Sano Chemicals, Inc.

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

Lead Product Addressing Recurrent Vulvovaginal Candidiasis (RVVC & VVC)
US Market $4-5 Billion USD

Seeking Strategic Partner or Out-licensing

Executive Summary

Innovative Technology: Occidiofungin (OCF) is a potent first in class true fungicidal drug with applications for the treatment of vaginal, oral/GI, dermal, and systemic fungal infections. OCF is pan-fungicidal and capable of curing recurrent and drug resistant fungal infections. Our lead application is aimed at RVVC.

Clinical Utility: Common route of application at the site of infection without the need of extensive education or training. OCF does not need co-administration with any other drugs.

Favorable Economics: Experienced scientists working at in house research and manufacturing labs drug product for clinical testing resulting in no delays of clinical trials. Existing insurance reimbursement code is available for VVC and RVVC.

Compelling Preclinical Validation: GLP genotoxicity/mutagenicity studies and GLP toxicokinetic animal studies demonstrate drug product safety compared to current antifungal treatments. There is no discernable systemic adsorption of OCF following intravaginal application. **FDA QIDP and Fast Track designations awarded by meeting an unmet medical need.**

Clinical Candidate: IND application (IND 160729) is approved to proceed with Phase 1 human SAD and MAD clinical trials. SAD Dosing was completed in May 2024. Clinical data demonstrated patients were no discomfort or comfortable according on 5-point Likert scale, and all scored the treatment as entirely acceptable. No discomfort or adverse effects were noted.

Intellectual Property: Patents on composition and use, and manufacture of antifungal have been issued in USA, Europe, and Asia. There are multiple pending applications. Patent protection for RVVC product till October 2035. Follow-on formulations for 2nd generation products are under evaluation for IP extension towards systemic, dermal, and oral/GI applications.

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 and fungistatic.

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

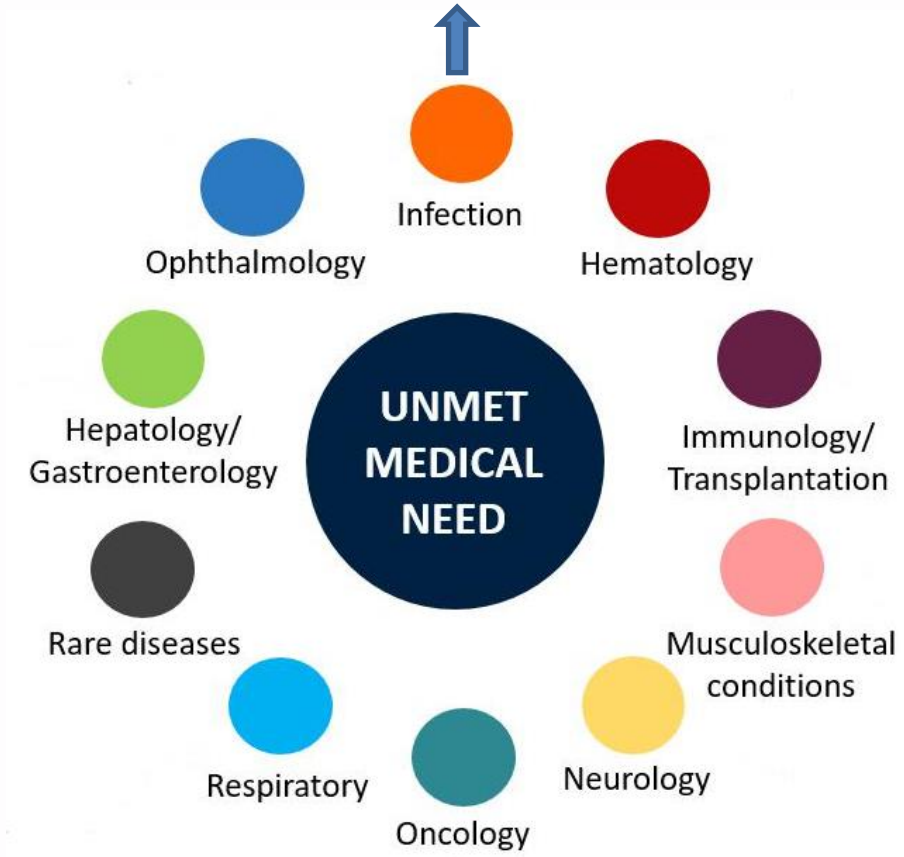
Antifungal resistance has increased dramatically and is projected to get worse.

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
- Avoidance sexual intimacy
- Uncomfortable during all activities

Recurrent Vulvovaginal Candidiasis (RVVC)



VVC – RVVC Treatment Continuum

Standard Course of Treatment:

Common Yeast Infections (TAM)

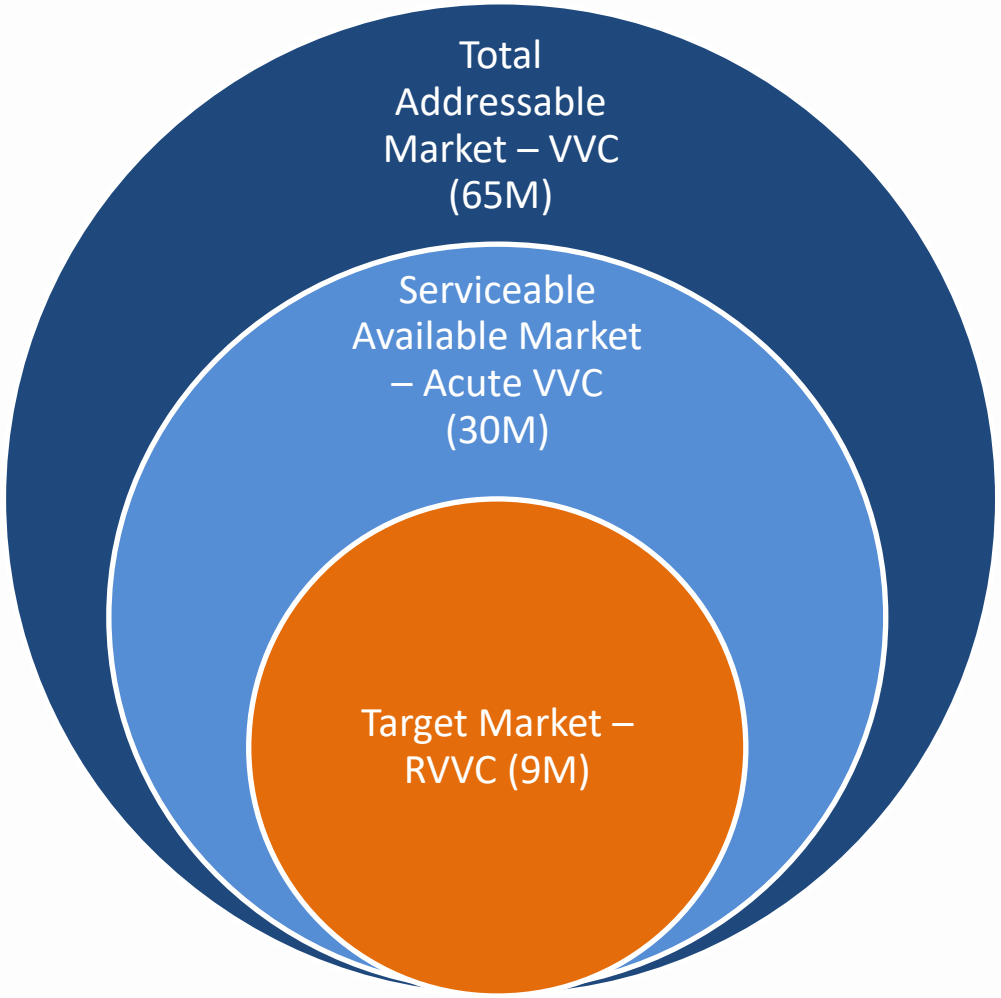
- Treat with over-the-counter products
- 40-45% of women annually (~65M in US)

