

Marinomed Biotech AG Presentation

Corporate Presentation



Equity Story

Restart after successful restructuring



Experienced management team



Clinically proven potential **disruptive** technology



Late-stage assets in partnering



Lean and efficient business model



Finance restructured – **Profits** from asset sale



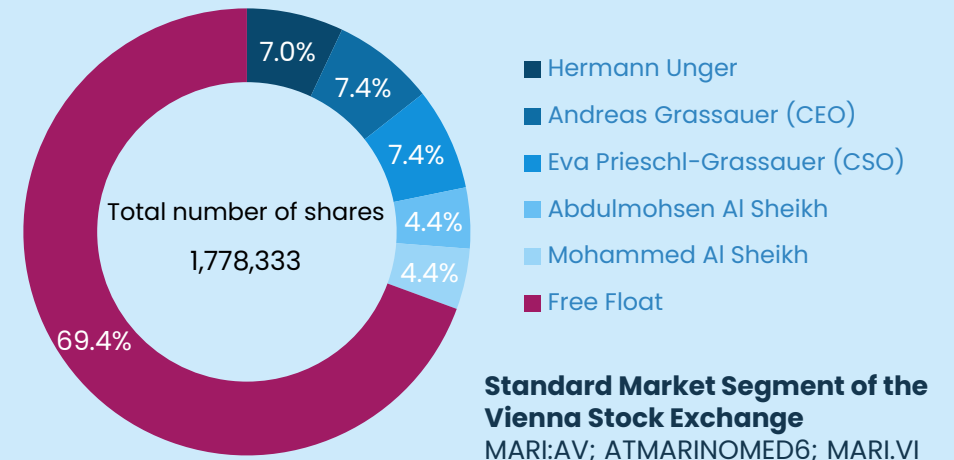
Andreas Grassauer
Chief Executive Officer



Eva Prieschl-Grassauer
Chief Scientific Officer



Gabriele Ram
Chief Financial Officer



Challenges of the past

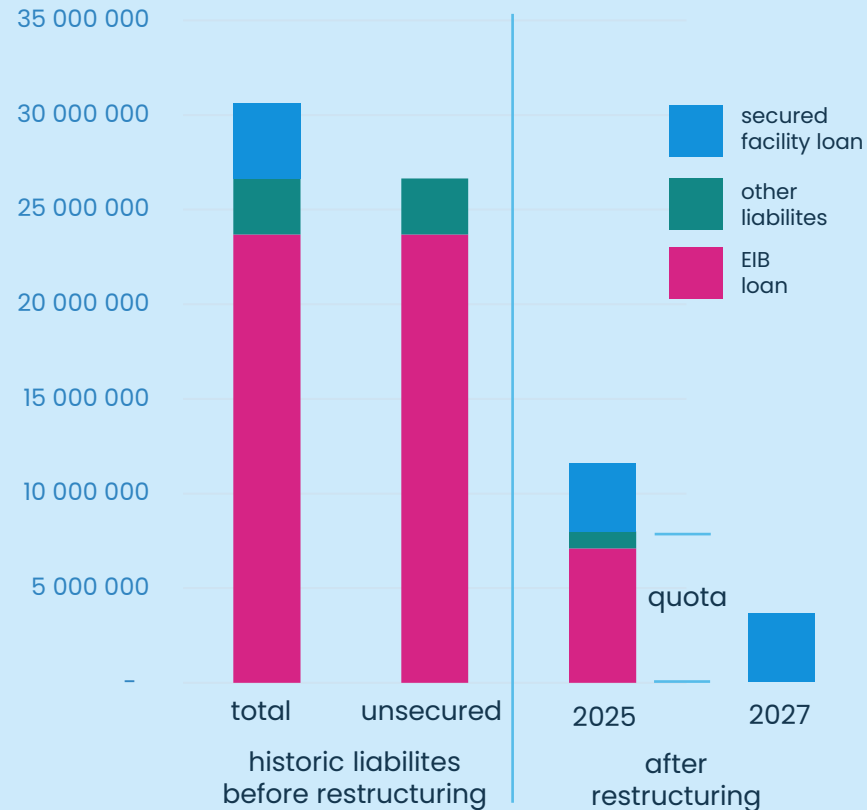
- Two strategically independent business units
- Sales downturn in one business unit after pandemic
- Stability issues with lead product candidates
- Variances in financial forecast
- Business critical debt structure
- Liquidity -issues

Restructuring proceedings conducted from Aug 24 – Jan 25



Consequences of the restructuring

Massive reduction of debt and restructuring gain

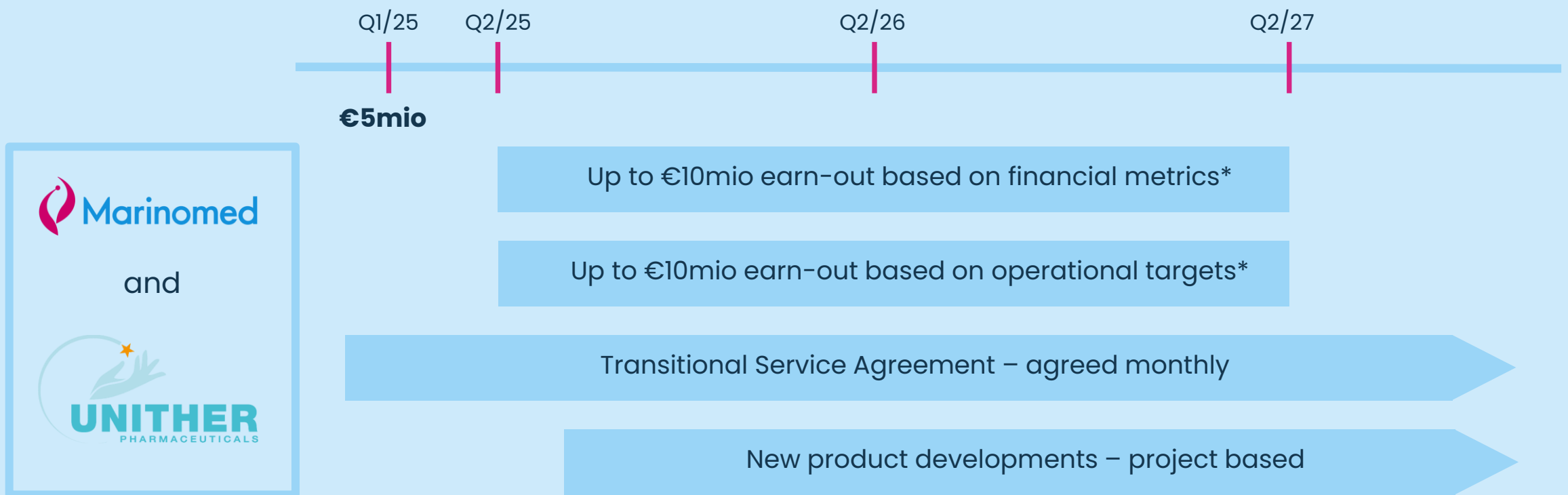


- Remaining quota liabilities: **EUR 8mio**
 - EIB EUR 7,1mio
 - Other EUR 0,8mio
- Quota payments within two years in 5 tranches
- No interest on unsecured liabilities
- Restructuring profit of **EUR 18,9mio** in Q1 2025 (non-cash effective)
- Continuation of facility loan



