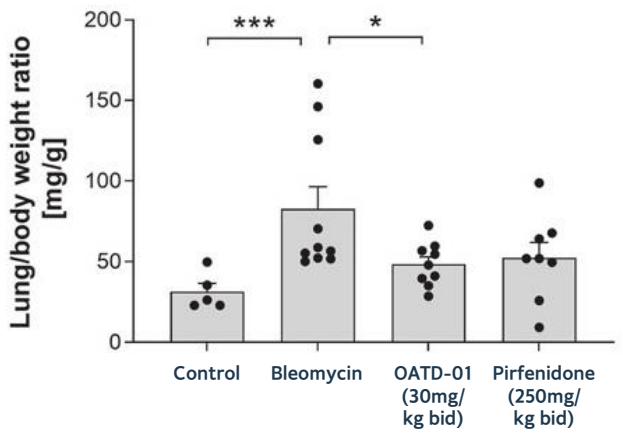
OATD-01 | attenuates lung fibrosis in mice

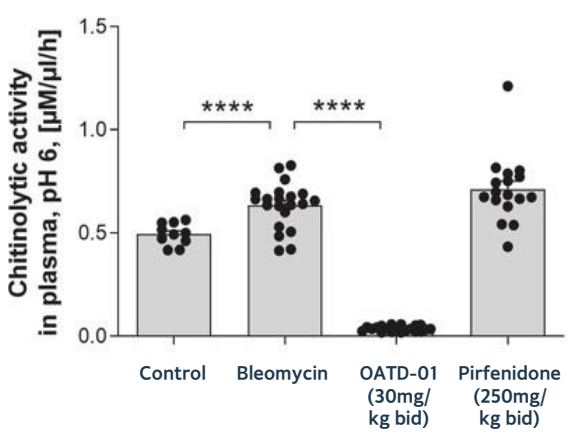


OATD-01 reduces features of pulmonary fibrosis in bleomycin induced model

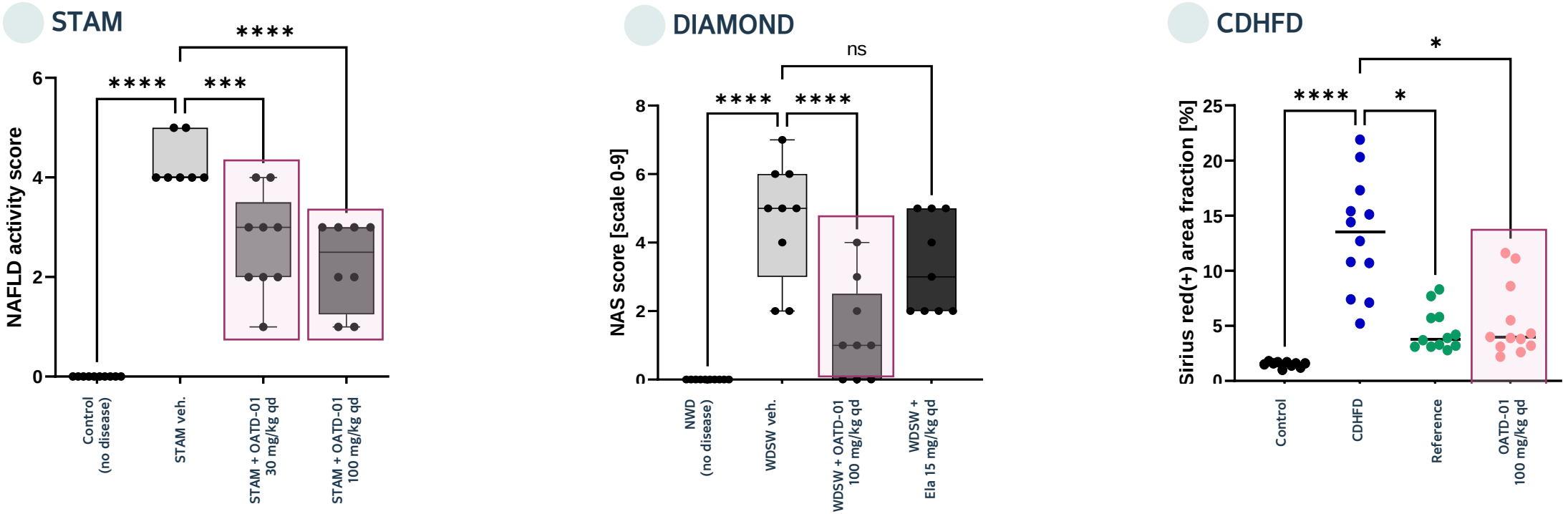








OATD-01 | efficacious in multiple models of NASH in mice and rats



OATD-01 reduced the hallmarks of non-alcoholic liver disease in mice (STAM and DIAMOND) and fibrosis in rats (CDHFD) and mice (STAM)