Acute Yeast Infections (SAM)

- Approximately 50% all infections are acute
- Fluconazole, Clotrimazole (less and less effective)

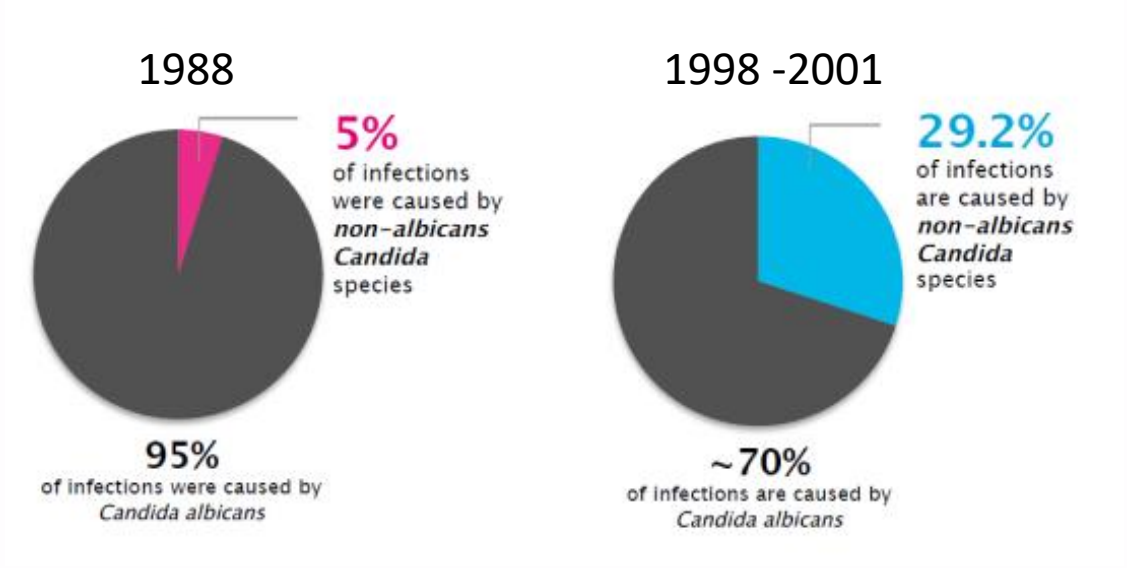
Recurrent Yeast Infections (TM)

- ~15% of all incidents are RVVC **(~9M US)**
- **Unmet Medical Need - Market in US Estimated at $4 to 5 Billion**



Dramatic Increase in RVVC

Rise of *non-albicans* infections



- Prior to introduction of triazole antifungals, only 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 making treatment more challenging.
- Fluconazole doses have nearly doubled since 2005.
- 60% of patients require higher initial doses to treat infection causing more adverse side effects.
- The dosing trend may be another indicator of increasing resistance.

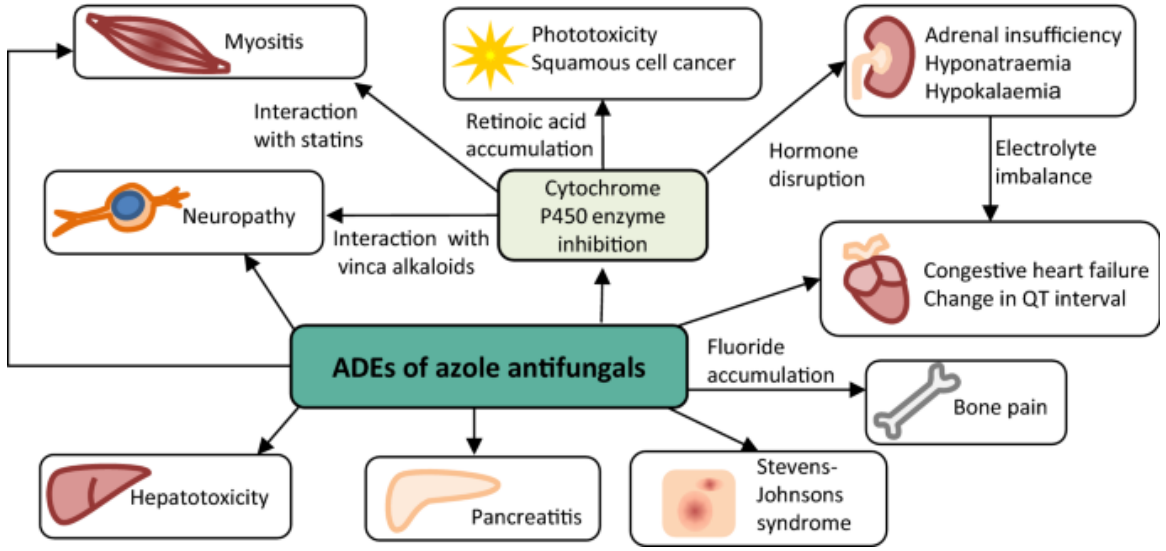
Marchaim D, et al. Fluconazole-resistant Candida albicans vulvovaginitis. Obstet Gynecol. 2012;120(6):1407-1414

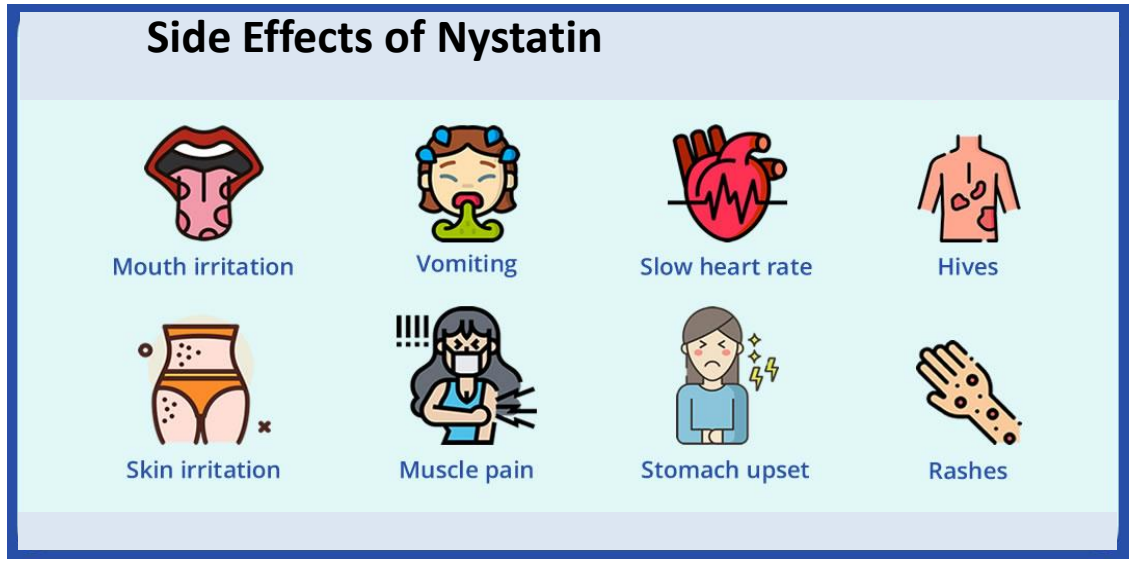
Richter SS, et al. Antifungal susceptibilities of Candida species causing vulvovaginitis and epidemiology of recurrent cases. J Clin Microbiol. 2005;43(5):2155-2162

