Sano Chemicals, Inc.

A therapeutics development company specializing in first-in-class drugs

Lead Product Aimed to Cure Recurrent Vulvovaginal Yeast Infections (RVVC)
US Market $4-5 Billion USD

Seeking Support for Phase 2 Clinical Trials ($15 M)

Occidiofungin The Fungus Killer™

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Executive Summary

Innovative Technology: First-in-class antifungal with fungicidal activity with applications for the treatment of oral, vaginal, dermal, and systemic fungal infections. First antifungal drug capable curing recurrent and drug resistant fungal infections.

Clinical Utility: Common route of application without the need of extensive education or training. Existing insurance reimbursement code available for vulvovaginal candidiasis (VVC) and recurrent vulvovaginal candidiasis (RVVC).

Favorable Economics: A short five-day application at the site of infection, compared to the only other FDA approved drug for the treatment of recurrent vulvovaginal candidiasis (RVVC) which belongs to existing fungistatic class of antifungal requiring a six-month oral administration.

Compelling Preclinical Validation: GLP genotoxicity/mutagenicity studies and GLP toxicokinetic animal studies demonstrate drug product safety and reduced side effects compared to current antifungal treatments.

Regulatory Clearance: IND application (IND 160729) approved to proceed with Phase 1 SAD and MAD clinical studies. In-house manufacturing capabilities of the drug product for clinical trials. QIDP and Fast Track designations.

Intellectual Property: Patents on composition and use, and manufacture of antifungal have been issued in USA, Europe, and Asia. Multiple pending applications. Patent protection for RVVC product till October 2035.

Strong Team: Experience in science, running companies, and creating growth drivers for strategic partners.

An Urgent Unmet Need

Up to 9% of Women suffer from an untreatable Recurrent Vulvovaginal Candidiasis (RVVC) infection.

This is an annual patient population size of ~9M women in the US and >130M women Globally suffering without an effective treatment.

THE PROBLEM

Yeast Infections have become resistant to the current standard of care.

Existing treatments are only suppressive.

Women have had no new treatment alternatives in over 20 years.

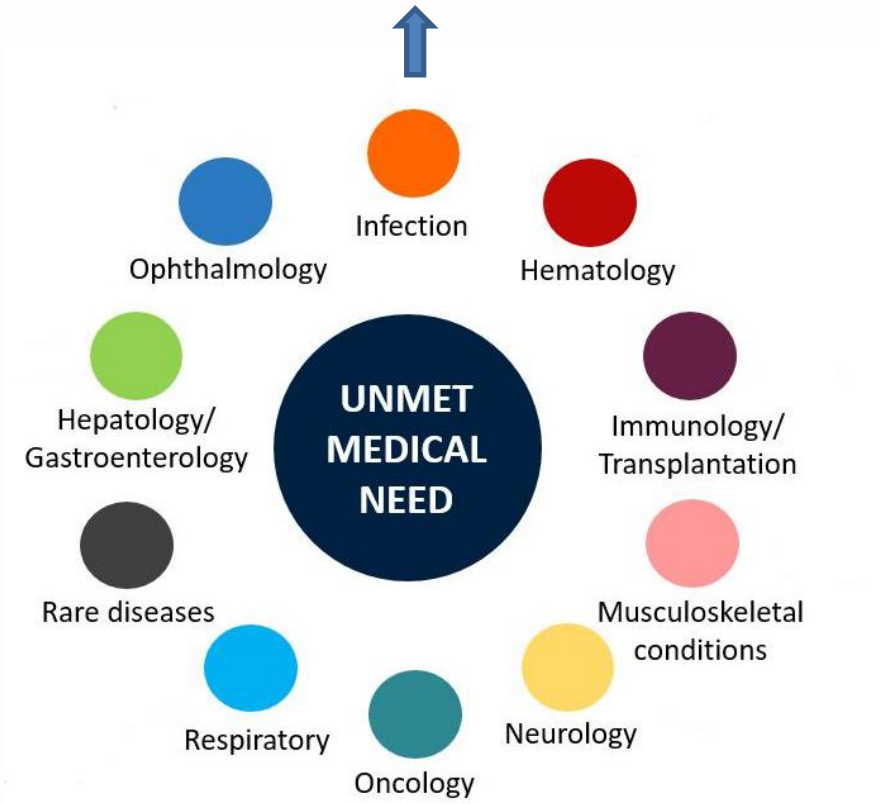
Antifungal resistance has increased dramatically and is projected to get worse.

Symptoms of Recurrent Vulvovaginal Candidiasis (RVVC) a Serious Fungal Infection

IMPACTS ON QUALITY OF LIFE:

- Discomfort and Pain
- Higher rates of clinical depression
- Anxiety and stress
- Missed work
- Avoid sexual intimacy
- Uncomfortable during all activities