OATD-01 | Pre-clinical and phase I data strongly support further development

Compelling Data

- Efficacy proven in multiple animal models
- Convincing translational data
- Excellent pharmacological profile
- Demonstrated safety in animals and humans (129 subjects exposed)

High unmet need in sarcoidosis

- Sarcoidosis is a systemic inflammatory disease characterized by formation of immune granulomas in various organs
- Over 90% of sarcoidosis patients develop pulmonary sarcoidosis with granulomata in lungs
- CHIT1 is significantly overexpressed in sarcoidosis patients

OATD-01 | significant market opportunity for disease-modifying profile

Global sarcoidosis treatment sales with current treatment options are estimated at about US$188m* as steroids and other immunosuppressive drugs are inexpensive

However, the market is likely to completely change in the coming years.

The two most advanced compounds are:

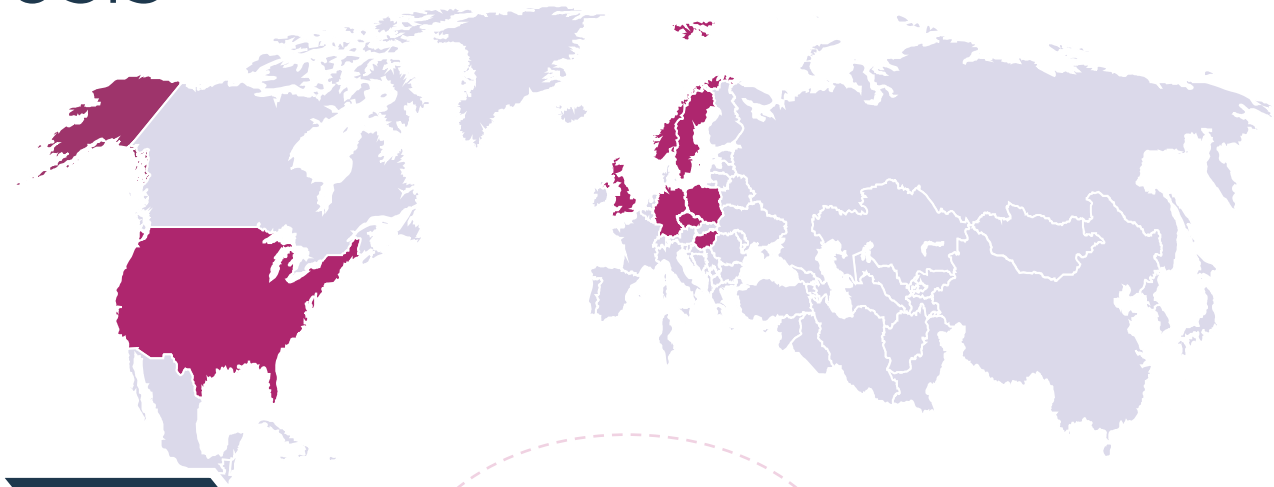
- **namilumab** (anti-GM-CSF (biologics); Ph2 studies; Kinevant)
- **efzofitimod** (neuropilin-2 modifier (biologics); Ph3 studies; aTyr Pharma)

Molecure estimates a value for the sarcoidosis market at maturity for a disease-modifying treatment could be over US$1.5bn**.

*EvaluatePharma. **Company estimates

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.



*IND submission	*CTA submission	*FDA & EMA* approvals	*FPFV	Intermediate checkpoint	*LPLV	Results and *CSR
Q2 2023	Q3 2023	Q3 2023	Q4 2023	H1 2024	H2 2024	2025

20 to 30 outpatient sites in the EU and US

Each patient treated for 12 weeks

~90 male and female patients with active pulmonary sarcoidosis

Treatment goals

- Improve symptoms
  - reduce the granulomatous burden
  - improve lung function
  - improvement of the radiological image
- Improve QoL

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

OATD-02 | first in class dual ARG1-ARG2 inhibitor

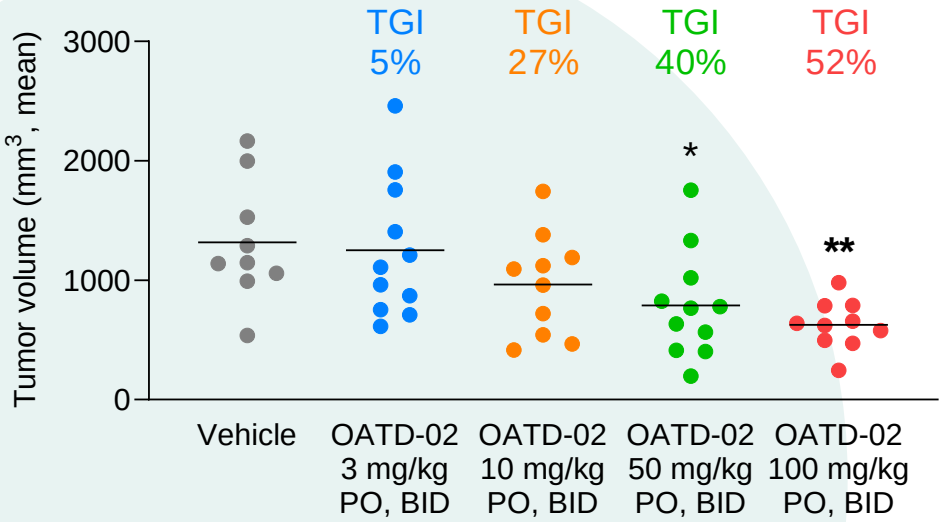
Molecure is the only company offering a dual arginase (ARG) inhibitor with **high intracellular activity**