Current Treatment Concerns

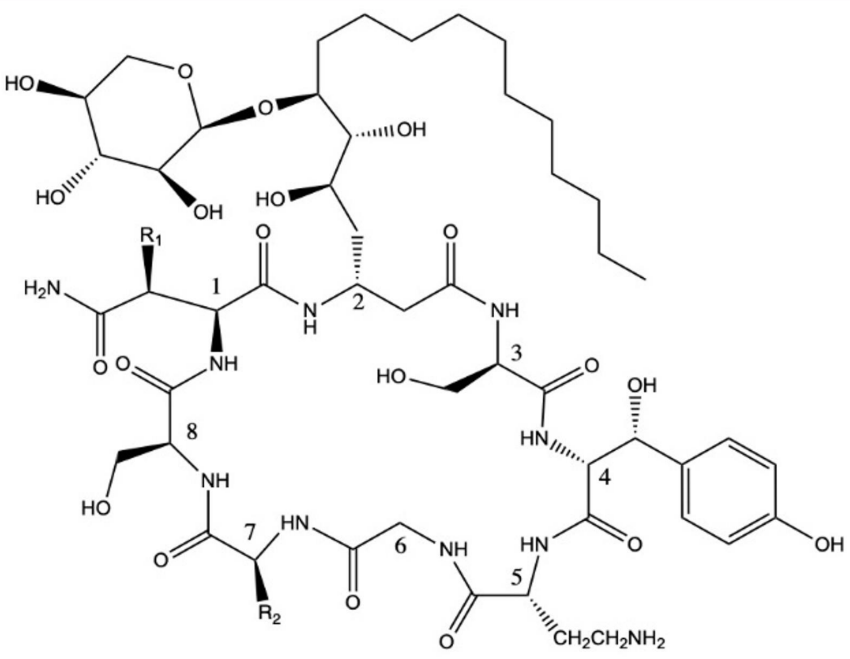
Chronic yeast infections (RVVC) are treated with existing products that are:

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





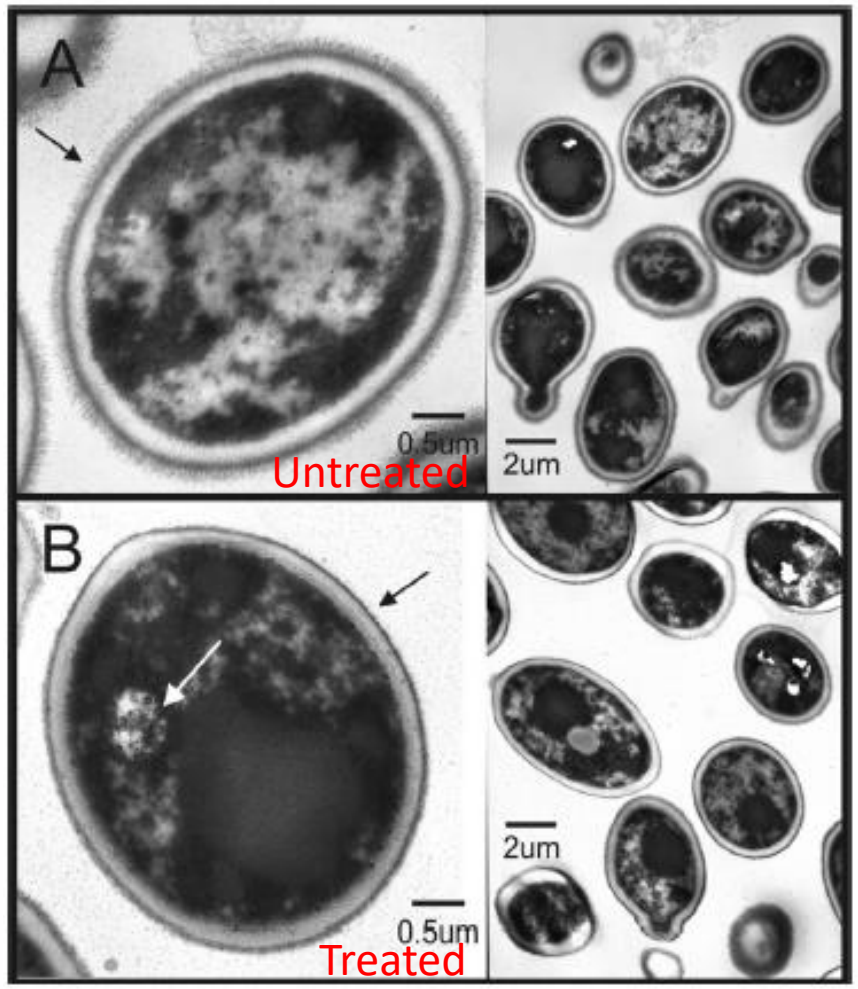
Discovery and Development of *Occidiofungin* (OCF)



Occidiofungin
Cyclic
Glycolipopeptide

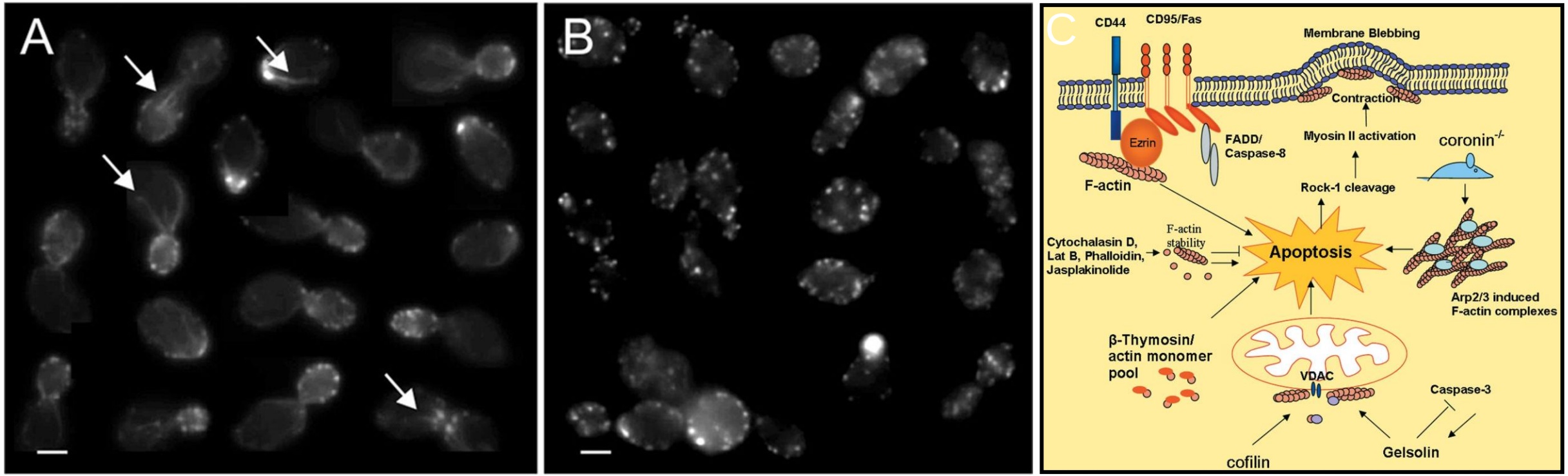
- Our scientific team discovered, characterized, developed, formulated and named Occidiofungin (The Fungus Killer ™).
- OCF has sub-micromolar to low micromolar pan-fungicidal activity originating as a natural bacterial product.
- Our lead agent, OCF is extremely stable and rapidly induces fungal apoptosis. The target ligand (actin), OCF molecular composition, mechanism of action and rapid effect prevents fungal development of resistance.
- Additional analogs are being engineered and formulated for dermal, oral/GI and systemic applications.