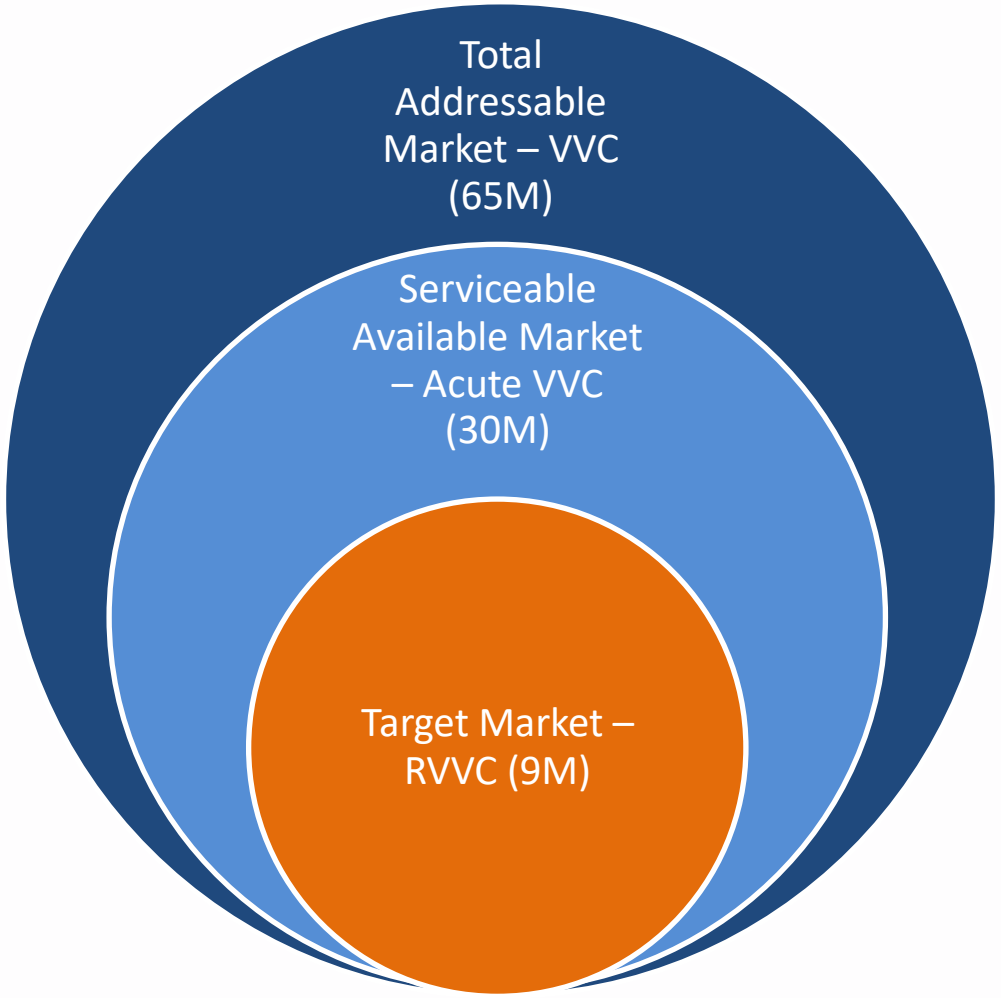
Recurrent Vulvovaginal Candidiasis (RVVC)



VVC – RVVC Treatment Continuum

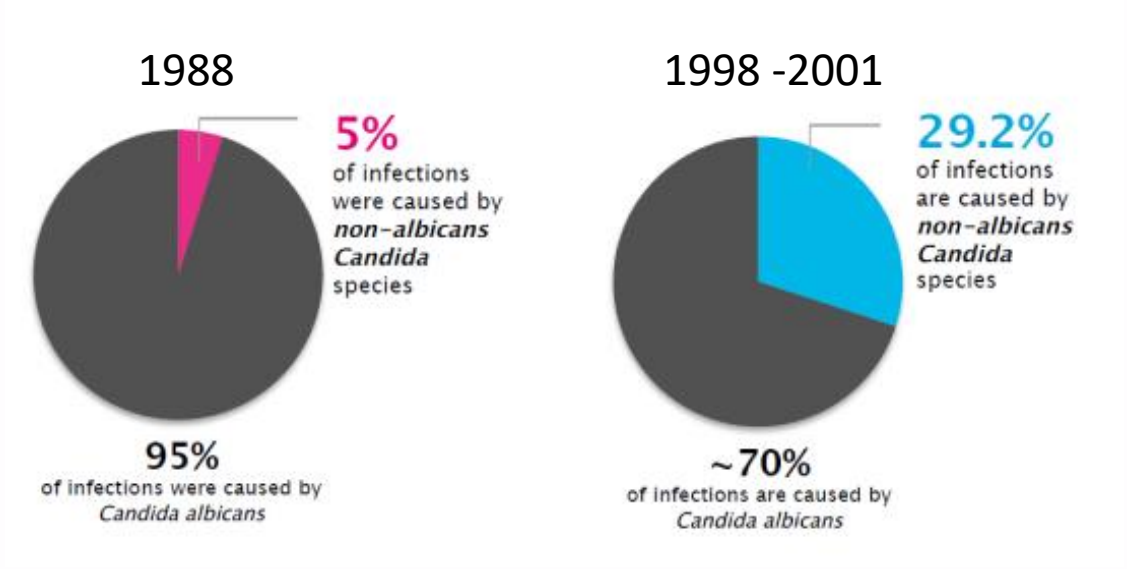
Standard Course of Treatment:

- **Common** Yeast Infections (TAM)
  - Treat with over-the-counter products
  - 40-45% of women annually (~65M in US)
- **Acute** Yeast Infections (SAM)
  - Approximately 50% all infections are acute
  - Fluconazole, Clotrimazole (less and less effective)
- **Recurrent** Yeast Infections (TM)
  - ~15% of all incidents are RVVC **(~9M US)**
  - **Unmet Medical Need Market Estimated at $4 to 5 Billion**



Dramatic Increase in RVVC

Rise of *non-albicans* infections



- Prior to introduction of triazole antifungals, 5% of infections were caused by non-albicans species.
- Following introduction of triazoles in 1988, non-albicans species accounted for 30% of vaginal yeast infections in vaginal isolates collected between 1998 to 2001.

- Management of fluconazole refractory disease is extremely difficult with limited options, and new therapeutic modalities are needed.
- Non-albicans species are less susceptible to all azole drugs
- Many are resistant to commonly prescribed antifungal agents, make treatment more challenging.
- Fluconazole doses have nearly doubled since 2005.
- 60% of patients require higher initial doses to treat infection.
- The dosing trend may be another indicator of growing resistance.

