



# THARIMMUNE

*Unlocking Immunology for a Better Tomorrow*

+

**Intract  
Pharma** 

**Announce Letter of Intent to  
Combine Companies**

*September 30, 2024*

Nasdaq: THAR | [www.tharimmune.com](http://www.tharimmune.com)





Intract Pharma, Ltd. | [www.intractpharma.com](http://www.intractpharma.com)



## Forward Looking Statements

Certain statements in this presentation are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, contained in this press release, including statements regarding Tharimmune's or Intract's future financial or operating performance, the timing and design of Tharimmune's future Phase 2 trial, Tharimmune's and Intract's expectations with respect to the Merger, including the timing of entering into a definitive agreement, the timing of closing thereof, the pro forma ownership of the combined company, anticipated financing plans, the combined company's strategy, future operations, future financial position, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "depends," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "target," "should," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such forward-looking statements are based on the beliefs of management, as well as assumptions made by, and information currently available to, Tharimmune and Intract's management. Tharimmune may not actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Factors that may cause such differences, include, but are not limited to, those discussed under Risk Factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2023 and other periodic reports filed by Tharimmune from time to time with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent Tharimmune's and Intract's views as of the date of this release. Subsequent events and developments may cause Tharimmune's views to change; however, Tharimmune does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements to reflect new information, future events or circumstances or to reflect the occurrences of unanticipated events, except as may be required by applicable law. These forward-looking statements should not be relied upon as representing Tharimmune's views as of any date subsequent to the date of this release.

## Tharimmune (Nasdaq: THAR) + Intract Pharma (UK) Transaction Summary

 Deal Terms	<ul style="list-style-type: none"><li>• THAR signs non-binding LOI to acquire all outstanding shares of privately held Intract Pharma</li><li>• THAR remains in US (Bridgewater, NJ) and continues to trade on Nasdaq (THAR)</li><li>• Intract becomes wholly-owned subsidiary in UK (London)</li></ul>
 Ownership	<ul style="list-style-type: none"><li>• THAR shareholders own 51% of the combined company</li><li>• Intract shareholders own 49% of the combined company</li></ul>
 Use of Capital	<ul style="list-style-type: none"><li>• THAR: cash-on-hand as of 6/30 (~\$8 m); continue to develop TH104 + TH023</li><li>• Intract: continue to develop high-value oral biologics platform technology and progress on pharma collaborations</li></ul>
 Leadership Team	<ul style="list-style-type: none"><li>• Management: Randy Milby (CEO); Thomas Hess (CFO) Vipul Yadav (President &amp; CSO); Sireesh Appajosyula (COO); Nir Barak (CMA)</li><li>• Board : Leonard Mazur (Independent); Kelly Anderson (Independent); Lynn Bui (independent) Randy Milby (Chairman); Sireesh Appajosyula; Vipul Yadav</li></ul>

# A Transformative Combination Creates Best-in-Class Immunometabolic Company

**THARIMMUNE**



NASDAQ-listed biotech company focused on immunology & oncology	<b>Synergy of clinical assets and follow-on oral biologics/peptide platform</b>	Private biotech company with oral biologic & peptide expertise
Phase 2 asset with near-term readouts with registrational trial potential in 2026	<b>Diverse &amp; differentiated portfolio across immuno-metabolic conditions</b>	Best-in-class high-growth oral large molecule R & D (autoimmune mAbs & GLP-1s)
Opportunity for higher returns with expanded clinical indications	<b>Strengthened regulatory, clinical, and drug development execution</b>	Cost-efficiencies through shared & operational resources
Increased opportunities for funding and strategic alliances for clinical stage assets	<b>Unlocks shareholder value through expanded pipeline and platform synergies</b>	Potential for delivery platform licensing and partnership opportunities