Occidiofungin (OCF)



- **First-in-class** composition **broadly effective** against the fungal kingdom
- **Potent** antifungal (fungicidal) activity
  - Demonstrates submicromolar cidal activity
  - All other antifungals in clinic are static except for amphotericin-B (Extreme Toxicity)
- **Novel mechanism of action is Apoptosis**
  - Even at sub-fungicidal concentrations, it blocks fungal pathogenesis by preventing mucosal adherence and pseudohyphal formation
- **Rapidly Fungicidal against drug resistant yeasts such as *Candida auris***

Mechanism of Action:
Actin Visualization Using Phalloidin-TRITC



OCF disrupts higher order actin cables and stimulates mitochondrial oxidative burst triggering apoptosis

(Franklin-Tong, 2008)

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Broad Spectrum of Activity

Strain	Occidiofungin (µg/ml)	Voriconazole (µg/ml)	Fluconazole (µg/ml)
Rhizopus spp. *Mucor spp.* *Fusarium spp.*	4-8	16 ->16	-
Aspergillus spp.	2-4	1-2	-
**Candida albicans* **Candida krusei* **Candida tropicalis*	1-4	-	16 -> 64
#Candida auris 35646 *#Candida auris 35651*	1-2	-	-
#Cryptococcus neoformans	1-2	-	2-4

Other susceptible fungi:

- *Alternaria alternata*
- *Aspergillus fumigatus*
- *Geotrichum candidum*
- *Microsporum gypseum*
- *Microsporum canis*
- *Penicillium spp.*
- *Pythium insidiosum*
- *Trichophyton mentagrophytes*
- *Candida glabrata*
- *Candida paratropicalis*
- Dimorphic fungi (4) – not published

MIC data:
* - Azole resistant
# - Caspofungin resistant

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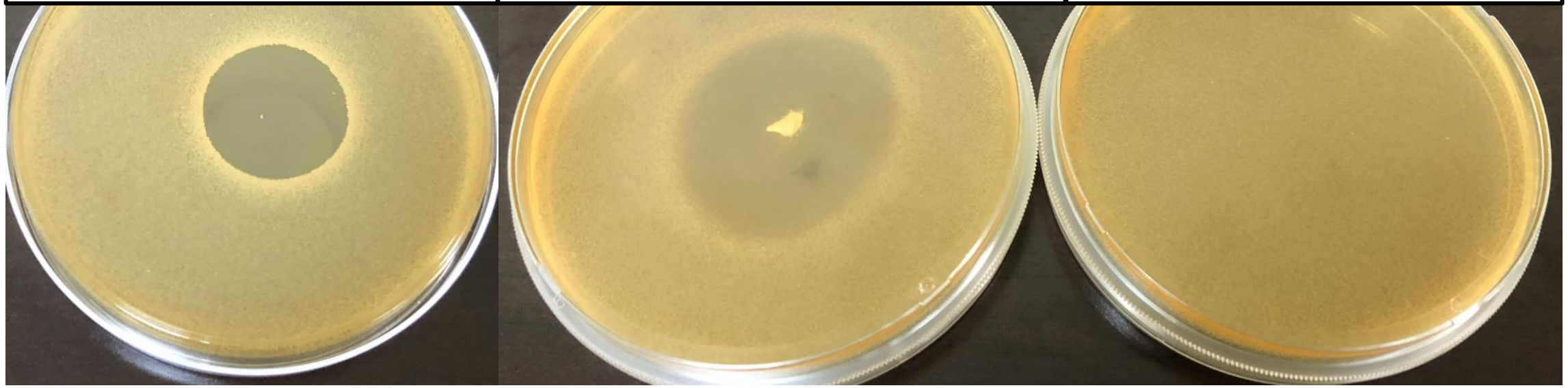
Fungicidal Activity of Occidiofungin Compared to Miconazole (Monistat3)

100 µg of OCF in 20 µL	800 µg of miconazole in 20 µL Monistat3	0 µg of OCF in 20 µL



Clear Zone of Fungicidal Activity

Hazy Zone of inhibition Fungistatic Activity

8X concentration over OCF

No Activity

OCF001 – For Treatment of RVVC

The Problem:

- Yeast Infections have become **resistant to the current standard of care**.
- **Existing treatments are only suppressive and fungistatic**.
- 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 – 2028 | Target End of Phase 2 – 2026 – explore out-license/sell) – Fast Track

Only three to five applications

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Recent Activity in the Antifungal Space

Company	CIDARA THERAPEUTICS	Pfizer	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* Failed RVVC Phase 2 trial	In Phase 2 studies for invasive fungal infections *IV and Oral Formulations* Not for RVVC	VVC; RVVC *Oral Formulation* Notable side effects	RVVC in non-childbearing *Oral Formulation* Notable side effects	Invasive aspergillosis *Oral Formulation* Not effective against yeast
Announced Deals	• $460M*	• $543M**	• $593M***	• Unknown	• $480M
Partnerships	• Melinta (US)* • Mundipharma (EU) • July 27, 2022	• Acquired phase 2 Basilea • Nov 13, 2023	• GSK Partnership*** • Commercial • March 30, 2023		• Shionogi**** • May 2022

- $460M Melinta deal: Melinta paid $30M upfront and $20M upon FDA approval; add $410M milestones; tiered royalties 10-15% on sales

** $543M = $37M Upfront and $110 milestones to Pfizer + $396M in previous milestone obligations

*** $590M GSK deal: $90M upfront + $503 in milestone payments; 5-15% tiered royalties on sales

**** $480M Shionogi deal: $100M upfront + $380M milestone payments; double digit royalties on sales – Deal to market the drug in Asia and Europe

Source: company websites and financial statements

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DEVELOPMENT OF AN RVVC DRUG PRODUCT AND FORMULATION

Manufacturing of OCF (API) in House

- 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 of manufacturing

Established Chemistry Manufacturing and Controls (CMC) in House

- 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 - Completed

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

Preclinical Small / Large Animal Studies - Completed

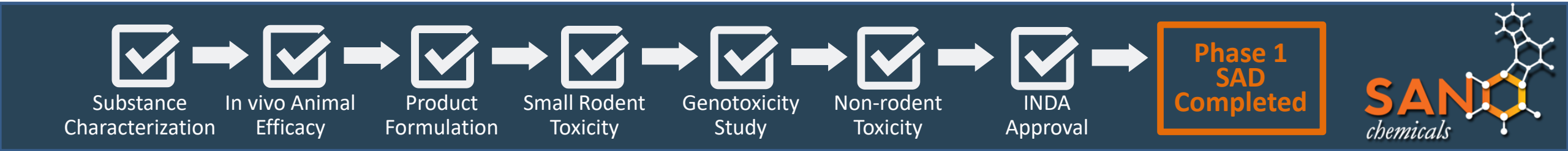
- Repeat intravaginal high dose study in mice.
- GLP repeat intravaginal high dose study in rabbits
- GLP Toxicokinetic study in rabbits

U.S Food and Drug Administration

IND application (IND 160729) Approved

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

PHASE 1 SAD CLINICAL TRIALS Completed in 2024



Clinical Trial Updates and Targets

Phase 1 SAD

3 Cohorts: (0.075 mg of OCF/gram of gel), (0.150 mg of OCF/gram of gel), & (0.300 mg of OCF/gram of gel)

- 24 patients - 6 subjects and 2 placebo per cohort

J&S Studies, College Station Texas:

- Has conducted over 400 clinical trials since 1985

Results:

- Patients ages 19-45 years had no clinically significant changes in vitals, gynecological exams, ECGs, and blood and urine samples
- All patients found treatment to be acceptable
- All patients found treatment to have no discomfort or comfortable outcomes
- One adverse event in cohort 1 reported – menstrual cramps unrelated to trial participation

5-Point Likert Scale

Current Level of Vaginal Discomfort				
1	2	3	4	5
Very Uncomfortable	Moderately Uncomfortable	Slightly Uncomfortable	No Discomfort	Comfortable

Overall Level of acceptability				
1	2	3	4	5
Totally unacceptable	Slightly unacceptable	Neutral	Slightly acceptable	Acceptable

Cohorts 1, 2, & 3 Likert Scale (1-5)	**Range of Likert Scores One hour After Dose**	**Range of Likert Scores One Day After Dose**
Cohort 1 (8 Subjects)		
Current Level of Vaginal Discomfort	4 to 5	4 to 5
Overall Level of Acceptability	5 to 5	5 to 5
Cohort 2 (8 Subjects)		
Current Level of Vaginal Discomfort	4 to 5	4 to 5
Overall Level of Acceptability	5 to 5	5 to 5
Cohort 3 (8 Subjects)		
Current Level of Vaginal Discomfort	4 to 5	4 to 5
Overall Level of Acceptability	5 to 5	4 to 5

- No statistical significance between subjects receiving placebo or drug.