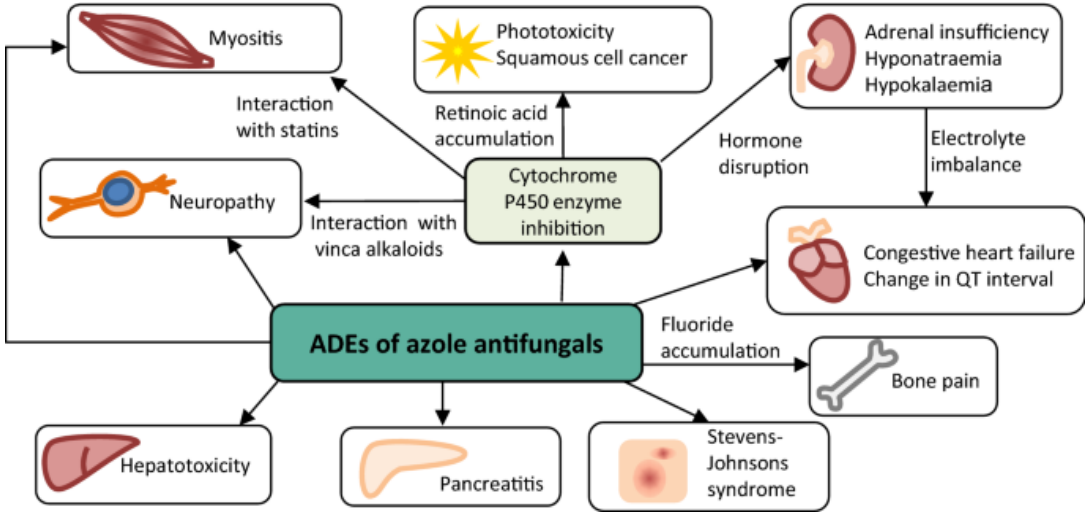
Marchaim D, et al. Fluconazole-resistant Candida albicans vulvovaginitis. Obstet Gynecol. 2012;120(6):1407-1414

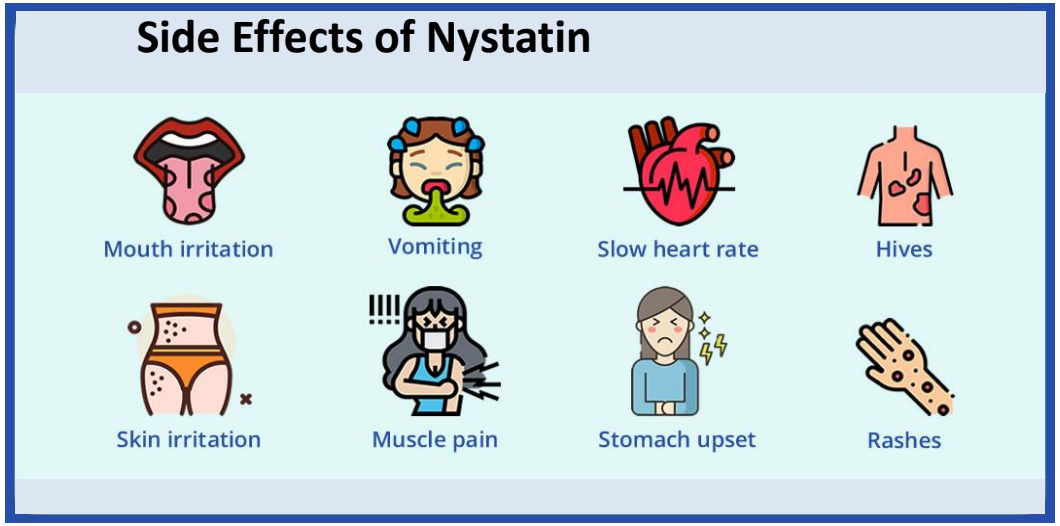
Richter SS, et al. Antifungal susceptibilities of Candida species causing vulvovaginitis and epidemiology of recurrent cases. J Clin Microbiol. 2005;43(5):2155-2162

Current Treatment Concerns

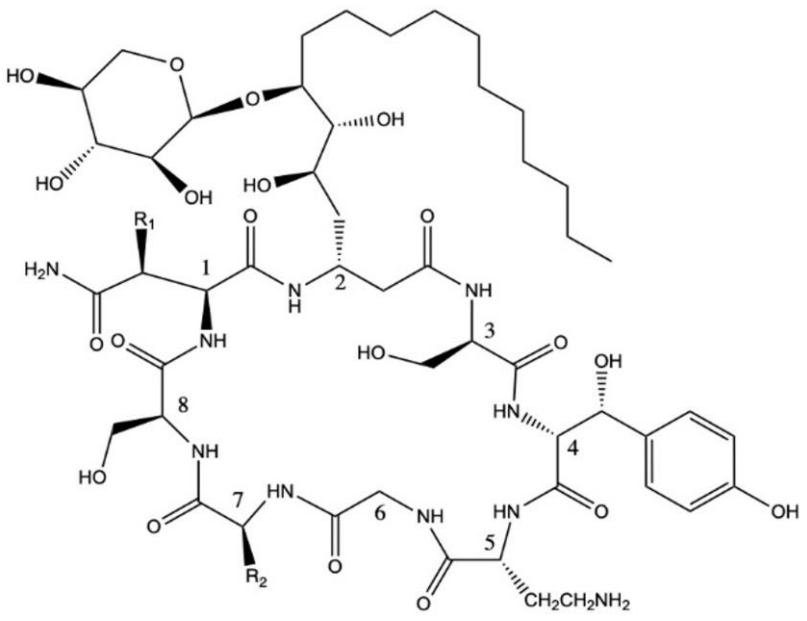
Chronic yeast infections (RVVC) are treated with existing products that are:

- Over prescribed;
- Becoming less and less effective;
- 6 months of longer treatment regimen
- Interfering with birth control;
- Interfering with other medical prescriptions;
- Causing unwanted side effects reducing patient compliance;
- Contributing to serious side effects (**kidney & liver toxicity**).