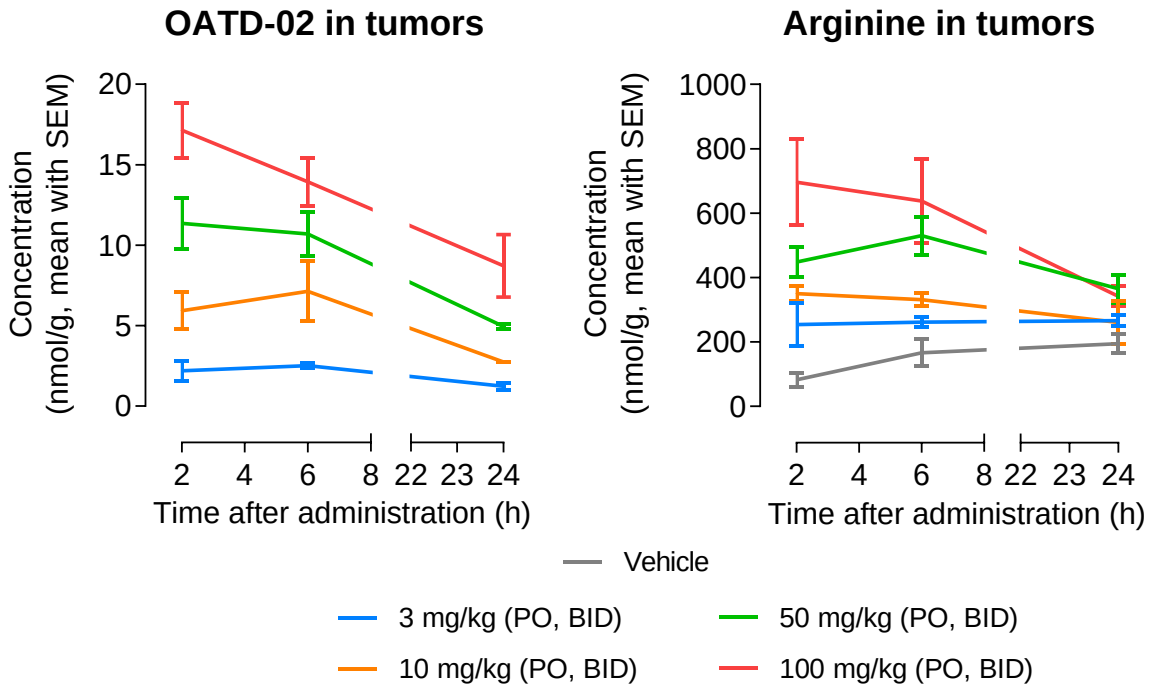
OATD-02

- Highly potent, orally active dual ARG1/ARG2 inhibitor with intracellular activity
- Restored arginase-suppressed T cell-mediated immune functions
- Significant anticancer efficacy as monotherapy and in combinations in multiple tumor models with no toxicity
- Predicted favorable human pharmacokinetic
- Patent protection until 2037
- Clearly defined pharmacological profile
- Entered the clinic in 2023

OATD-02 | exhibits dose-dependent therapeutic effect in a multiple tumor models

Significant dose-dependent effect was demonstrated in multiple models (here CT26)