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Clinical Trial Updates and Targets

Phase 1 MAD

2 Cohorts: low & moderate

- 24 Patients – 9 subjects and 3 placebo per cohort
- 7 Day Repeat Dose

Target: Phase 1 MAD Clinical Trial Completion By Q3 of 2025

Target: Phase 2 Clinical Trial Completion By Q2 of 2026

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Why OCF Strategy is More Cost Efficient

Why Strategy Matters

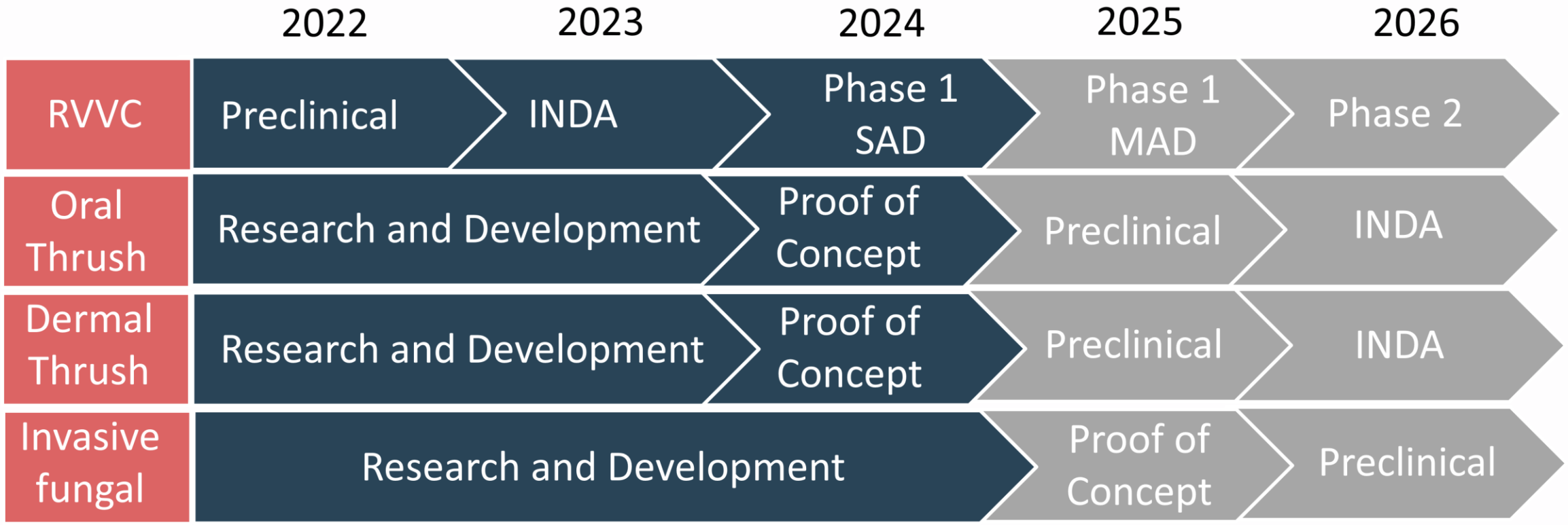
- Topical / Mucosal Strategy – cost efficient and possible higher patient compliance due to “no discomfort” reported in Phase 1 SAD
  - Oral administration increases likelihood of:
    (1) toxicity,
    (2) adverse reactions, and
    (3) Increase in clinical resistant strains
- Clinical Strategy – well 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

Better Patient Compliance

Development Timeline

Occidiofungin - The Fungus Killer™



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, Diagnostician, Mycology and Infectious Diseases

Shien Lu, PhD
Co-founder, Biochemistry, Microbiology and Bioengineer

Steve Pruett, PhD
Co-founder
Immunotoxicologist

John Ferreira
Advisor, GMP and QC

Tim Hiebert, MD, DVM
Advisor, Investor

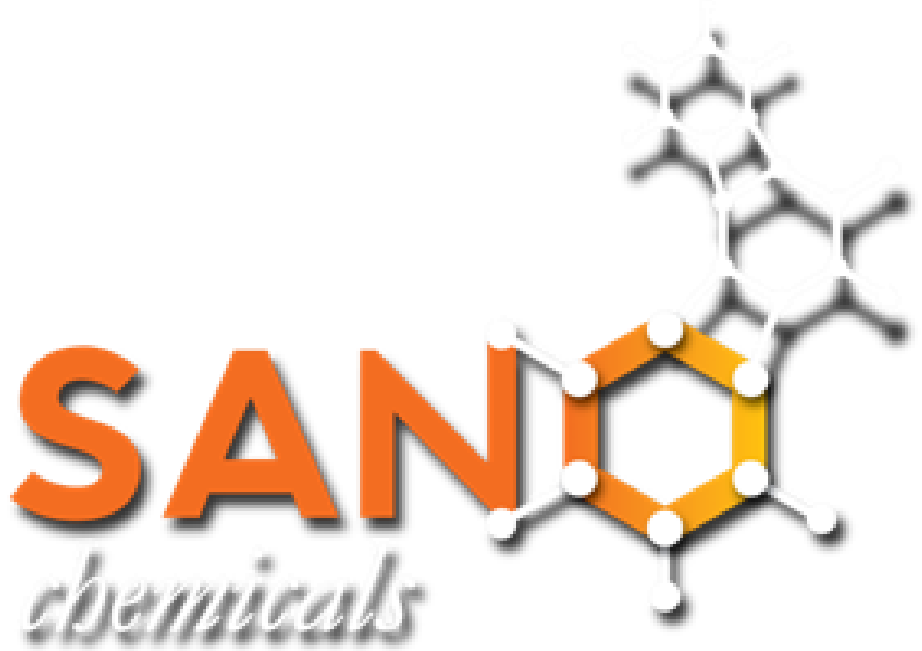
Jeff Libson, JD
Legal Advisor, Cooley, LLP

George Atiee, MD
Chief Medical Officer
Prior Experience Including:
- Senior Director, Associate Medical Director at ICON
- VP and Medical Director, Worldwide Clinical Trials