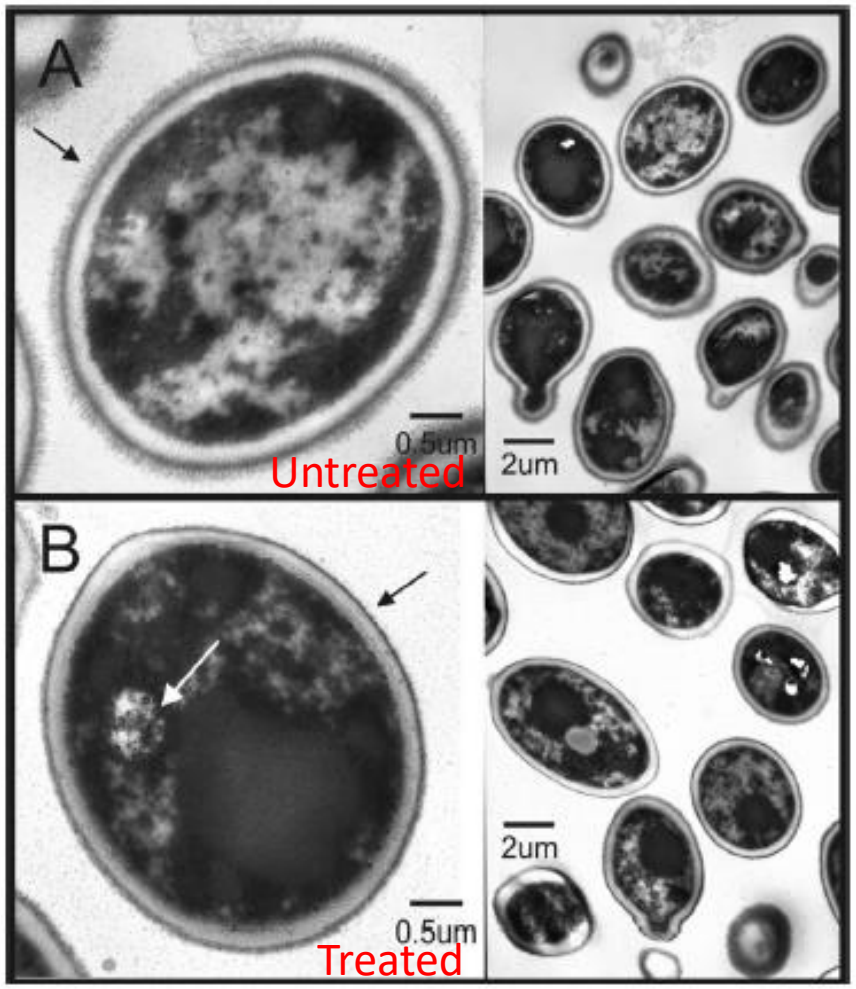
Discovery and Development of *Occidiofungin* (OCF)



Occidiofungin

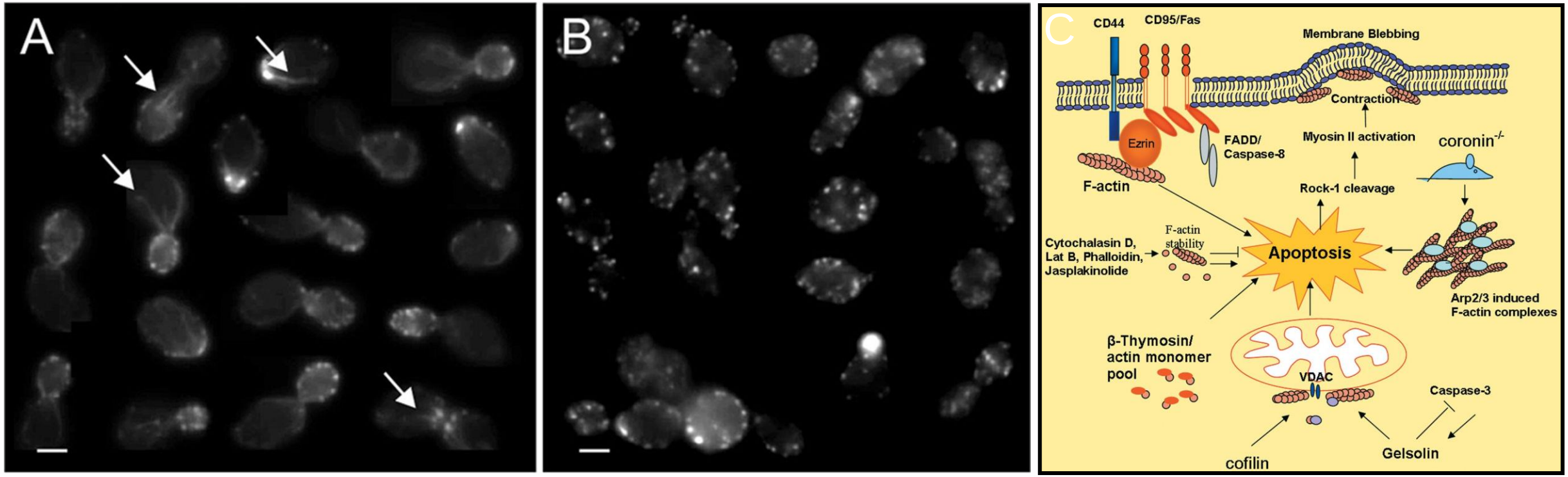
- We developed the antifungal compound, a glycolipopeptide named occidiofungin, for further evaluation
- Our scientific team engineered the production of the potent antifungal agent.
- This lead agent is a potent first-in-class antifungal therapeutic.
- Additional analogs are being engineered for systemic applications