Divestment of the Carragelose business

2 earn-out and 2 service income streams following the sale of Carragelose



Unither Pharmaceuticals

To Summarize



Contract development & manufacturing organization
Focused on key pharmaceutical niches



Worldwide leader on BFS technology
5 billion unit doses capacity



Liquid Stick-Pack pioneer
600 million unit doses capacity



Global CDMO
Industrial Footprint on **4 continents**
Products sold in more **than 100 countries**
(France, USA, Brazil, China)



Growing business
€475 million turnover and
2164 employees in 2023



Private company
28% owned by management
72% private equity fund



The Marinosolv Technology



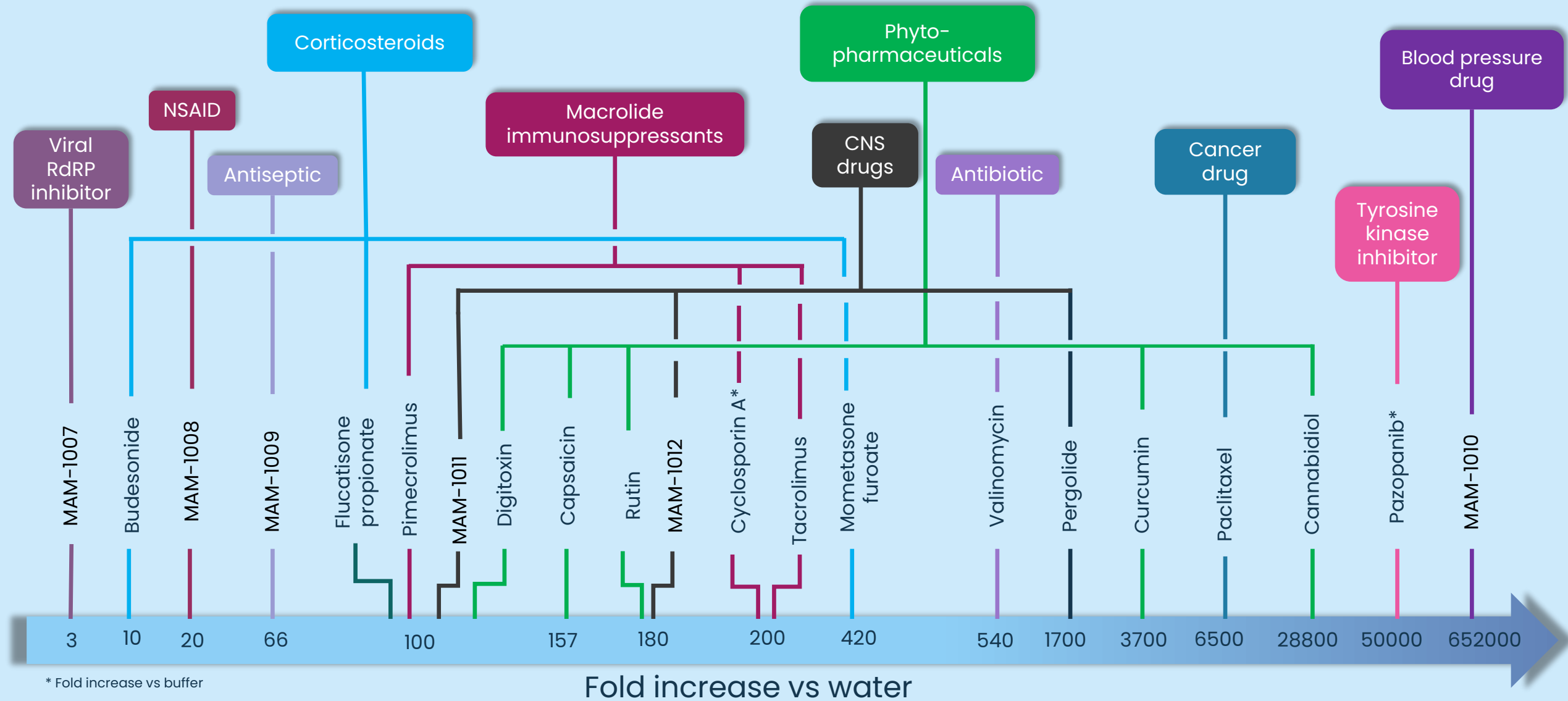
The need for solubilization technologies

- > 15.000 drugs are in development*
- > 20.000 drugs have failed in the last 30 years*
- > 2989 approved small molecule drugs **