# Expanded Leadership with Deep Pharmaceutical Experience

## Executive Team



**Randy Milby, RPh, MBA**  
Chief Executive Officer



**Sireesh Appajosyula, PharmD**  
Chief Operating Officer



**Thomas Hess, CPA**  
Chief Financial Officer



**Nir Barak, MD**  
Chief Medical Advisor



**Vipul Yadav, PhD**  
President & Chief Scientific Officer



## Expanded Board

**Leonard Mazur**  
Independent Director



**Kelly Anderson**  
Independent Director



**Lynne A Bui**  
Independent Director



**Randy Milby**  
Chairman of the Board

**Sireesh Appajosyula**  
Director

**Vipul Yadav**  
Director

## Synergy Through Clinical-Stage and Follow-On Oral Biologics Pipeline

Candidate	Indication(s)	Preclinical	Phase 1	Phase 2	Anticipated Milestones
<b>TH104</b> (nalmefene) Buccal Film	<b>Moderate-to-Severe Chronic Pruritis in Primary Biliary Cholangitis</b>				<b>2025:</b> Ph2 Topline Readout
<b>TH023</b> (Oral anti-TNFα mAb)	<b>Multiple Autoimmune Indications</b>				<b>2H 2025:</b> Ph1 Topline Readout
Oral mAb and GLP-1 Peptide Programs  Several Ongoing Big Pharma/Biotech Partnerships  <i>Next Gen Platform Development</i>	<b>Autoimmune and Metabolic Indications</b>				<b>2H 2025:</b> Lead candidate selection
<b>Antibodies/Knob Domains/ADCs</b>	<b>PD-1/HER2/HER3 + Oncology &amp; Metabolic Targets</b>				<b>2025:</b> Lead selection + IND enabling studies

\*pending discussions with FDA; \*\*Partnered with Intract Pharma; Exclusive mAb supply by Celltrion Inc., Intract/Tharimmune has granted ROFR to Celltrion, Inc.



**THARIMMUNE**

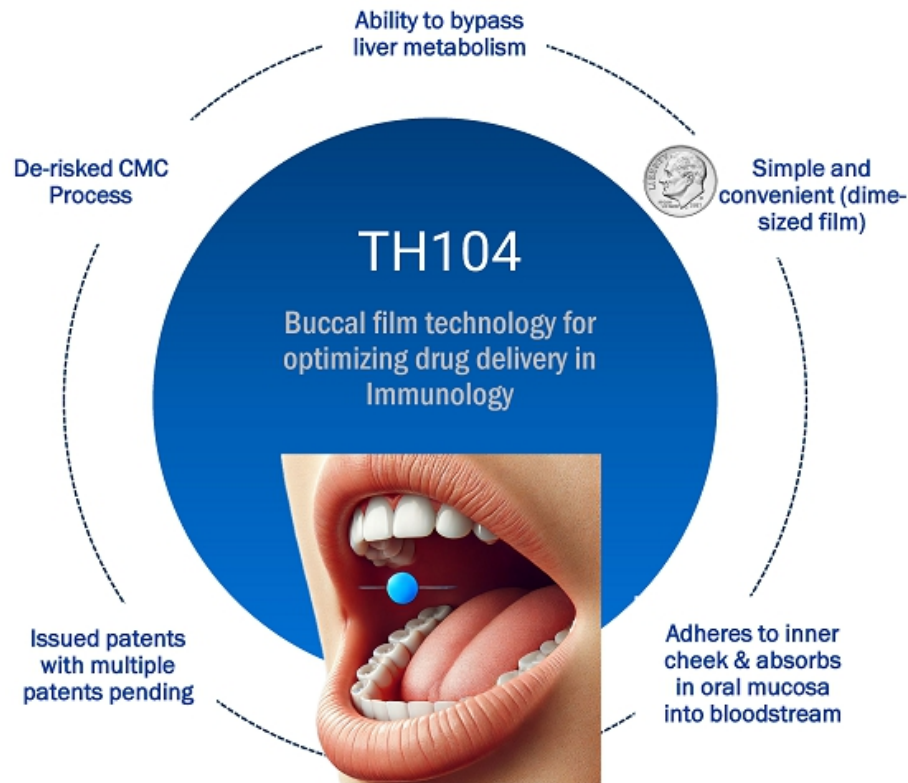
**Lead Candidate:**

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**TH104**



# TH104: Proprietary Transmucosal Buccal Film Avoids First-Pass Liver Metabolism



Phase 1 study demonstrated TH104 oral film had comparable safety and tolerability to IV