Occidiofungin (OCF)



- A **first-in-class** composition **broadly effective** against the fungal kingdom
- **Potent** antifungal (fungicidal) activity
  - Demonstrates submicromolar inhibitory activity
- **Novel mechanism of action**
  - Even at subinhibitory concentrations, it blocks fungal pathogenesis
- **Rapidly Fungicidal against drug resistant yeasts**

Mechanism of Action:
Actin Visualization Using Phalloidin-TRITC



(Franklin-Tong, 2008)

OCF disrupts higher order actin cables

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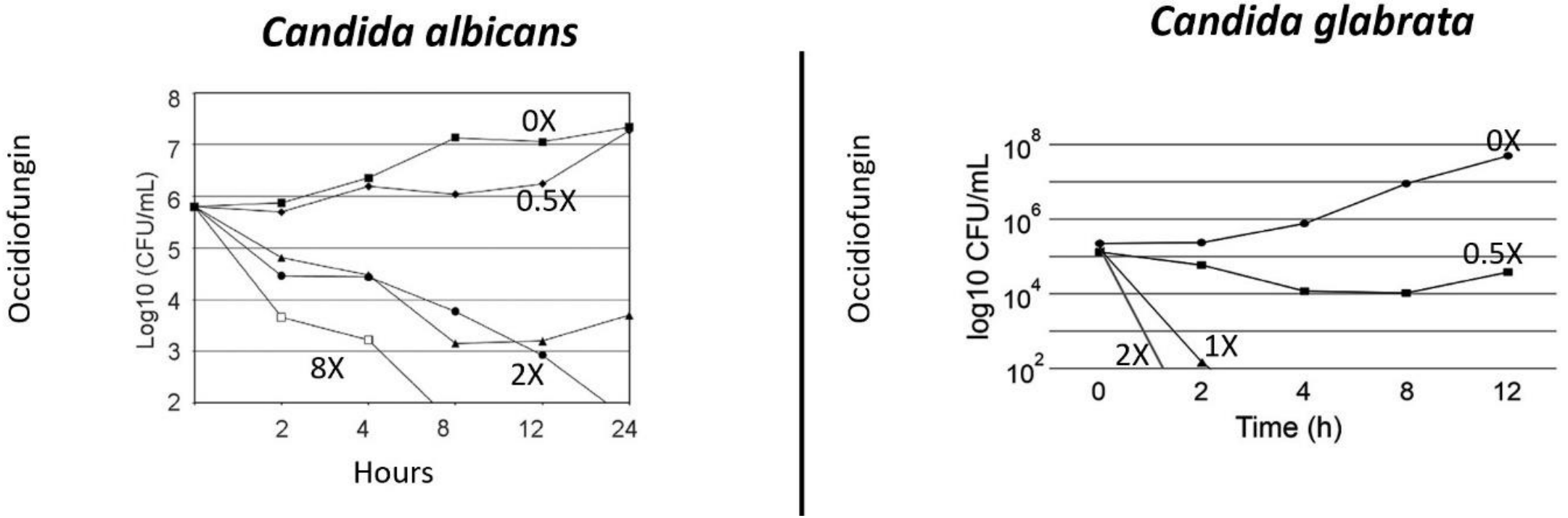
OCF001 – Gel Formulation



- Occidiofungin is rapidly fungicidal compared to other antifungals.
- Occidiofungin is fungicidal against albicans and non-albicans species
- Limited exposure has prolonged fungicidal activity.

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OCF001 – For Treatment of RVVC

Problem

- Yeast Infections have become **resistant to the current standard of care**.
- **Existing treatments are only suppressive**.
- Until recently, there have been no new therapies with a new mechanism of action to treat these infections in over 20 years.

OCF001 Gel Solution

- Potent fungicidal activity against all Candida spp.
- No Concurrent Therapies Needed
- 3 or 5-day intravaginal application
- No discernable absorption from vaginal cavity
- Preclinical toxicokinetic studies show drug product safety
- RVVC (Target Approval – 2026/27)