90% of drugs in development fall into the two low solubility categories***

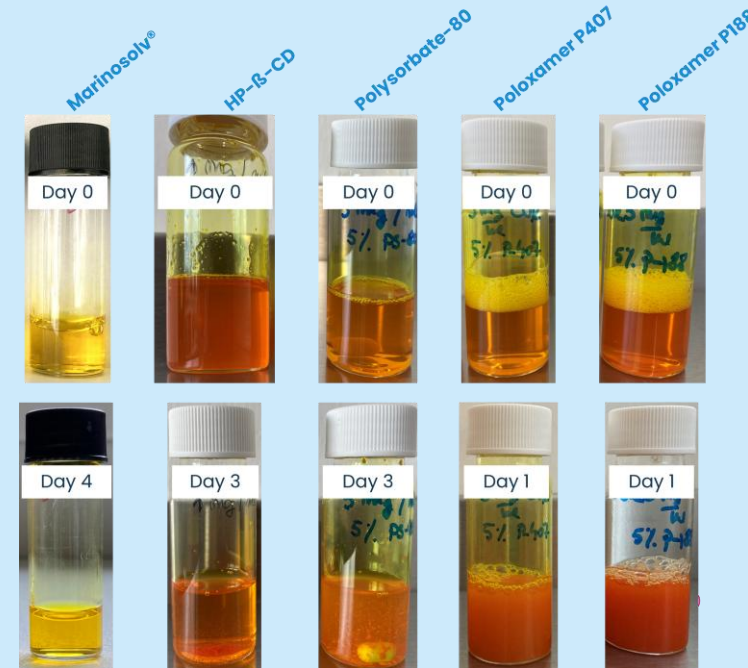
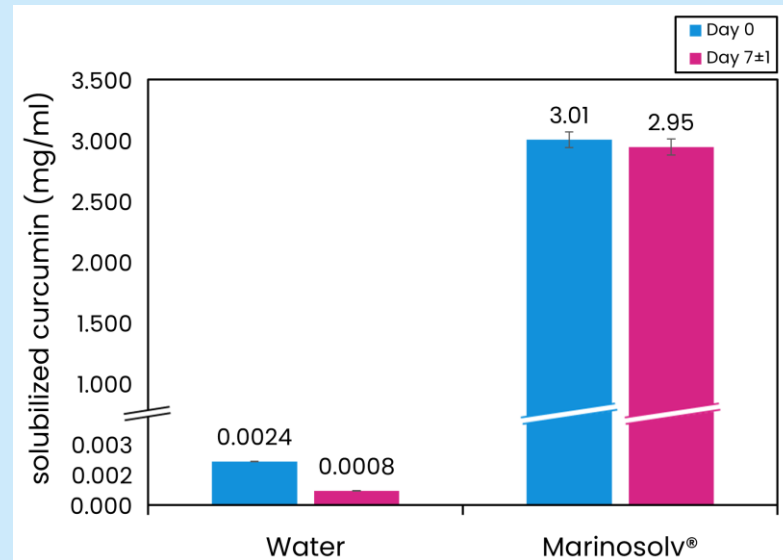


Marinosolv® Solubility Scale



* Fold increase vs buffer

Solubility of Curcumin in Marinosolv®



Source:

Enhancing the Solubility and Permeability of Small Molecules Using the Marinosolv® Technology

Whitepaper September 2024

Pipeline in-house projects

Late-stage projects with low risk and meaningful upside potential

Pharmaceutical Products

Therapeutic Area	Product Indication	Status	Pre-clinical	Phase I	Phase II	Phase III	Filing
IMMUNOLOGY	MAM-1004-1/Budesolv Treatment of severe allergic rhinitis	Filing in preparation					
	MAM-1003-1/Tacrosolv Severe inflammatory eye diseases	Phase II clinical study					



Redefining the allergic rhinitis market



Current products in Allergic Rhinitis are suboptimal

Today there is no preservative free nasal steroid available on the market

Current standard

- X Suspension
- X Preservatives
- X Not sterile
- X Slow onset of action
- X High doses necessary



With Marinosolv[®]

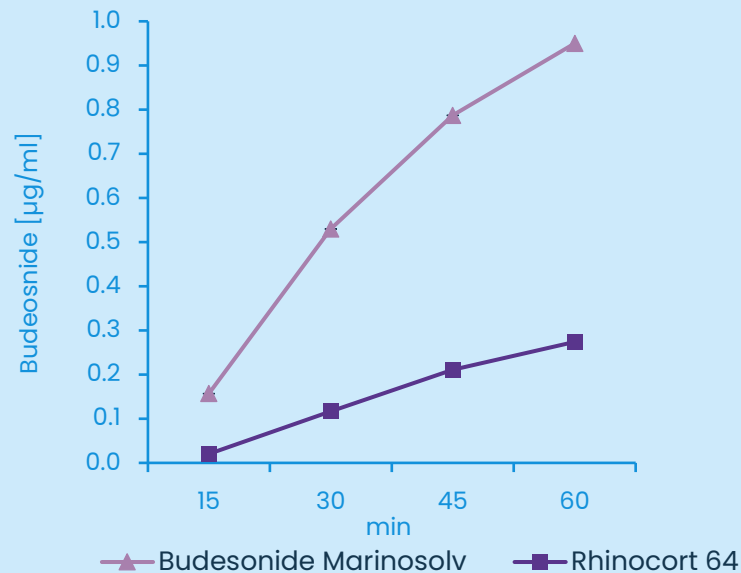
- ✓ Fully solubilized
- ✓ Preservative-free
- ✓ Sterile
- ✓ Fast onset of action
- ✓ Significantly lower dose



Marinosolv features increased bioavailability

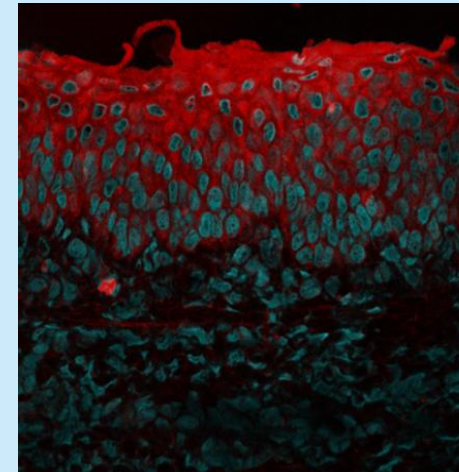
Solubilized formulations exhibit enhanced tissue permeation

Increased permeability of dissolved budesonide in 3D human nasal tissue culture

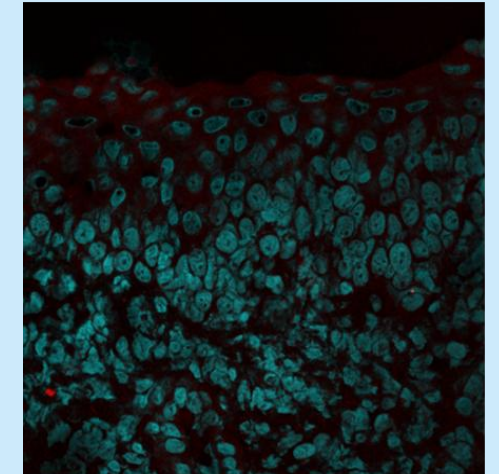


Marinosolv enabled budesonide (500 µg/ml budesonide) was compared to Rhinocort 64 suspension (1.28 mg/ml budesonide). Tissue budesonide concentration was measured by HPLC-MS.