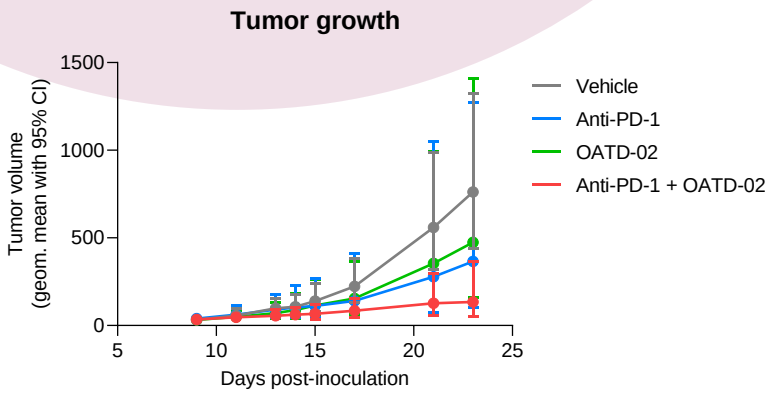


OATD-02 | improved the antitumour efficacy of immune-checkpoint inhibitors

OATD-02 enhanced the efficacy of anti-PD-1 antibody

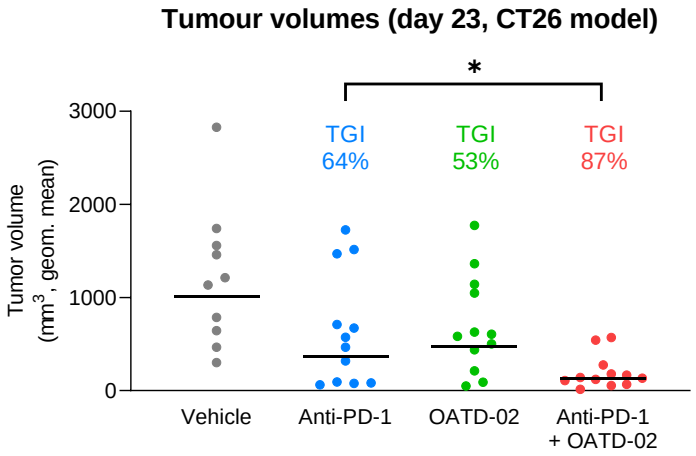
OATD-02 significantly improved the efficacy of anti-PD-1 antibody from TGI 64% to 87% (p = 0.0450)

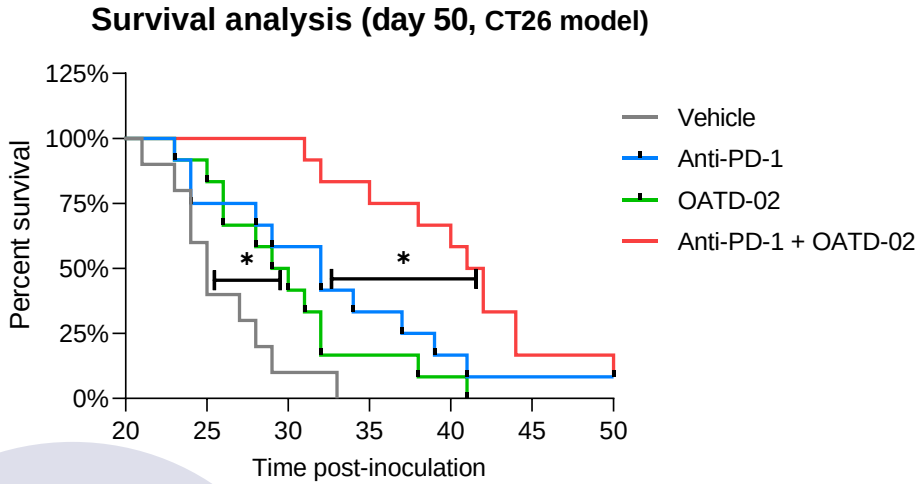
OATD-02 prolonged the life of tumour-bearing animals by 5 days in monotherapy (p = 0.0470) and significantly extended the survival of anti-PD-1-treated animals by 10 days (p = 0.0479)



OATD-02 dosed at 100 mg/kg (PO, BID) from day 1

Anti-PD-1 mAbs dosed at 2.5 mg/kg (IP) at days: 6, 10, 14, 18





OATD-02 | Addressing cancer with unmet need

Pancreatic ductal cancer (advanced, inoperable)
- current standard treatments comprise chemotherapy combinations (taxanes, gemcitabine, platinum derivates, irinotecan)
- ICI* (e.g., Keytruda, Opdivo, Yervoy) have not yet demonstrated significant efficacy
- 7MM** Pancreatic Cancer Market in 2022 - $1.8B

Metastatic colorectal cancer
- ICI effective in 15-20% subpopulation only (msi high, dMMR+)
- 7MM Colorectal Cancer Market in 2022 - $7.5B

Serous Ovarian Cancer
- ICIs not standard of care
- 7MM Colorectal Cancer Market in 2022 - $2.1B

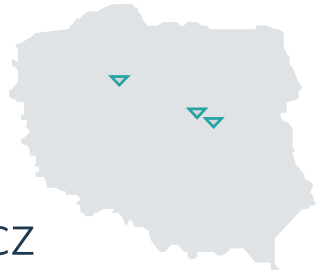
Renal Cell Cancer
- Targeted agents standard-of-care, ICIs with limited efficacy
- 7MM Renal Cell Cancer Market in 2022 - $3.4B