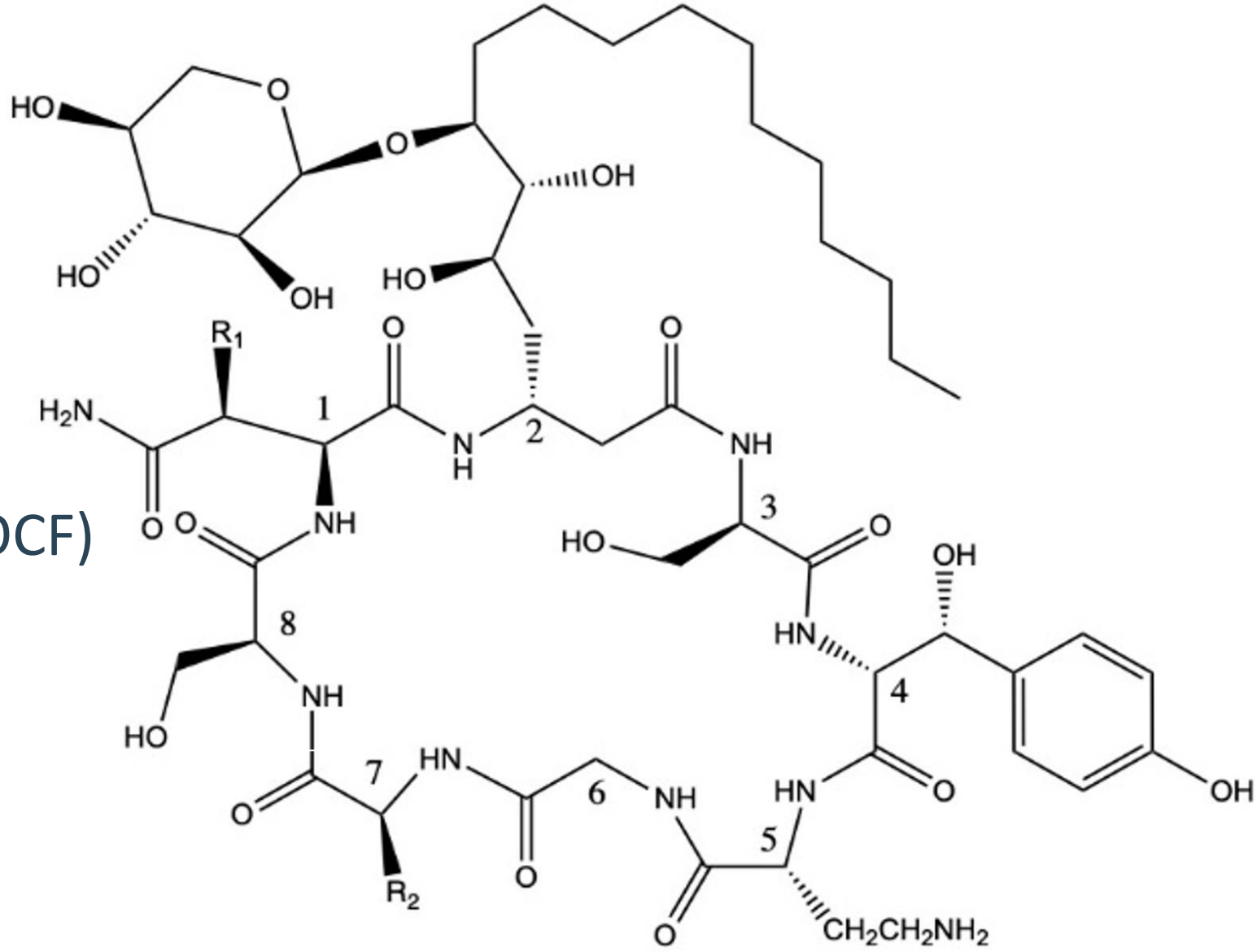
David Goodstein, MBA
Chief Financial Officer
Experience Including:
- Services 9 companies, operational controllership of IT budget of $80M and R&D budget of $300M
- Forecast accuracy within 2%

George Hlass, MBA
Business Development Advisor
- 20+ Years Business Development in Pharma Industry

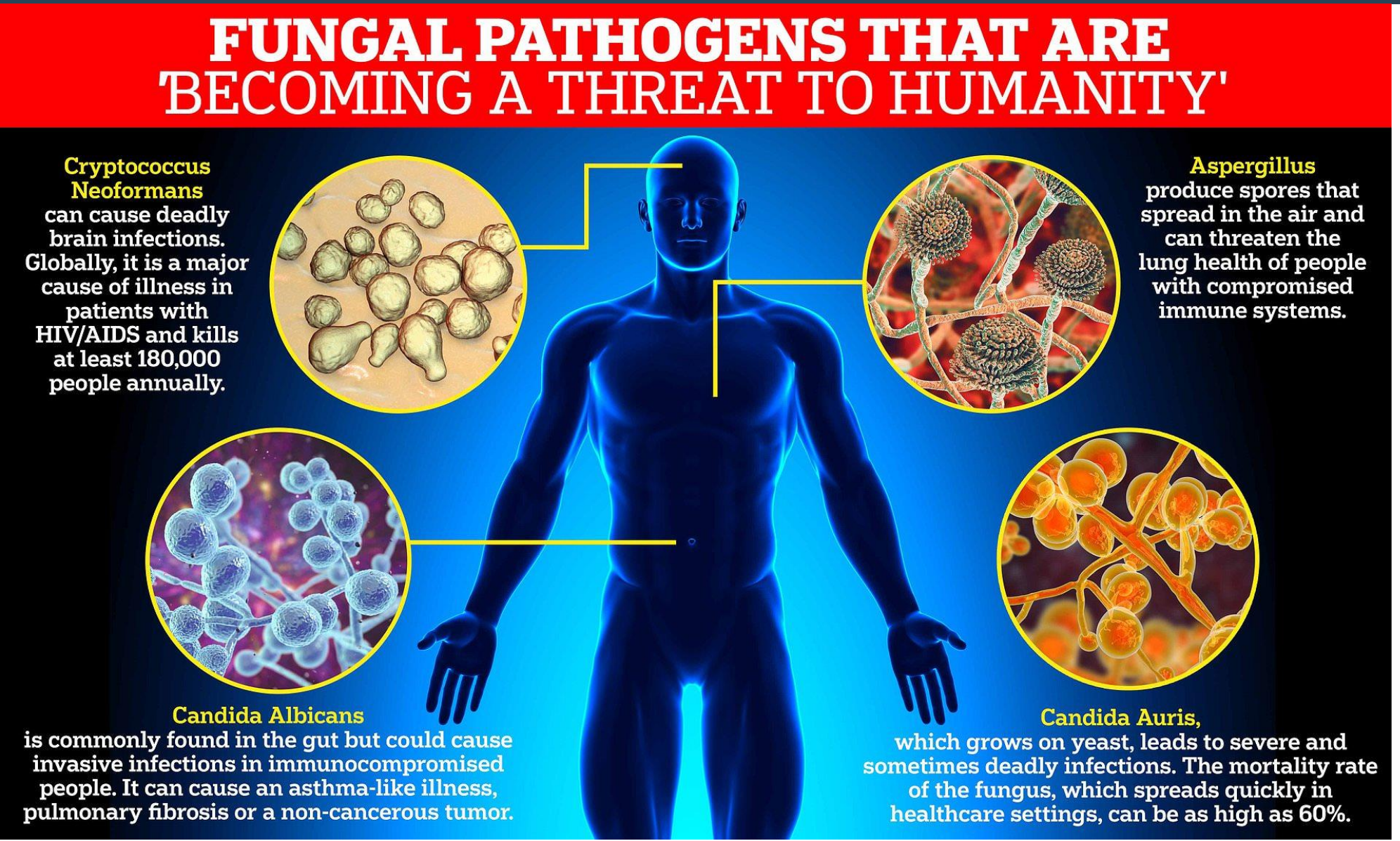
SUPPLEMENTAL INFORMATION



- Occidiofungin (OCF)



Occidiofungin (OCF)



<u>OCF Active Against:</u>

Candidiasis
- ~0.75 M Cases/year
- ~0.35 M Deaths/year

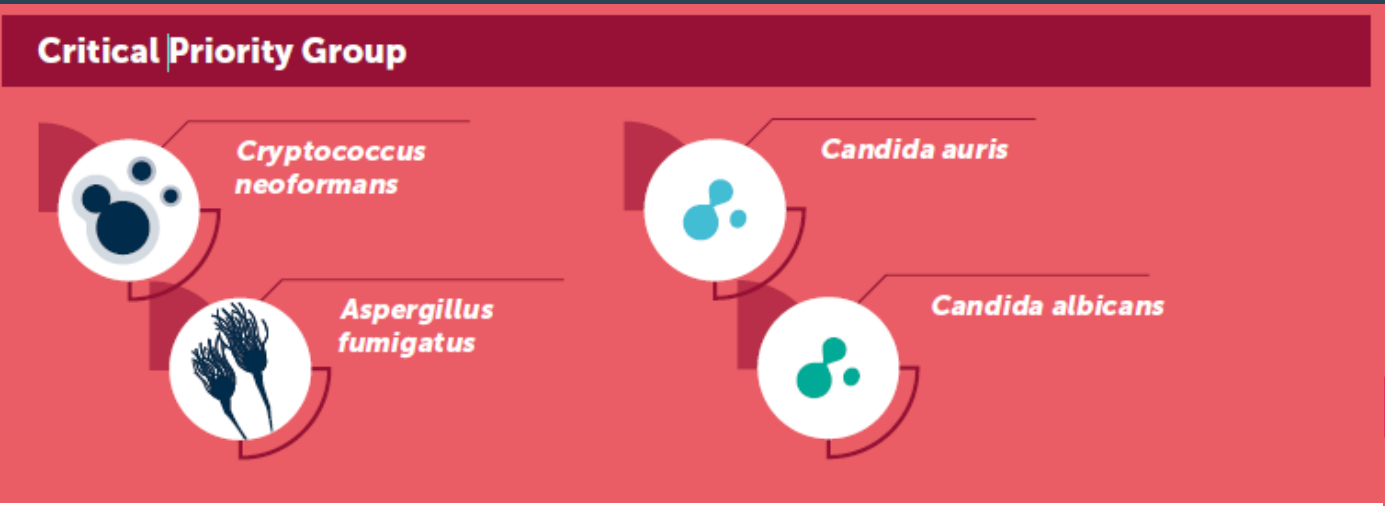
Aspergillus
- ~4 M Cases/year
- ~1 M Deaths/year