Solution with Marinosolv



Suspension

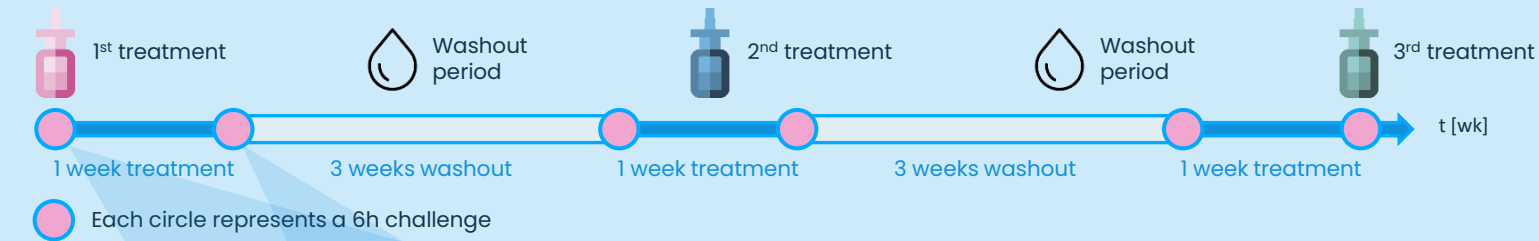


Legend: ■ Estradiol
■ Nuclei

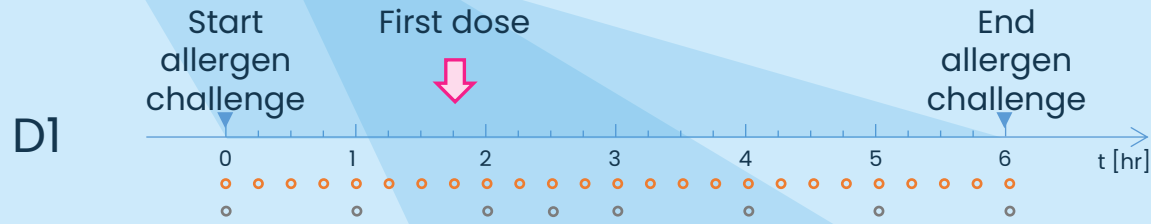
Marinosolv enables strongly increased permeation into the nasal tissue and thereby results in increased bioavailability and efficacy

Marinosolv enabled dissolution of Estradiol results in increased bioavailability

Clinical trial set-up

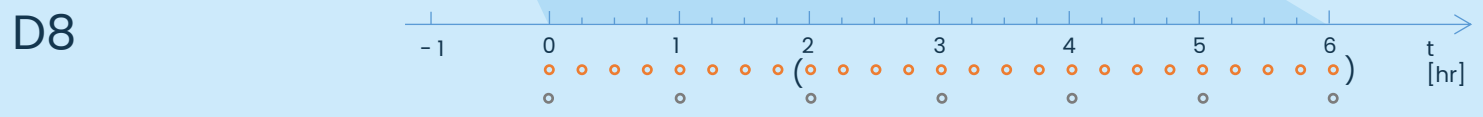


- Treatments:**
- Placebo
 - Rhinocort 64
 - Budesolv 10



Key Secondary Endpoint:
Onset of action

D2-7 Dosing 2 x 50 µl L/R in the morning

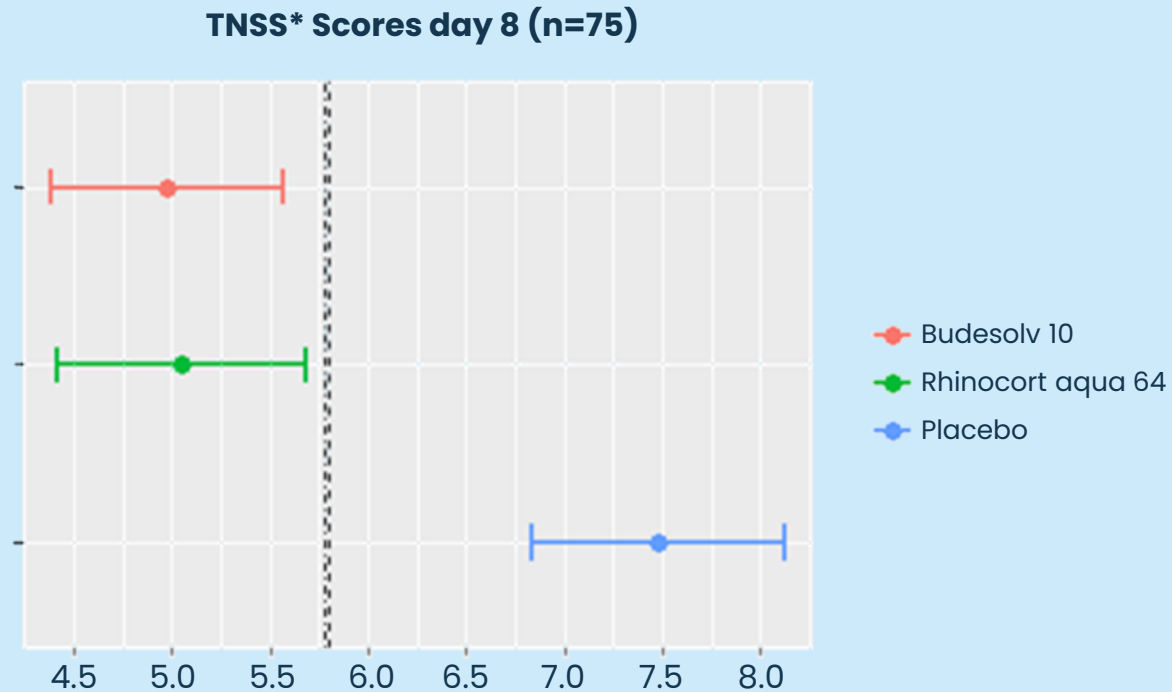


Primary Endpoint:
Therapeutic non-inferiority / equivalence (D8)

Legend ↓ 2 x 50 µl L/R ● TNSS* ○ Rhinomanometry () data points included in the mean score

Phase 3 study primary endpoint: Non-inferiority

*Budesolv clinically equivalent to the originator on day 8 in TNSS**

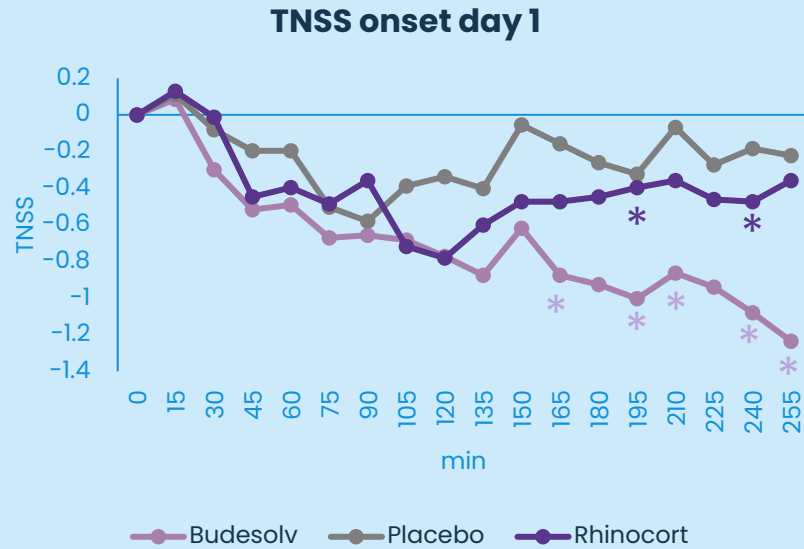


Treatment	Mean	SD	Median	N
Budesolv 10	4.98	2.57	4.47	75
Rhinocort Aqua 64	5.05	2.75	4.82	75
Placebo	7.48	2.80	7.47	75