Drug embedded on proprietary transmucosal film

- ✓ Once-Daily Dosing
- ✓ Rapid Onset
- ✓ High Absorption

Designed to bypass liver (*no first-pass effect*)

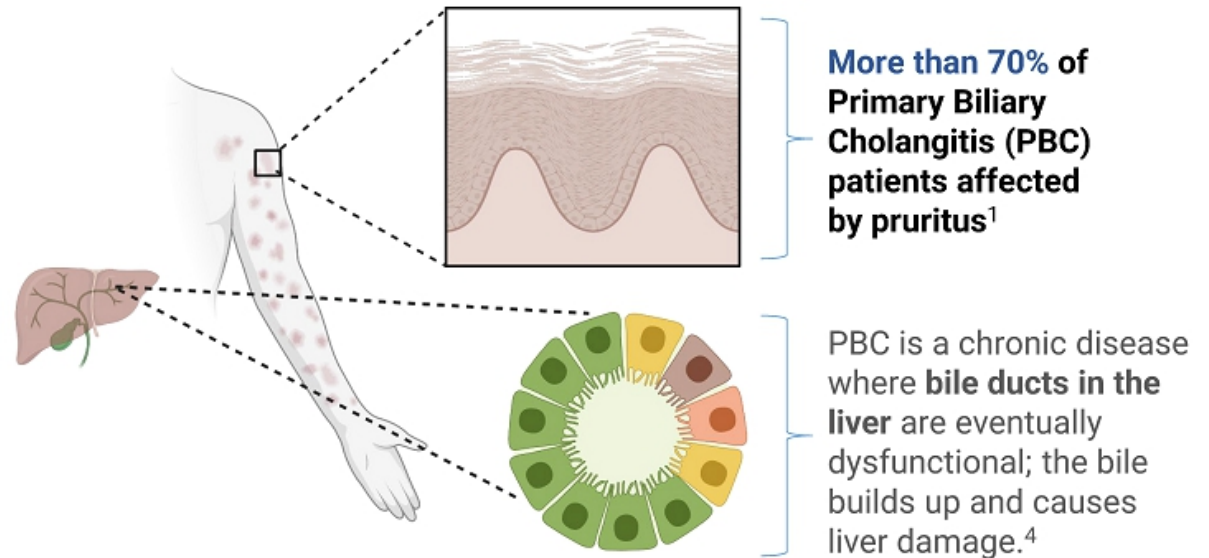
- ✓ Absorbs in oral mucosa & distributes to skin
- ✓ Designed for liver impaired conditions



# High Unmet Need: Moderate-to-Severe Chronic Pruritus (debilitating itching) in PBC

In patient testimonials, PBC itch is described as “the worst, most unimaginable itch”, like bugs crawling under the skin”.

- PBC is an **orphan disease** in the USA and Europe, with 178k patients in US.
- Affects men & women (rate higher in women: ~ 1 in 1,000 > 40 years old)<sup>2</sup>
- **65% of patients** have “worse **nocturnal** pruritus” with 71% of patients stating a disturbance in their sleep<sup>3</sup>