*ICI: Immune Checkpoint Inhibitors
**7MM: US, UK, DE, FR, IT, SP, JP

OATD-02 | Phase I clinical trial

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

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

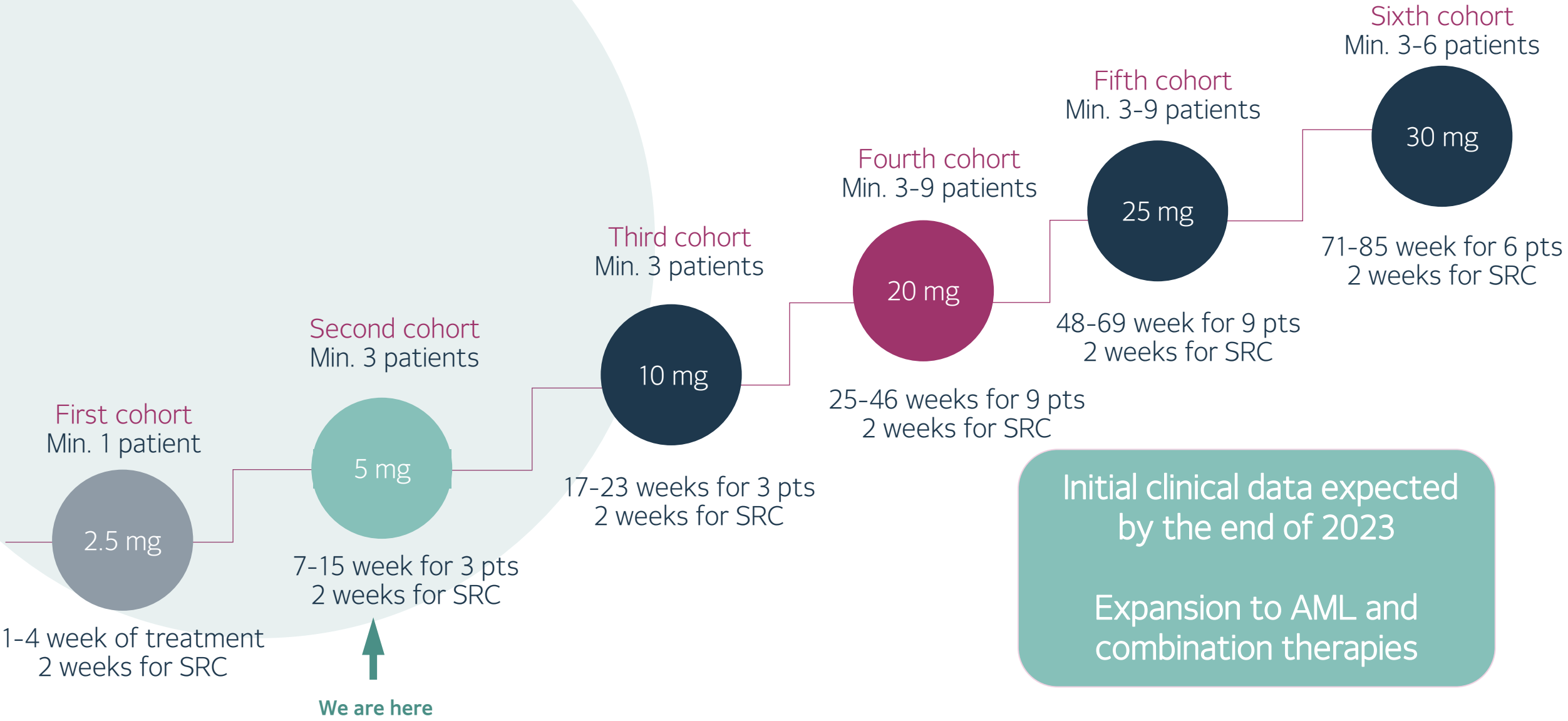


Study Duration: Approx. 1.5 years (Q1 2023 - H2 2024)

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

Colorectal cancer, platinum-resistant serous ovarian cancer, pancreatic ductal cancer, renal cell carcinoma

OATD-02 | administered to the second cohort of patients



Initial clinical data expected by the end of 2023

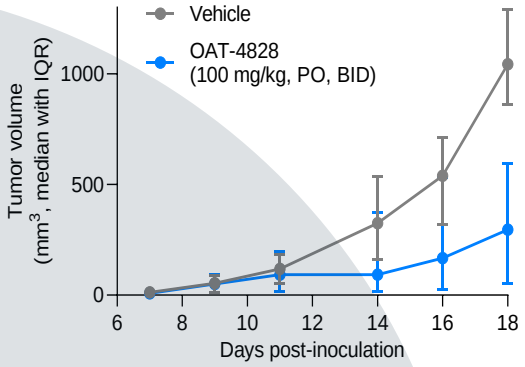
Expansion to AML and combination therapies