Cryptococcus
- Major cause of HIV related deaths

Severe asthma with fungal sensitization (SAFS)
- ~6.5 M Cases/year
- ~0.5 M Deaths/year

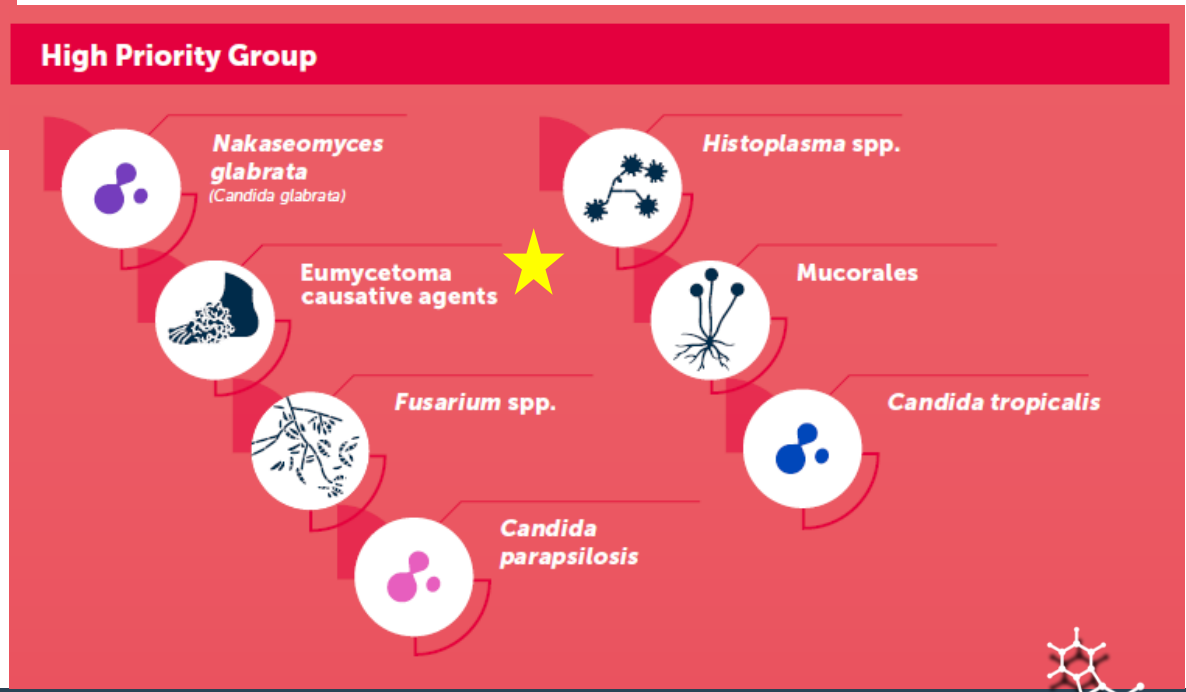
Fungal keratitis
- ~1 M Cases/year
- ~0.6 M blinded

WHO URGENT NEEDS



The reason for this urgency?

Difficulty in finding an effective solution



OCF has potent activity against these pathogens and should be considered a therapy for developing novel drug products to combat these pathogens.

★ Data to support activity of OCF is pending

WHO: Fungal Priority Pathogens (Oct 2022).

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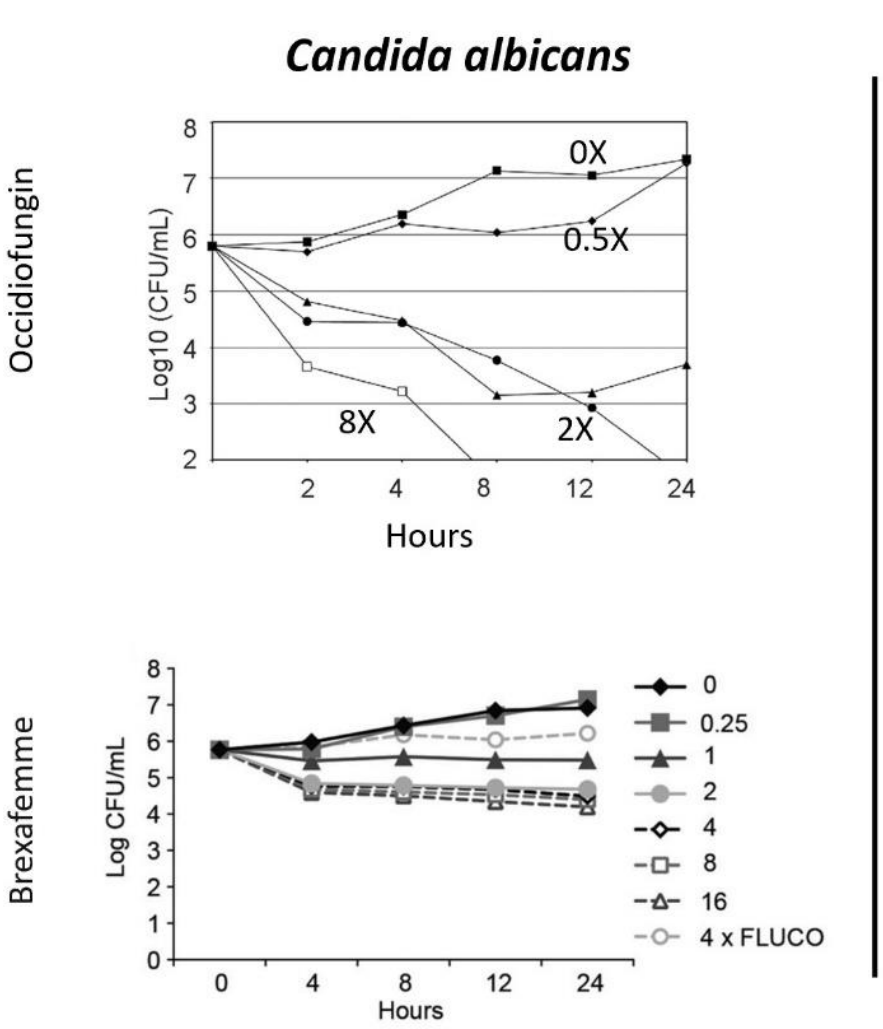
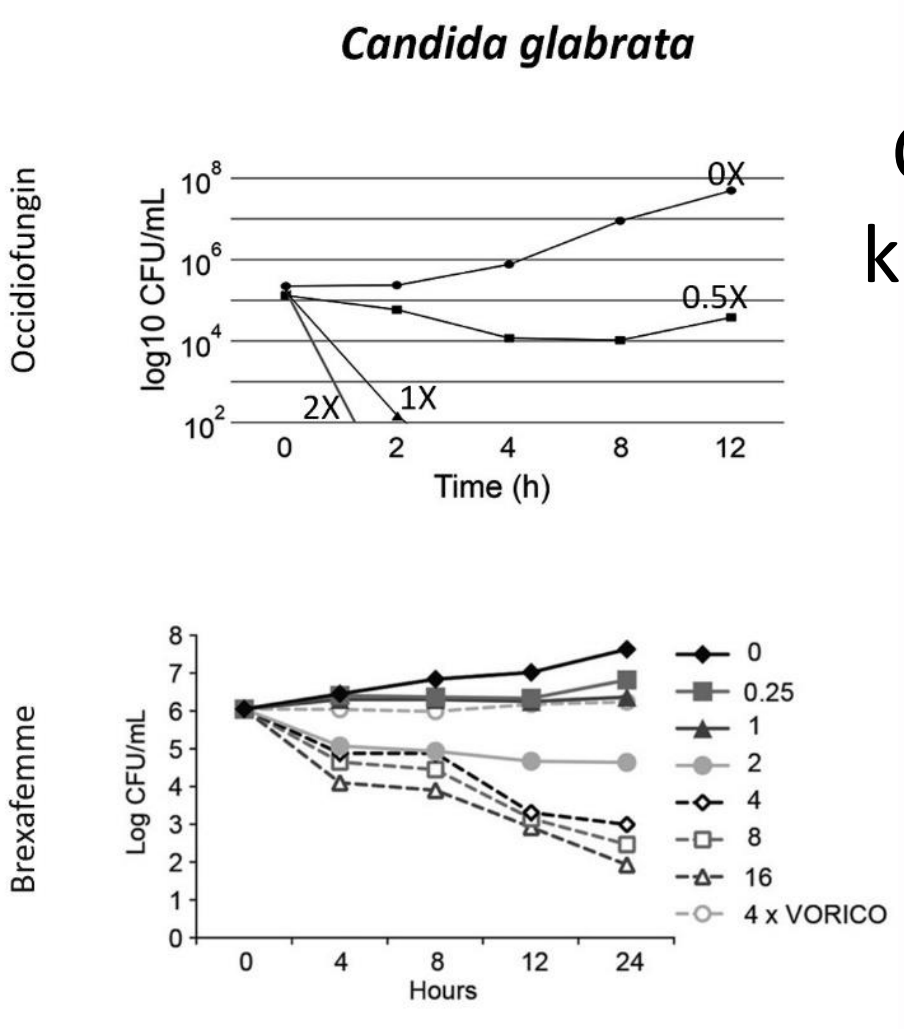
Occidiofungin versus Brexafemme Activity