Only three to five applications

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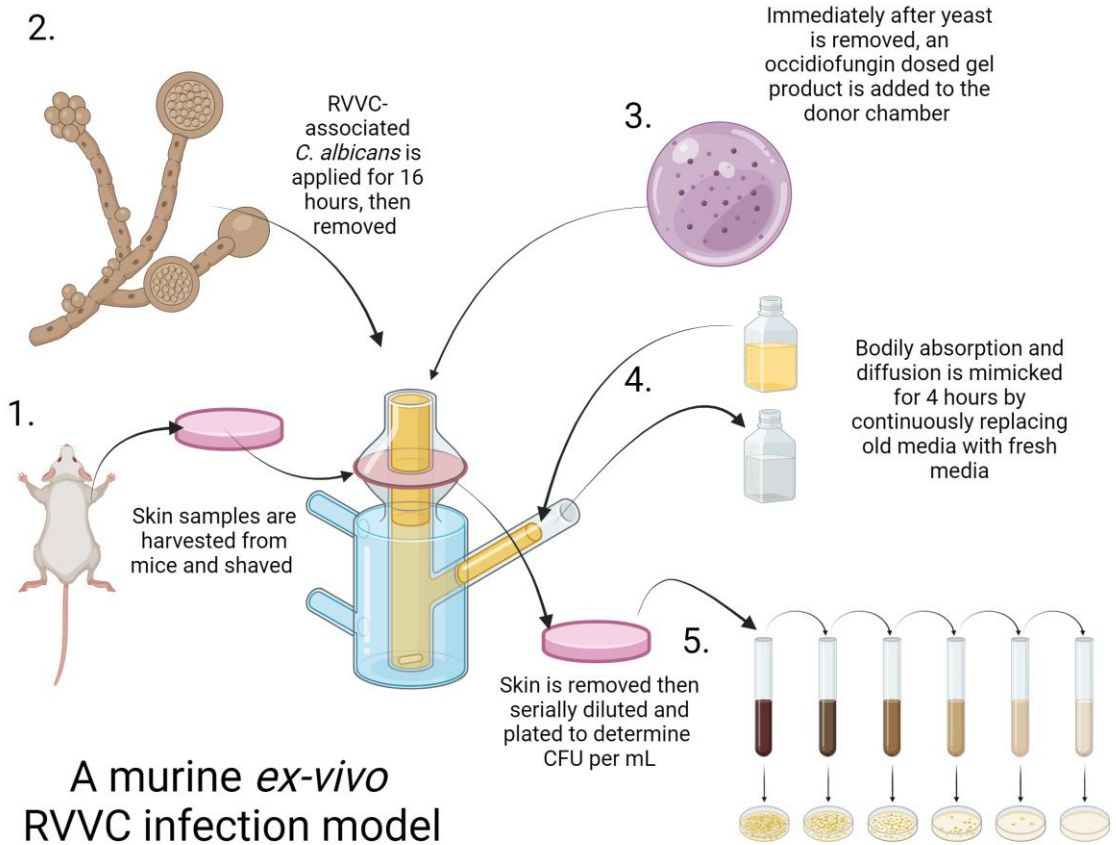
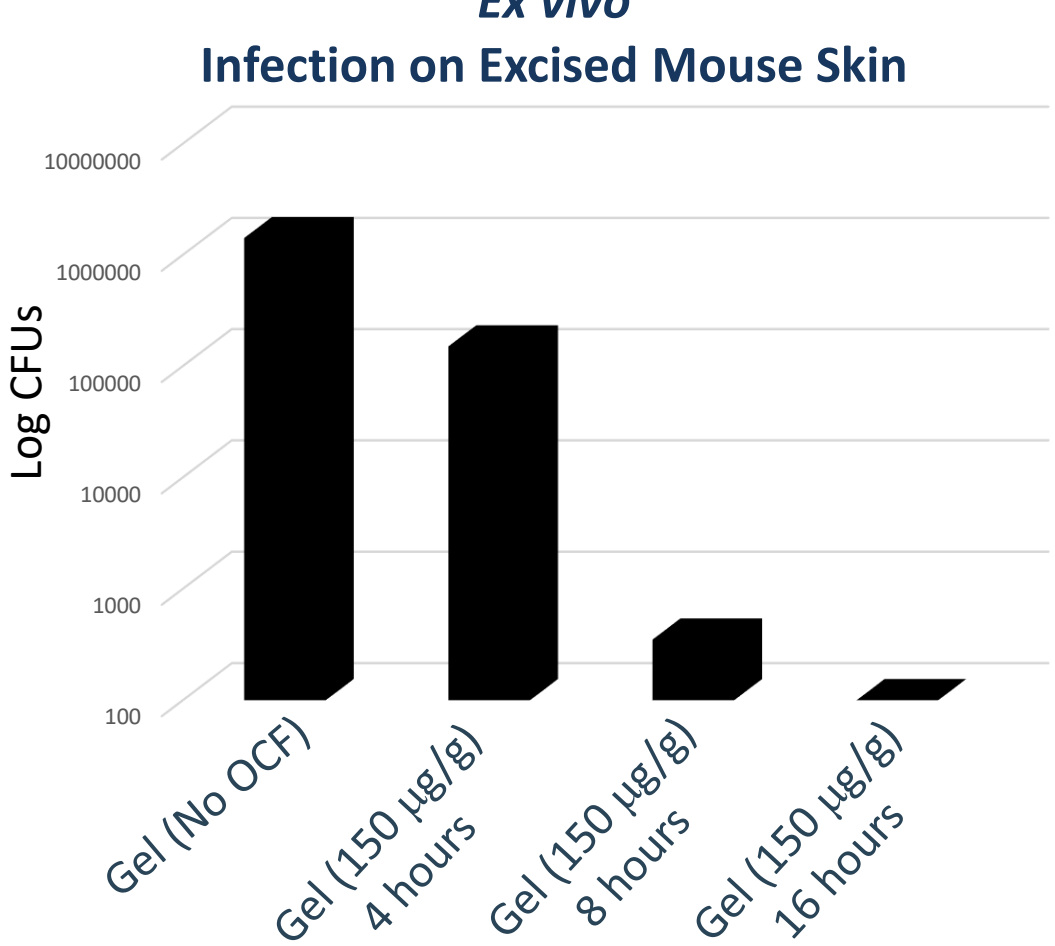
OCF001 – Gel Formulation