A promising pre-clinical pipeline

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

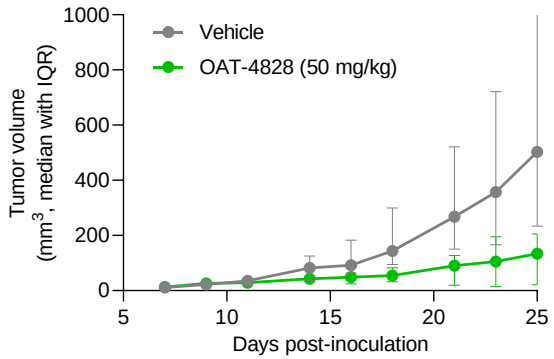
- Deubiquitinating enzymes (DUBs) **reverse the post translational modification of proteins by removing ubiquitin**
- Enhanced expression of DUBs can be seen in **both cancer and some inflammatory states**
- This makes DUBs a potentially very **important group of targets** for anticancer therapeutic agents

B16F10 melanoma



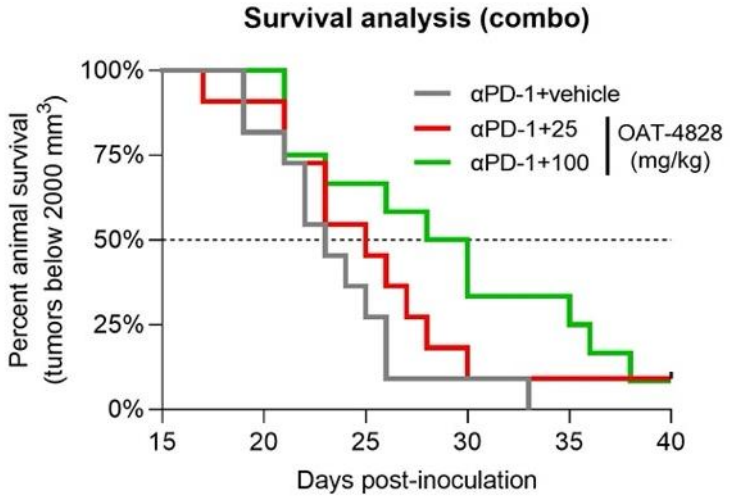
TGI 72% (100 mg/kg)

E0771 breast



TGI 62% (50 mg/kg)

Survival analysis (combo)



Validated translational potential

Mechanism of action involves activation of T cells

Significant efficacy as monotherapy and in combinations

mRNA Platform | discovering medicines of the future

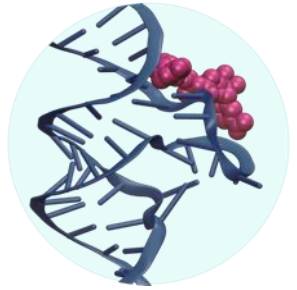
Small molecules targeting RNA to prevent downstream RNA translation

GENE OF INTEREST
UTRs of RNA

2D RNA STRUCTURE
OF DRUGGABLE REGIONS

3D STRUCTURE

BOUND SMALL MOLECULE
- NO TRANSLATION -
NO PATHOLOGICAL PROTEIN



1 Selection of functional targets, with unique properties

STRUCTURAL BIOINFORMATICS
OMIC DATA BIOLOGY

2 Combination of biological and bioinformatics methods to find 2D structure of druggable regions

BIOINFORMATICS, BIOPHYSICS

2a Dynamic modeling for tertiary structure determination and binding pocket identification

HTS, MEDICINAL CHEMISTRY

3 High throughput screening of potential binders and refining of leads with wet lab chemistry

Ongoing

Sequence → *In silico* SHAPE-MaP → **Druggable Secondary structures** → *In silico* CryoEM X-ray → **3D structure of RNA** → Docking (virtual screening) → **Small molecule** → Validation (wet lab) → **Active Small molecule** → NMR X-ray → **3D structure of the complex** → Docking (virtual screening) → Hit to Lead and Lead Optimization → **Optimized Lead compound**

Our approach

- Selection of functional regions of mRNA for undruggable protein targets
  - Identify locally stable and robustly folded sequences in the functional regions of the RNA of interest with the potential to form pockets accessible by small molecules
  - These secondary structures are not influenced by, and formed independently of flanking sequences
- Using a combination of software prediction and wet lab methods to solve 3D structure
  - Using SHAPE and Next Generation Sequencing to probe and confirm the more reactive, single stranded nucleotide sequences of 2D structure
  - Finely determined 2D structures are the basis for the resolution of the 3D structure (CryoEM, NMR, our proprietary algorithms)
- Virtual screening for druggable RNA fragment
  - Using the combination of physics- and machine learning-based scoring in our high throughput virtual screening engine
- Experimental verification
  - Validation of binding of early hits in molecular and cellular environments (dye or indicator displacement assays, whole cell-omics)