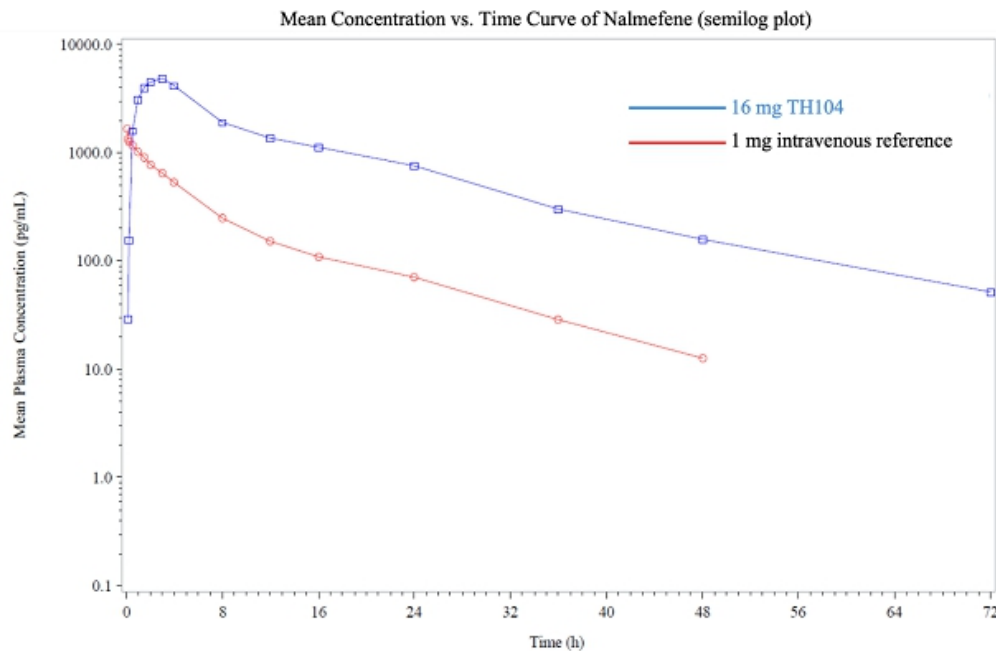
1. Gungabissoon U, et al. BMJ Open Gastro 2022;9:e000857. doi:10.1136/bmjgast-2021-000857

2. <https://www.healthywomen.org/condition/primary-biliary-cholangitis-pbc>

3. Rische et. al. Itch in Primary Biliary Cholangitis: A Patients' Perspective Acta Derm Venereol 2008; 88: 34-37

4. <https://www.niddk.nih.gov/health-information/liver-disease/primary-biliary-cholangitis/definition-facts>

# TH104 Demonstrated Favorable Pharmacokinetic Profile Compared to IV Dosing



## Pharmacokinetic profile of oral transmucosal delivery of TH104 comparable to IV delivery

### PK Profile:

- **Primary endpoint of the absolute bioavailability\*: 0.459 (45.9%)**
- Median time to maximum concentration ( $C_{max}$ ): 2.0 hours
- Mean half-life ( $T_{1/2}$ ): 14 hours

### AE Profile:

- Treatment emergent adverse events (TEAEs) reported in 8 subjects (40.0%) in TH104 group; 7 subjects (36.8%) in IV
- All reported TEAEs were considered mild in severity
- Most frequently reported TEAE in both groups was dizziness (4 TH104 group; 7 intravenous)
- TEAEs reported in at least 2 subjects in any treatment group were nausea (3 in each group) and somnolence (3 in each group).

\*fraction (or percentage) of the administered dose absorbed into the systemic circulation compared to an equivalent intravenous dose of nalmefene