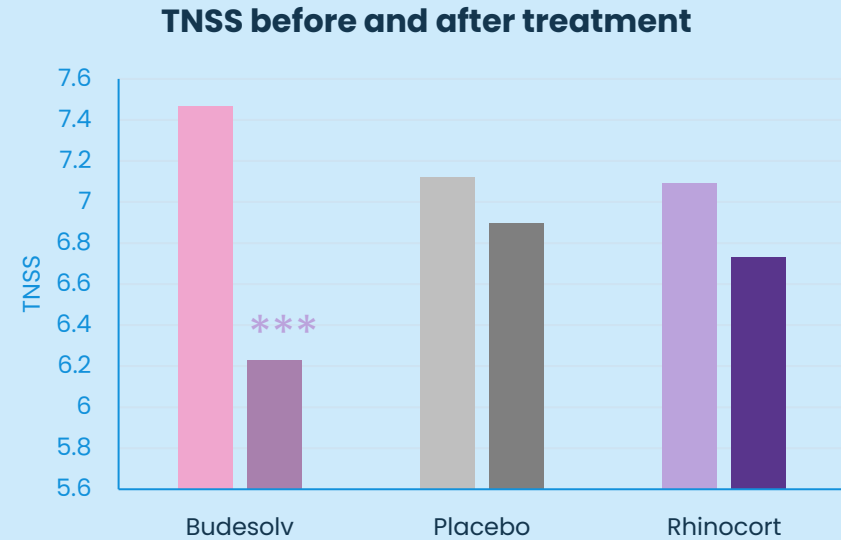
Reduction of TNSS* for Budesolv non-inferior vs. originator and superior over placebo

Phase 3 study key secondary endpoint: Superiority

Budesolv superior over originator on day 1 in TNSS – faster onset of action*



Significant reduction of allergic symptoms after the first dose of Budesolv compared to marketed product

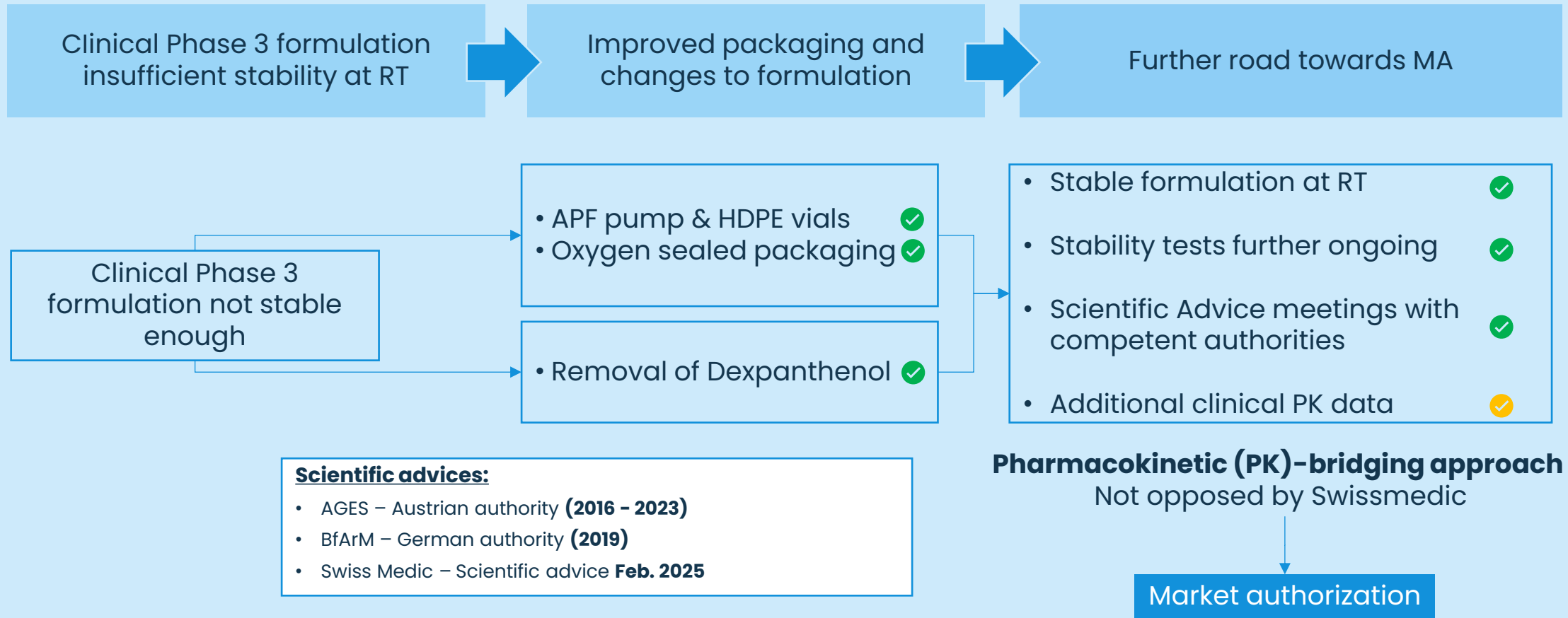


Significant reduction of TNSS after the first dose of Budesolv compared to marketed product

Budesolv is the first intranasal corticosteroid with immediate symptom relief after the first dose

*TNSS = total nasal symptom score (runny nose, itchy nose, congestion, sneezing)

Path towards intended going to market product and regional specific filing strategies



Filing strategy – addressing the difference between study medication and marketed product

Pharmacokinetic (PK)-bridging approach Not opposed by Swissmedic

PK study

bioequivalence between *Budesolv 10* (study medication) and *Budesolv ND 10* (intended market product) via measurement of systemically available budesonide.