AI-driven drug discovery | following market trends

Early signals that AI companies increase development efficiency

Biopharma target to validated lead
~24-36 months

Leading AI companies
~10-20 months

40-60%
reduction in time

Benchmark for industry costs through preclinical studies — **~USD 25-50 mn**

Preclinical costs in leading AI biotechs — **~USD 5-15 mn**

40-80%
reduction in cost

Source: McKinsey report from May 2023

by 2025

~50%

- reduction of time and cost from therapeutic target validation to clinical candidate nomination
- efficency improvement by reducing attrition rate of drug candidates nomination processes in further preclinical and clinical development

High value assigned to the AI driven discovery platform by the end of 2024

The platform will strenghten Molecure's position as a European leader in the discovery of small-molecule drugs that interact with mRNA

Commercialization and milestones

Commercialization models

Partnering – main form of revenue generation	
Program	**Preffered potential models and assumptions**
Clinical stage assets	○ exclusive global license for further development and commercialization $$/$$$ ○ development the 2nd asset through Ph2 PoC when first asset commercialized $$$ ○ possibility of retaining commercial rights in Poland / EU market for sarcoidosis; rare/orphan
Early stage programs	○ strong emphasis on early validation of the biological target, MoA + in vivo efficacy $/$$
mRNA	○ revenue-generating collaborations with other biopharma companies after in vitro PoC in mRNA targets selected by the partner: target & hit validation, design and optimization of drug-like-molecules using our mRNA discovery platform enhaced by generative AI ○ Direct outlicensing of Molecure newly discovered molecules targeting mRNA directly
Overall until 2025	○ 2-3 revenue generating partnerships in clinical (1) and early stage (1-2) pipeline

Summary of milestones

Potential milestones targeted by 2025

	Protein Targets	RNA Platform	BD/Financial/Operational
2023-2024	○ Two clinical assets in PhI/II multi center clinical trials in patients ○ Two candidates in formal preclinical development (internal pipeline + in-licensing) ○ Three new discovery programs in lead-optimisation	○ In vitro PoC reached for 2-3 high value mRNA targets ○ Drug-like molecules (leads) in 2 RNA-targeting small molecule programs ○ First profit-sharing collaboration on external targets	○ At least one clinical stage program partnered in a high-value deal ○ High value assigned to the AI driven discovery platform
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 one revenue generating collaboration in mRNA platform (including milestone payments)

Finance

Planned expenditures to fuel growth | H2 2023-2025

In total ~PLN 250 m (USD 62,5 m*)	
Clinical phase programs	~PLN 100 m | ~USD 25 m*
Discovery and preclinical development programs	~PLN 75 m | ~USD 19 m*
mRNA platform (including AI tools)	~PLN 25 m | ~USD 6 m*
General, administrative & BD expenses	~PLN 50 m | ~USD 12.5 m*