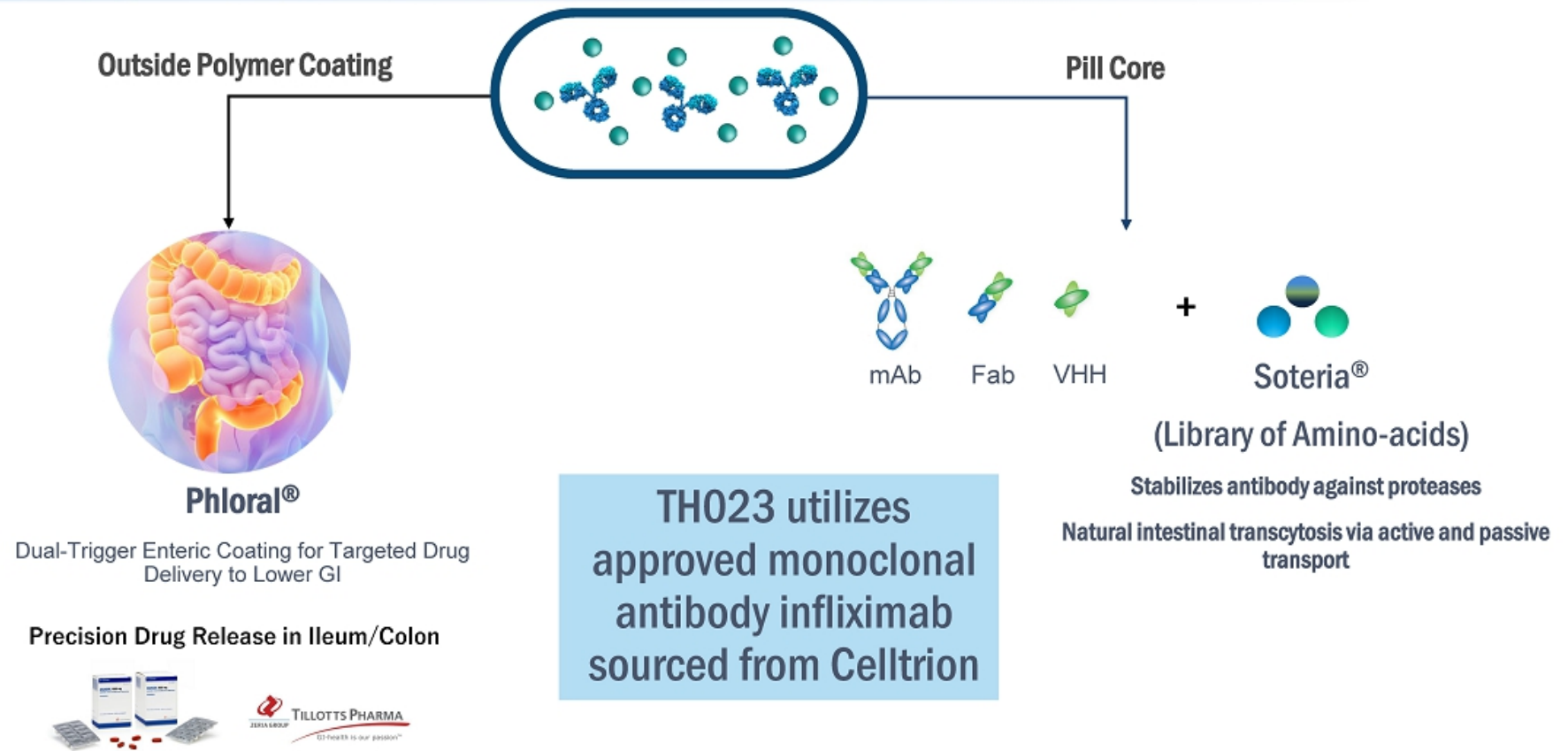
**THARIMMUNE**

**Combination with Intract  
Oral Biologics & Peptides**

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# Intract Utilizes Potential Best-in-Class Proprietary Oral Antibody Delivery Platform



# Phloral®: Multiple Clinical Studies Executed Including a Commercial Product in UC



## Inflammatory Bowel Disease

- ✓ EMA approved novel small molecule product (mesalamine) launched for first line treatment for UC in 2019.
- ✓ Passed Phase 3 trial in 817 UC patients<sup>1</sup>.

1. D'Haens et al., *Aliment Pharmacol Ther.* 2017;1-11

2. Allegretti et al., *Digestive Diseases and Sciences.* 2018.

3. Peiris et al., *Gut*2021;0-1.



## Clostridium difficile infection

- ✓ Phloral® coated capsules used for FMT trial to test efficacy in 51 C.diff patients<sup>2</sup>.
- ✓ Positive efficacy data shown with Phloral® capsules targeting FMT to the colon