Regarded as **proof for equivalence** of the local therapeutic activity at the site of action

Launch in Switzerland

Partner

Large scale production

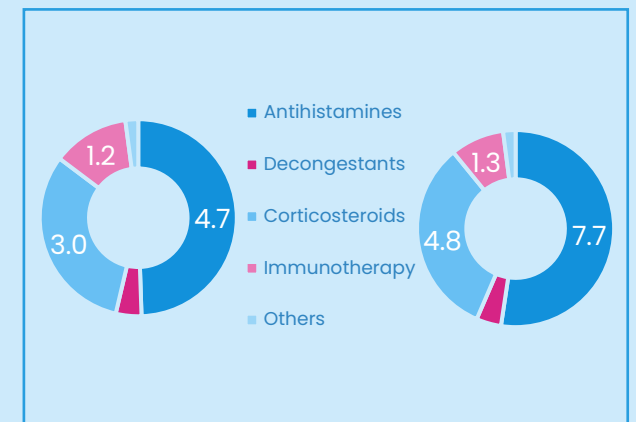
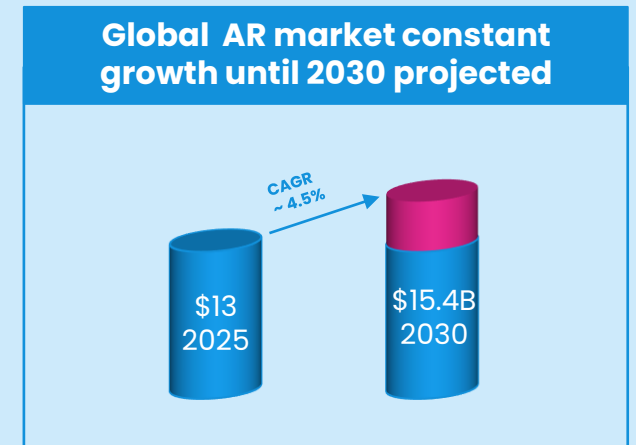
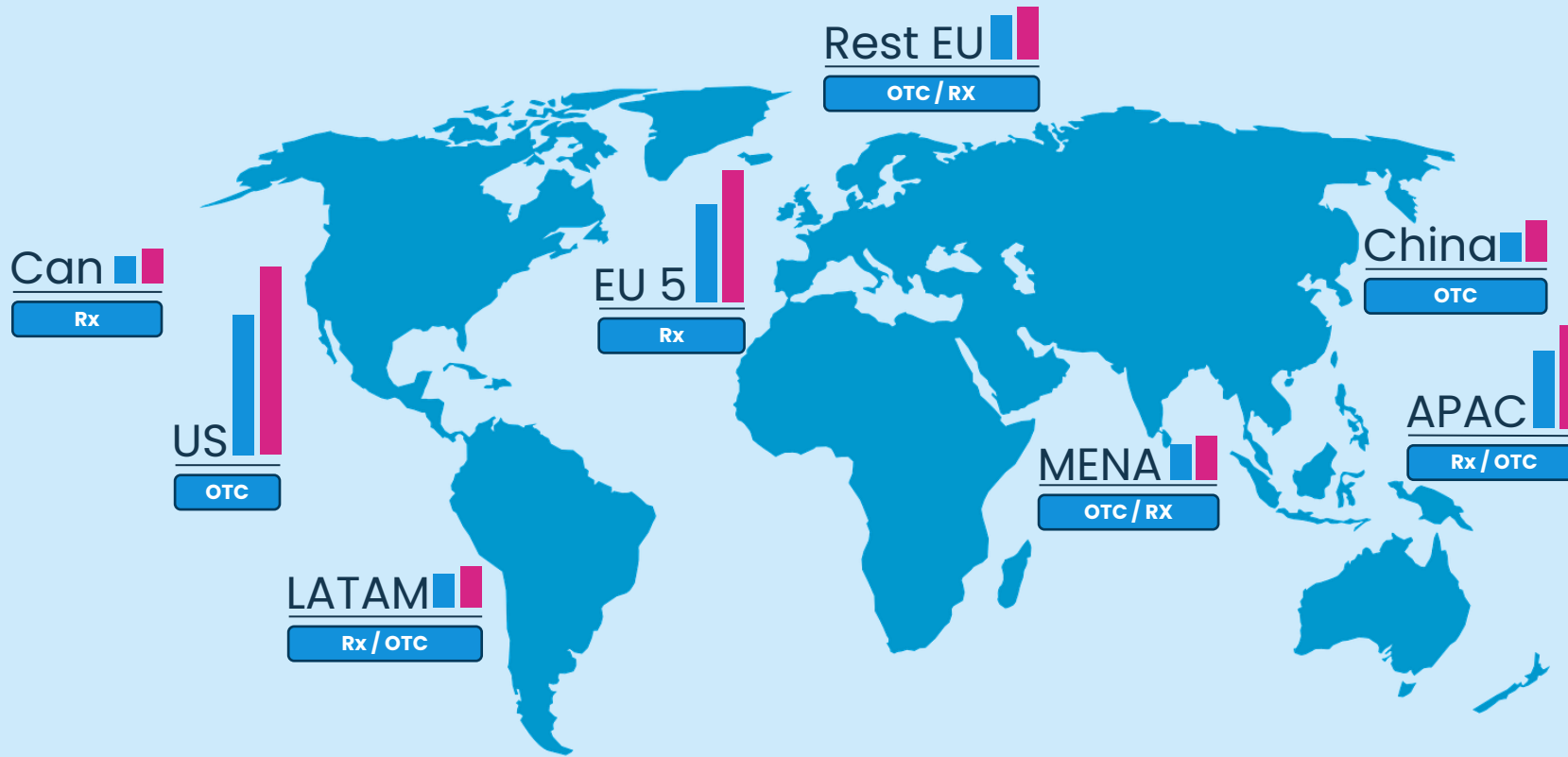
External CMO