** amounts rounded and converted at the USD exchange rate as of June 28 2023 - 4.05.*

Financing strategy

Financing sources

~20% | Cash

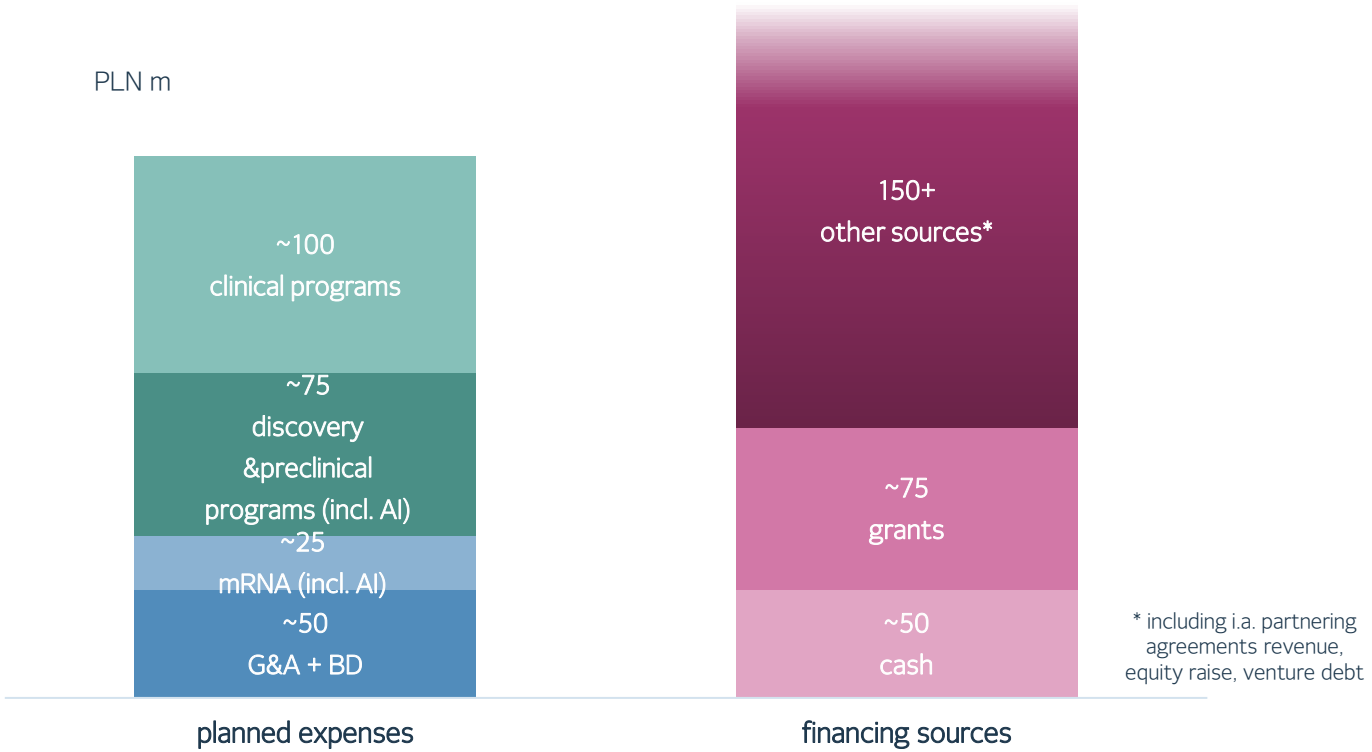
~30% | Grants

~50% | Other sources**

**Funding from the capital market and new partnering agreements

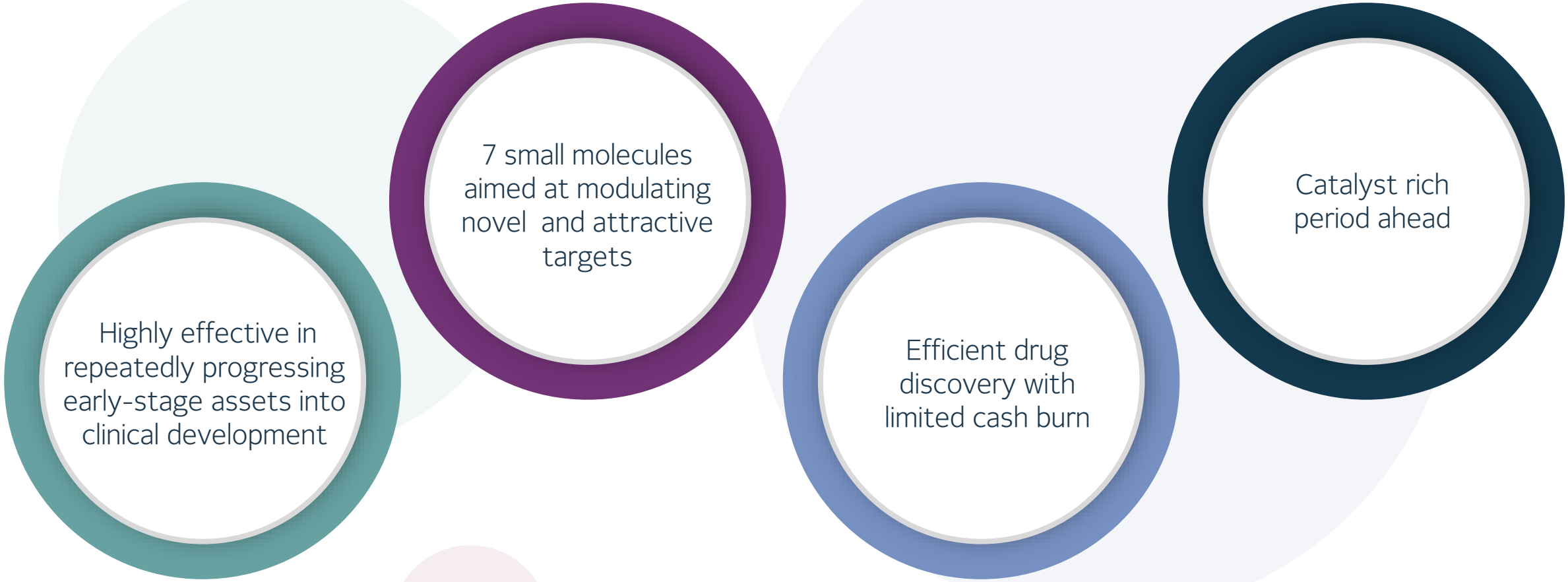
Molecure assumes that the implementation of the updated strategy will be financed from:

- Existing cash and cash equivalents (approx. PLN 50 m SD 12,5 m**, estimated for June 30, 2023).
- Existing (already granted) and future non-dilutive grants and subsidies (at least PLN 75 m; USD 25 m**)
- Financing from capital markets (within execution of Investment Authorized Capital), and revenue from at least one partnering transaction, only part of which would be required to cover total expenditures - a min. of PLN 150 m; USD 37,5 m**).



* *amounts rounded and converted at the USD exchange rate as of June 28, 2023 - 4.05.

Molecure | leading the vibrant Polish biotech sector



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Warsaw, 29 June 2023