A murine *ex-vivo* RVVC infection model using Franz cells



Recent Activity in the Antifungal Space

Company	CIDARA THERAPEUTICS	amplyx	SCYNEXIS	mycovia Pharmaceuticals	F2G
Molecule (class)	Rezzafungin (echinocandin)	Fosmanogepix (GWt1 inhibitor)	Ibrexafungerp (triterpenoid)	Otesaconazole (azole)	Olorofim (orotmide)
Lead indication	Rescue therapy for invasive candidiasis and candidemia *IV Formulation*	In Phase 2 studies for invasive candidiasis (including C. auris), invasive aspergillosis and rare molds in patients with limited treatment options, cryptococcal meningitis *IV and Oral Formulations*	VVC; RVVC *Oral Formulation*	RVVC in non-childbearing *Oral Formulation*	Invasive aspergillosis *Oral Formulation*
Funding to date	• $175M	• $198M	• $250M	• Unknown	• $283M
Partnerships	• Melinta (US)* • Mundipharma (EU)	• Acquired phase 2 (Pfizer)	• IPO (Phase 1); • GSK Partnership (commercial)**		• Shionogi***

* $460M Melinta deal: Melinta paid $30M upfront and $20M upon FDA approval; add $410M milestones; tiered royalties 10-15% on sales
** $590M GSK deal: $90M upfront + $510 in milestone payments; 5-15% tiered royalties on sales
*** $480M Shionogi deal: $100M upfront + $380M milestone payments; double digit royalties on sales

Source: company websites and financial statements

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DEVELOPMENT OF AN RVVC DRUG PRODUCT

Manufacturing of OCF (API)

- Established manufacturing process to support Phase 1-3 clinical trials
- Scalable manufacturing process
- Over 10 Lots of API produced demonstrating consistency in drug substance composition and purity
- Inhouse control of intellectual property developments in manufacturing
- No additional costs in delays in manufacturing

Established Chemistry Manufacturing and Controls (CMC)

- Upstream drug substance (API) processing
- Downstream drug substance (API) processing
- Intravaginal Gel Product Manufacture

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DEVELOPMENT OF AN RVVC DRUG PRODUCT

Preclinical Toxicity Studies

- GLP Bacterial Reverse Mutation Assay
- GLP *In vitro* Mammalian
- Mammalian Bone Marrow Erythrocyte Micronucleus Test

Preclinical Small / Large Animal Studies

- Repeat intravaginal high dose study in mice.
- GLP repeat intravaginal high dose study in rabbits
- GLP Toxicokinetic study in rabbits

U.S Food and Drug Administration

IND application (IND 160729) Approved

- FDA Approved INDA Phase 1
- **Qualified Infectious Disease Product (QIDP)**
- **Fast-Track**

PHASE 1 CLINICAL TRIALS BEGIN IN JANUARY 2024

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Why OCF Strategy is More Cost Efficient

Why Strategy Matters

- Topical / Mucosal Strategy – cost efficient and higher patient compliance
  - Oral administration requires long duration of treatment and increases likelihood of:

    (1) toxicity,

    (2) adverse reactions, and

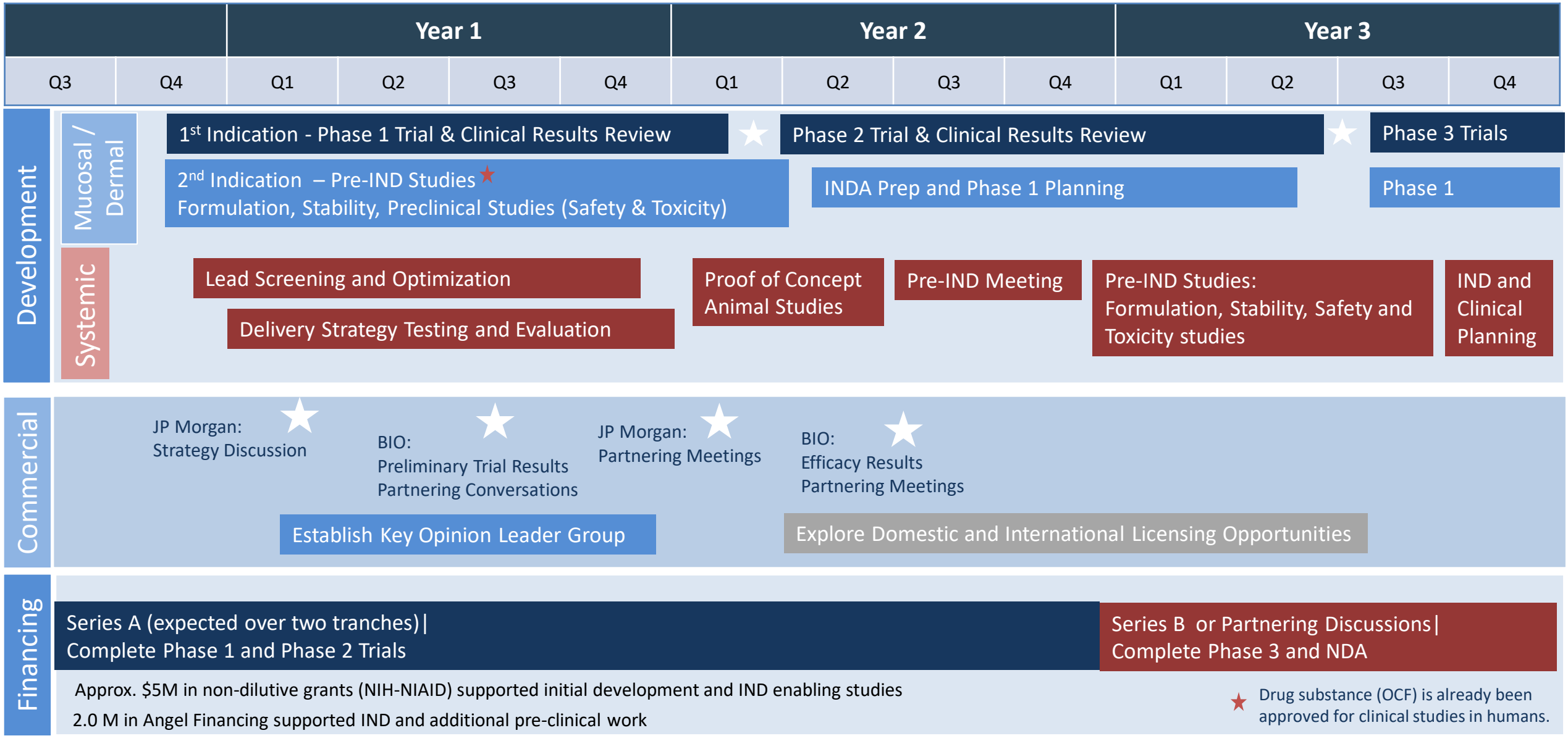
    (3) Increase in clinical resistant strains
- Clinical Strategy – well understood clinical approach
  - does not require prolonged administration and management
- Treatment Strategy – Selectively kills yeast; does not kill bacteria known to maintain healthy flora
  - Other strategies suppress and rely on the patient immune system to clear the infection