Dossier preparation, filing and processing until marketing authorization

External CMO & Partner



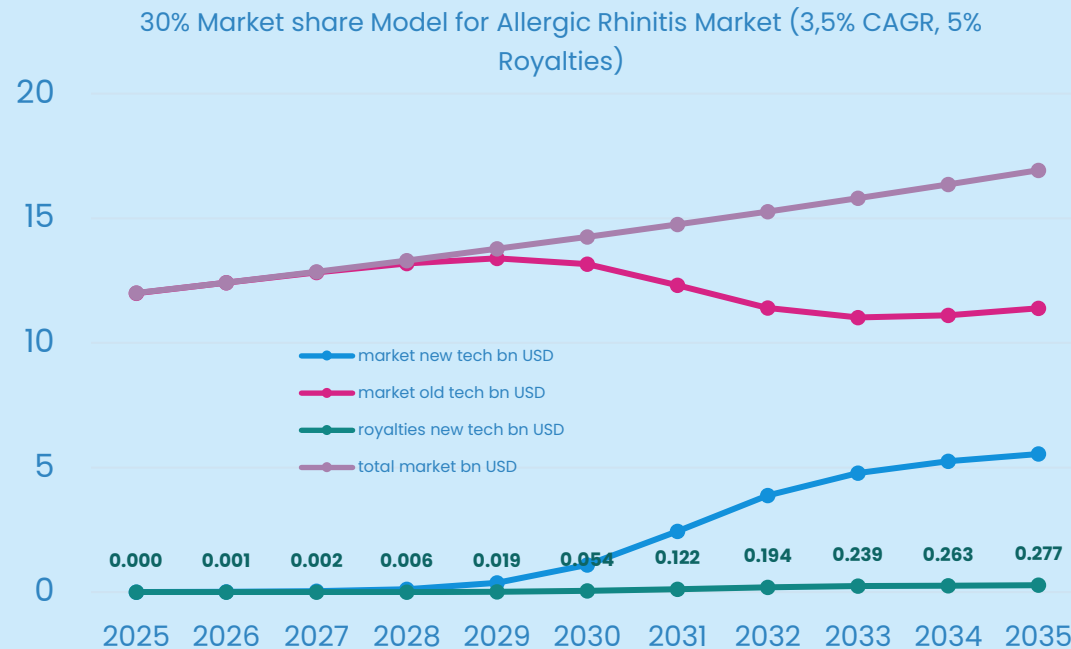
Global allergic rhinitis market is a USD 13bn underserved market with ~4,5% CAGR until 2030 driven by Antihistamines and Corticosteroids



*All data taken from: Coherent market insights report on treatment of Allergic Rhinitis (2023)

Model for launch of a disruptive treatment in allergy

Parameters: 30% target market share in 10 years – 5% technology royalty



Disruptive examples:

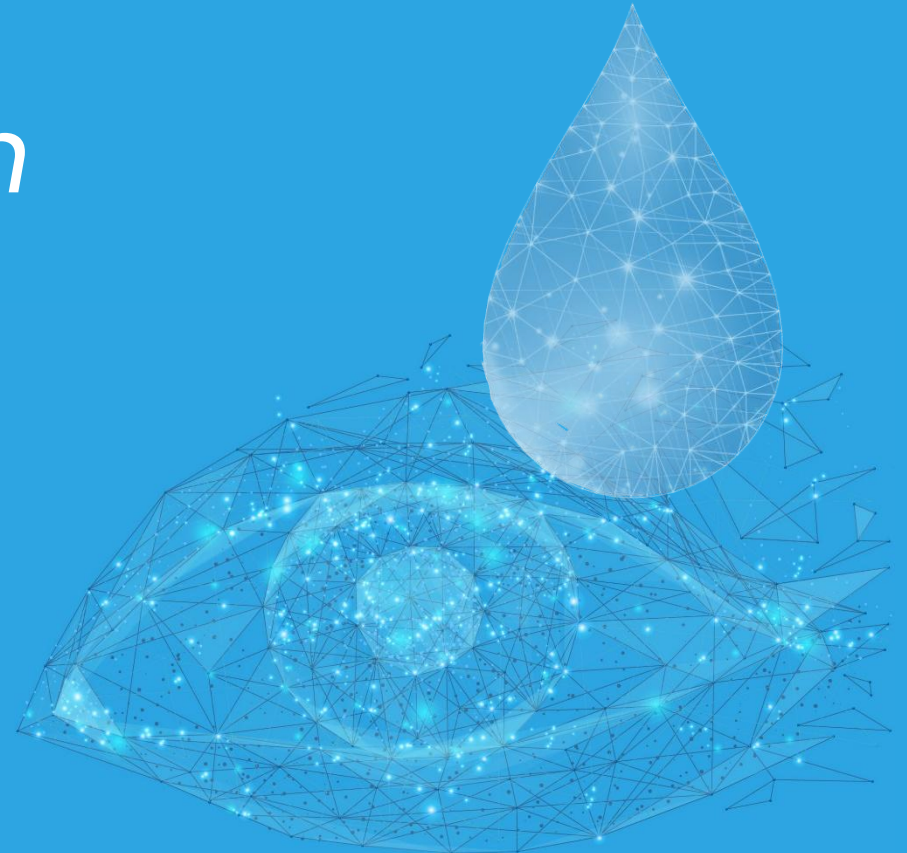
- Orenzia (Bristol-Myers Squibb) Arheumatoid Arthritis (RA) change fróm (IV) to subcutaneous (SC)
 - Herceptin IV → Herceptin SC (2013-2014 →2016 SC accounts for 80% of all applications)
 - CGRP-Ab Aimovig (Novartis) (monthly SC) (launch 2018 → 2024 635 Mn US\$) replaces oral forms e.g. Topiramate (2024 → 60 Mn US\$ 2030→10Mn US\$)
 - Rybelsus (Novo Nordisc) (oral) substitutes GLP-1-Agonists e.g. Ozempic (SC)
- Sales Development:
- 2011 (IV only) 1,4 Mrd. USD
 - 2012 (IV > SC) 1,6 Mrd. USD.
 - 2016 (IV < SC) 2,7 Mrd. USD
 - 2020 (total) 3,0 Mrd. USD,