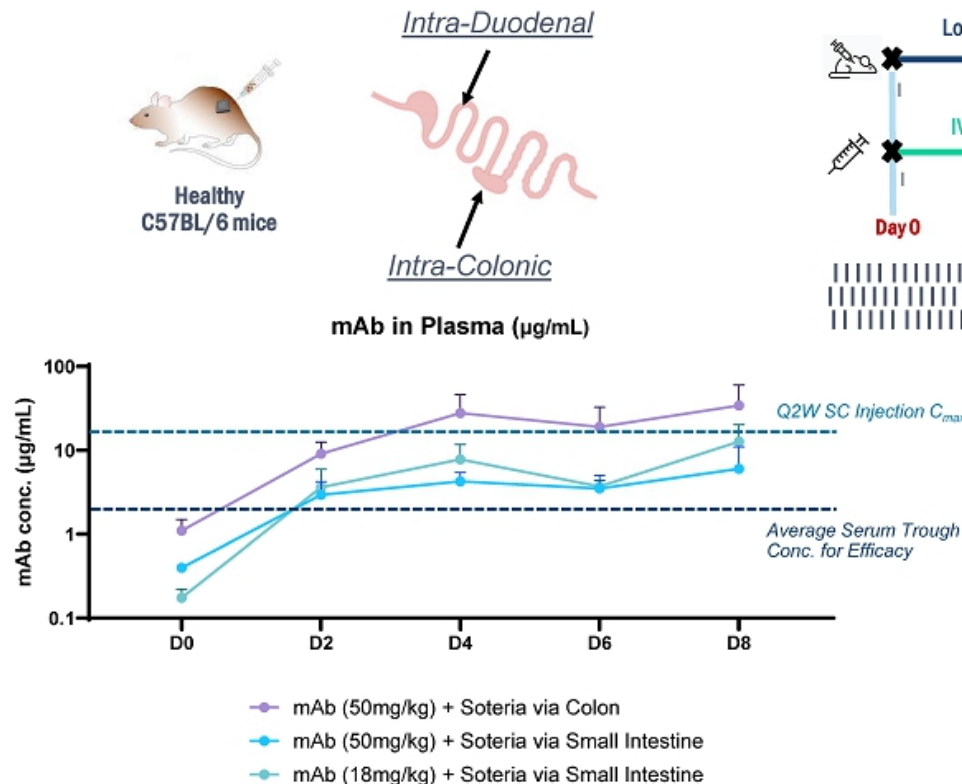


## Obesity/T2D

- ✓ Phloral® coated capsules of MCFA dosed to 20 subjects with a BMI of 30-40kg/m<sup>2</sup>.
- ✓ Significant decrease in calorific intake and increase in PYY hormone was demonstrated<sup>3</sup>.

# Soteria® Platform: mAb Serum Conc. Exceeds Trough and Matches SQ Injection Conc.

## In-vivo PK in Healthy Mice Following QD Dosing for 1wk



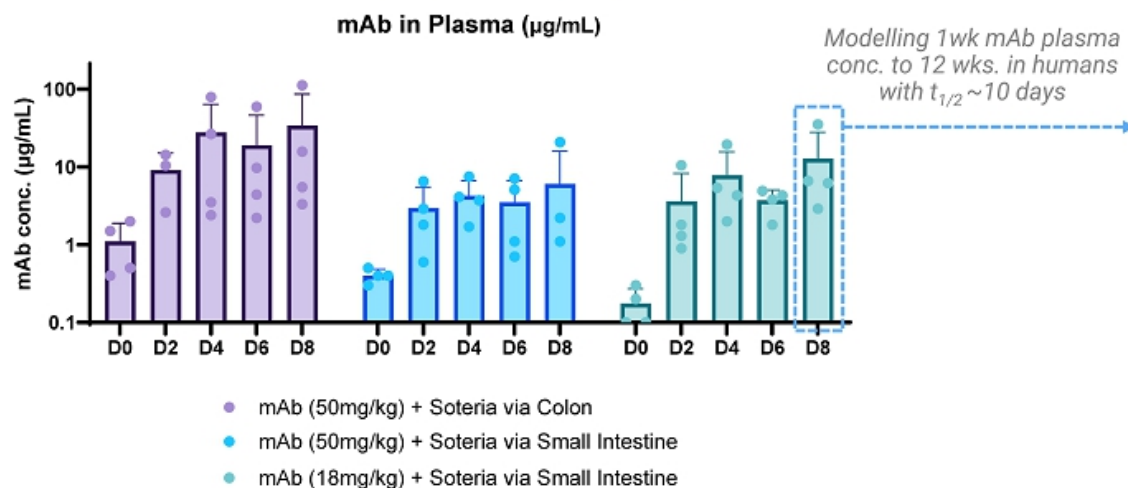
**Colon targeting** of mAb showed higher systemic conc. vs **small intestine delivery**, potentially due to better enzymatic stability and active transport receptor engagement