Treat Site of Infection

Shorter Treatment Duration

Better Patient Compliance

Development Timeline



Summary of Opportunity

The Problem:

There is a growing and unmet demand for novel therapeutics directed at drug-resistant pathogens

Billions are spent annually on fungal infection treatments
Increase in resistance is a major contributor to these costs

Our Solutions

Sano Chemicals is developing first-in-class assets to meet the demand for new, effective antifungal drug products (dermal, oral, intravaginal, and systemic applications).

Based on market deals, RVVC licensing agreements occur in or at the end of Phase 2 studies. We are **seeking a partnership** to support efforts to achieve a successful exit for the RVVC lead product.

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Our Team

Janice Miles, D.O.
Co-Chief Executive Officer
Women's Health
Prior Experience Including:

- Clinical Experience
- Board of the Mississippi Gulf Coast Women's Medical Association
- Board of Contexta Manufacturing

James L. Smith, PhD, MBA
Co-founder
Co-Chief Executive Officer
Anti-infective Development
Prior Experience Including:

- Product Leader at Oragenics Inc.
- VP of Ivigene Inc.
- Founder of Biotech Analyst Group
- Executive Director of Able Trust Foundation

Frank Austin, DVM, PhD
Co-founder
Mycology and Infectious Disease

Shien Lu, PhD
Co-founder
Microbiology and Bioengineer

Steve Pruett, PhD
Co-founder
Immunotoxicologist

Steve Unger, PhD
Advisor, GMP and QC

Tim Hiebert, MD, DVM
Advisor, Investor

Jeff Libson, JD
Legal Advisor, Cooley, LLP

George Atiee, MD
Chief Medical Officer
Prior Experience Including:

- Senior Director, Associate Medical Director at ICON
- VP and Medical Director, Worldwide Clinical Trials

David Goodstein, MBA
Chief Financial Officer
Experience Including:

- Services 9 companies, operational controllership of IT budget of $80M and R&D budget of $300M
- Forecast accuracy within 2%

George Hlass, MBA Business Development Advisor

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James Smith, PhD, MBA
CEO – **Drug Development**
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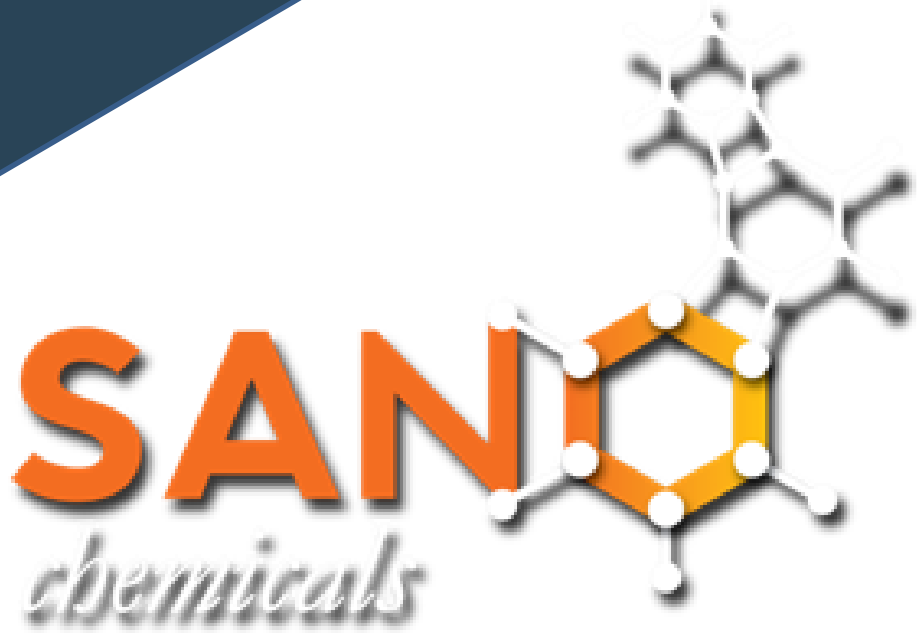
SUPPLEMENTAL INFORMATION



Existing Relationships

ICON

MISSISSIPPI STATE UNIVERSITY
DEPARTMENT OF
BIOLOGICAL SCIENCES

DPT
a Mylan company

MISSISSIPPI STATE UNIVERSITY
COLLEGE OF VETERINARY MEDICINE

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

VIRGINIA TECH

Larta
Institute
IDEAS, ENERGIZED

THE
UNIVERSITY
OF UTAH®

NIH
National Institute of
Allergy and
Infectious Diseases

TEXAS A&M
UNIVERSITY

TEXGHS
Texas Global Health Security
Innovation Consortium