30% target market share can provide ~250Mn USD technology royalties



Tacrosolv

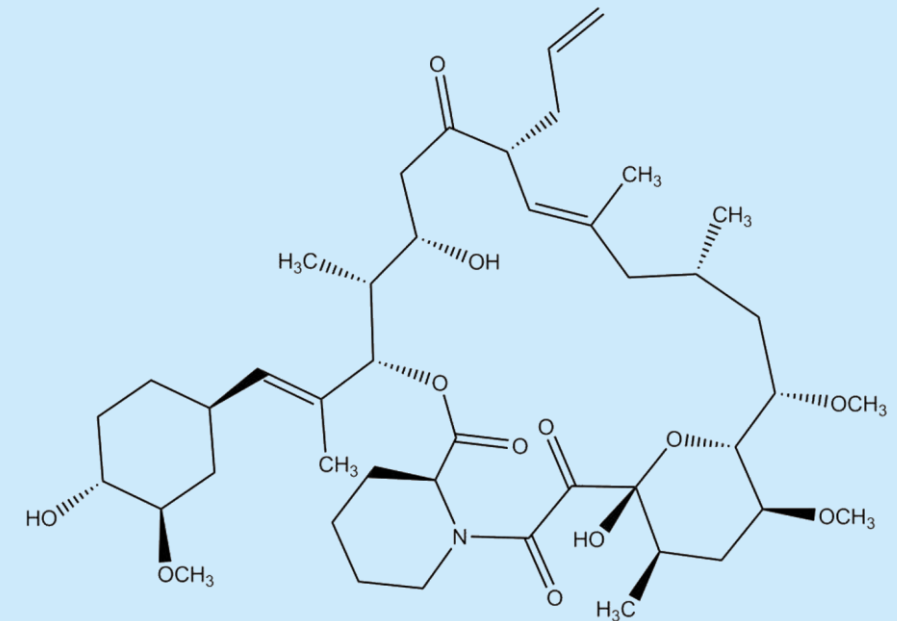
A new Tacrolimus *solution*



Tacrolimus: Highly potent macrolide immunosuppressant

A substance that could benefit so many more patients if solubilized

- **Highly hydrophobic** macrolide calcineurin inhibitor
- Immunosuppressive effect on T-cells and mast cells with indirect effects on many immune reactions
- **~100 times** more active than Cyclosporine
- Steroids usually should not be used longer than three weeks and are not routinely used in chronic inflammatory situations
- **Proof of concept** by a Tacrolimus containing drug marketed against vernal conjunctivitis in Japan and South Korea
- **No marketed product** in ophthalmology **available** outside Asia*

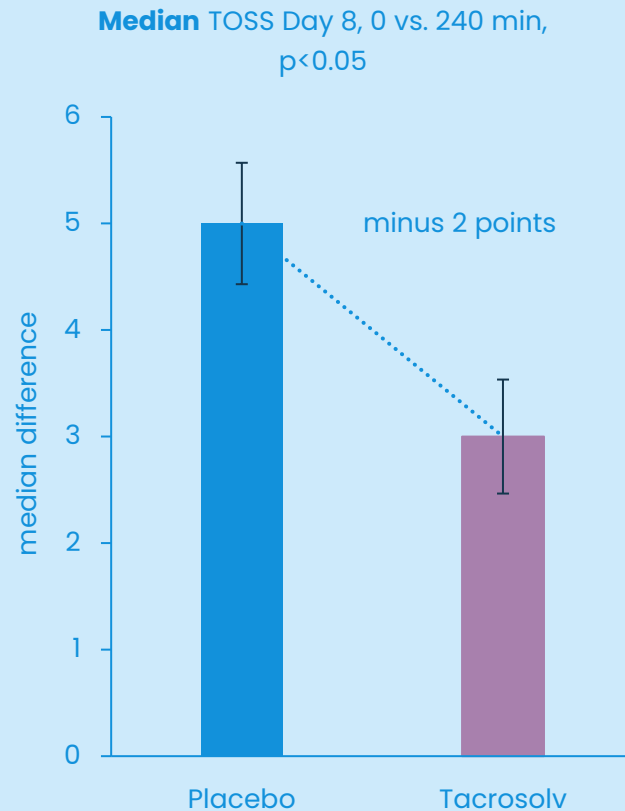


Potential to treat a multitude of ophthalmic inflammatory diseases



Tacrosolv solution (0.005%): Exploratory phase 2a

Day 8 mean change from baseline TOSS under allergen challenge (high dose)



TOSS =
Total ocular symptom score
represents typical inflammatory
symptoms of the eye.

Difference between
Tacrosolv and Placebo
was calculated by subtracting
TOSS at 0 minutes from
TOSS at 240 minutes
during continuous grass pollen
challenge.

Nasal symptoms on day 1
significantly reduced
→ **FAST ONSET!**



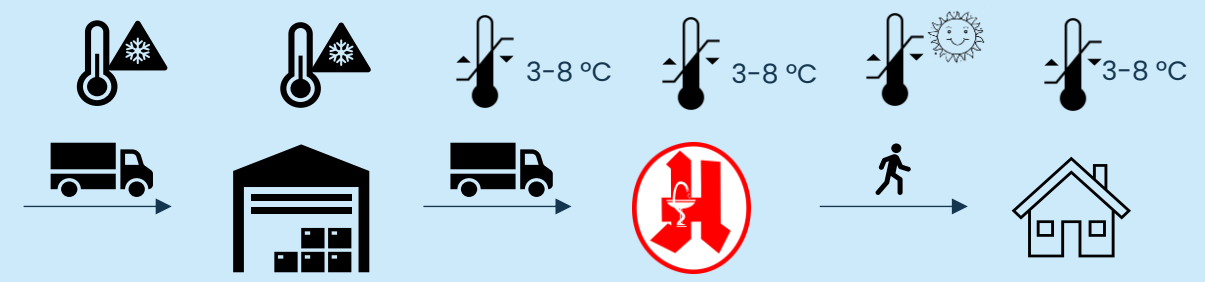
Targeted market eye drop product and distribution

- **Targeted concentration of API: 50 or 100 µg/ml**
- Clinical formulation optimized for stability with respect to concentration of excipients
- Shelf-life considering tacrolimus content and degradation:
 - 36 months at -20 °C
 - 9 months at 5 ± 3 °C
 - 10 days at 25 °C/60 % RH



Primary packaging:

- Single dose BFS vial / aluminum pouch
- 0,25 ml per vial



Long term storage up to 3 years

Pharmacy and patient storage

Tacrosolv summary and partnering strategy

Asset summary

- **Tacrolimus** is a **potent immunosuppressant** with a very low solubility in aqueous formulation
- Potential to address several **ocular surface inflammatory diseases**
- Increased bioavailability enables a **reduction of dose** and **increases permeability** into the ocular surface
- **Strong pre-clinical data**
- **Anti-inflammatory effect demonstrated** in model indication (allergic conjunctivitis)
- **Potential for orphan** disease indication

Partnering strategy

- Looking for an experienced partner in ophthalmology for further clinical development in chosen indications
- Available for full in-licensing / co-development or asset purchase
- IP protection (Marinosolv®) until 2036
- Classical license deal or co-development favored

Outlook & Strategy



Executing long term strategy

Turning innovation into profits

**Sale of
Carragelose
portfolio**

**Development & license deals for
Budesolv & Tacrosolv**

**Expand Solv4U technology
partnerships & Services**

Focus on strategy execution and cash flows



Financial calendar & IR contact

Financial Calendar 2025

16.04.2025	Publication of the Results 2024
11.06.2025	Annual General Assembly
17.09.2025	Publication of 2025 half year results

Upcoming Events

2.-3.04.2025	Münchener Kapitalmarktkonferenz
12.-15.05.2025	Frühjahrskonferenz 2025 - Frankfurt

Research Coverage	GBC AG, Matthias Greiffenberger
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