**No dose effect** observed between 50 and 18mg/kg, potentially due to intestinal epithelial transport saturation.

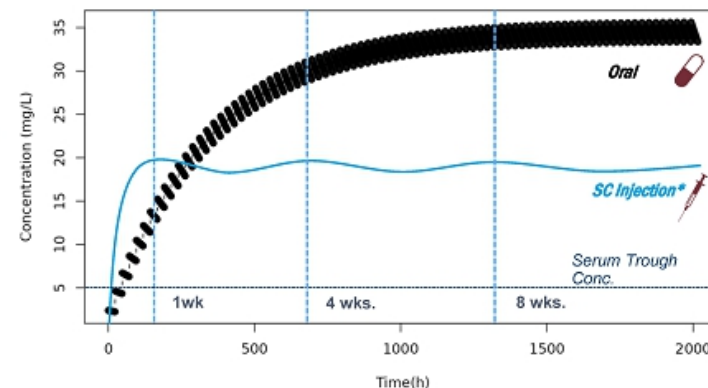
**QD dosing** of antibody enables build-up in plasma levels due to  $t_{1/2}$  of ~3-4 days in mouse.

# Soteria® Platform: Serum Conc. Can Exceed Injection Trough and Cmax with QD Dosing

PK Plot with Individual Mouse Data Points



The time course of concentrations



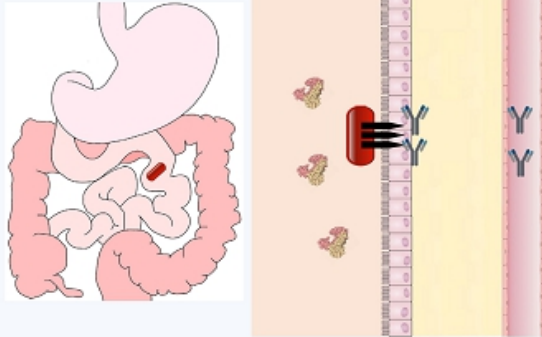
- All arms reached **> therapeutic serum trough concentration** for injectable mAbs in humans.
- When 1wk plasma conc. is modelled in humans with a  $t_{1/2}$  of 10days, the **mAb concentration surpasses Q2W 240mg SC injection PK profile.**

\*Schreiber et al., Gastroenterology, 2021; 160:2340-2353

# Intract Platform Compared to Other Technologies in Development

## Orally Ingestible Devices

Rani Therapeutics    BIORA Therapeutics    BIOGRAIL



≡ Drug Loaded Needles

- ❌ No enzyme protection if deployment fails
- ❌ CMC/COGS/Safety challenges
- ⚠️ Injection into tissue for systemic delivery hampered by deployment failures

## Oral Antibody Platform Technology

Intract Pharma  + THARIMMUNE





● Enzyme Stabilizer + Amino Acids

- ✅ Enzyme protection for high local tissue exposure
- ✅ CMC/COGS
- ✅ Modest permeation enhancement



# High Pharma Interest in Oral Therapies Against Traditional Injectable Biologics





**Target**                       **$\alpha4\beta7$  integrin**

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**Indication(s)**                      **IBD**

**Target**                      **IL-23**

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**Indication(s)**                      **IBD and Psoriasis**




**Target**                      **IL-17**

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**Indication(s)**                      **Psoriasis**







**Small Molecules**                      **\$2.4b Acquisition**





**Small Molecules**                      **\$3.2b Acquisition**

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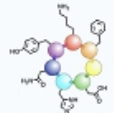




**Cyclic Peptide**                      **NASDAQ Listed**

**Small Molecule**                      **NASDAQ Listed**  
**Raised >\$450m**

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**Cyclic Peptide**                      **\$1b Licensing Deal**




**Small Molecules**                      **\$2.4b Acquisition**



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**Small Molecules**                      **C 4**  
**X D**  
**sanofi**

**\$0.5b Licensing Deal**

## A Transformative Combination Creates Best-in-Class Immunometabolic Company

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**Intract  
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Opportunity for higher returns with expanded clinical indications	<b>Strengthened regulatory, clinical, and drug development execution</b>	Cost-efficiencies through shared & operational resources
Increased opportunities for funding and strategic alliances for clinical stage assets	<b>Unlocks shareholder value through expanded pipeline and platform synergies</b>	Potential for delivery platform licensing and partnership opportunities