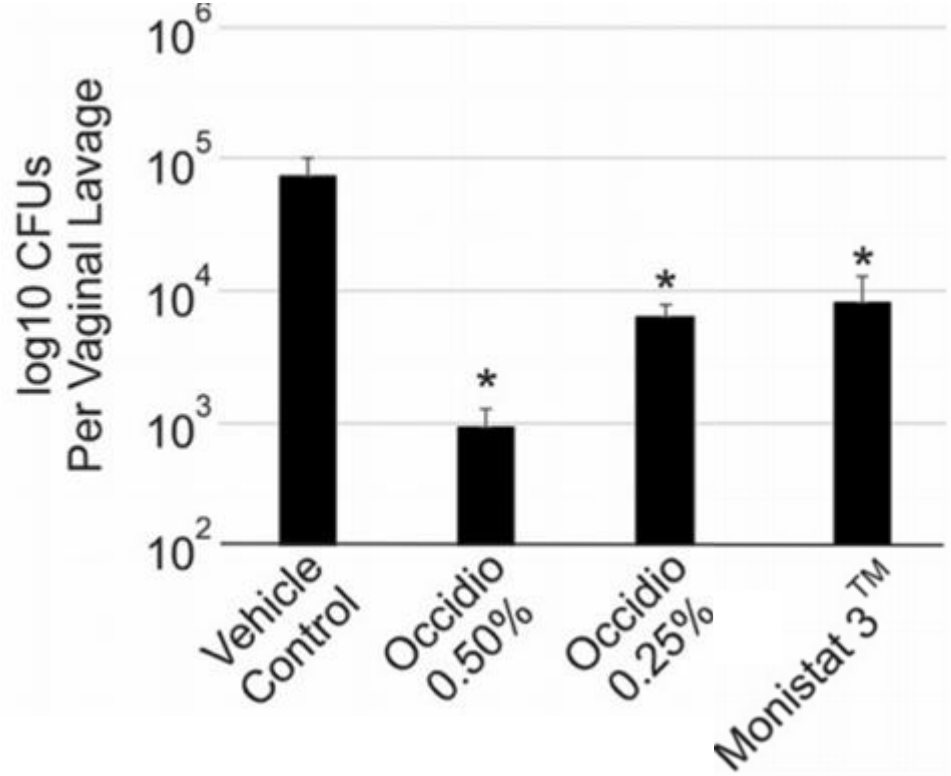




Comparison of the kill kinetic assays for occidiofungin and for Brexafemme ™

Occidiofungin is a true fungicidal antifungal

OCF001: Gel Product Formulation

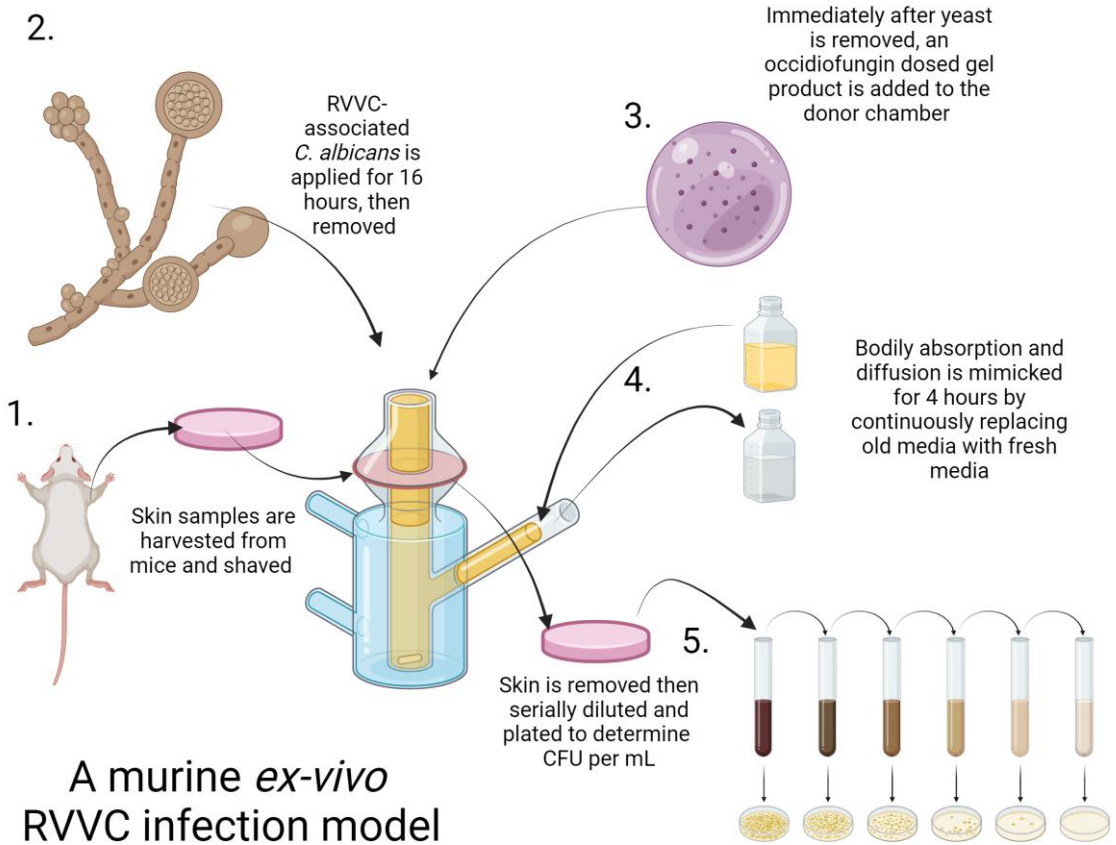


Head-to-Head Compare with Monistat, Monistat 3™ (**4% miconazole**). Note concentrations

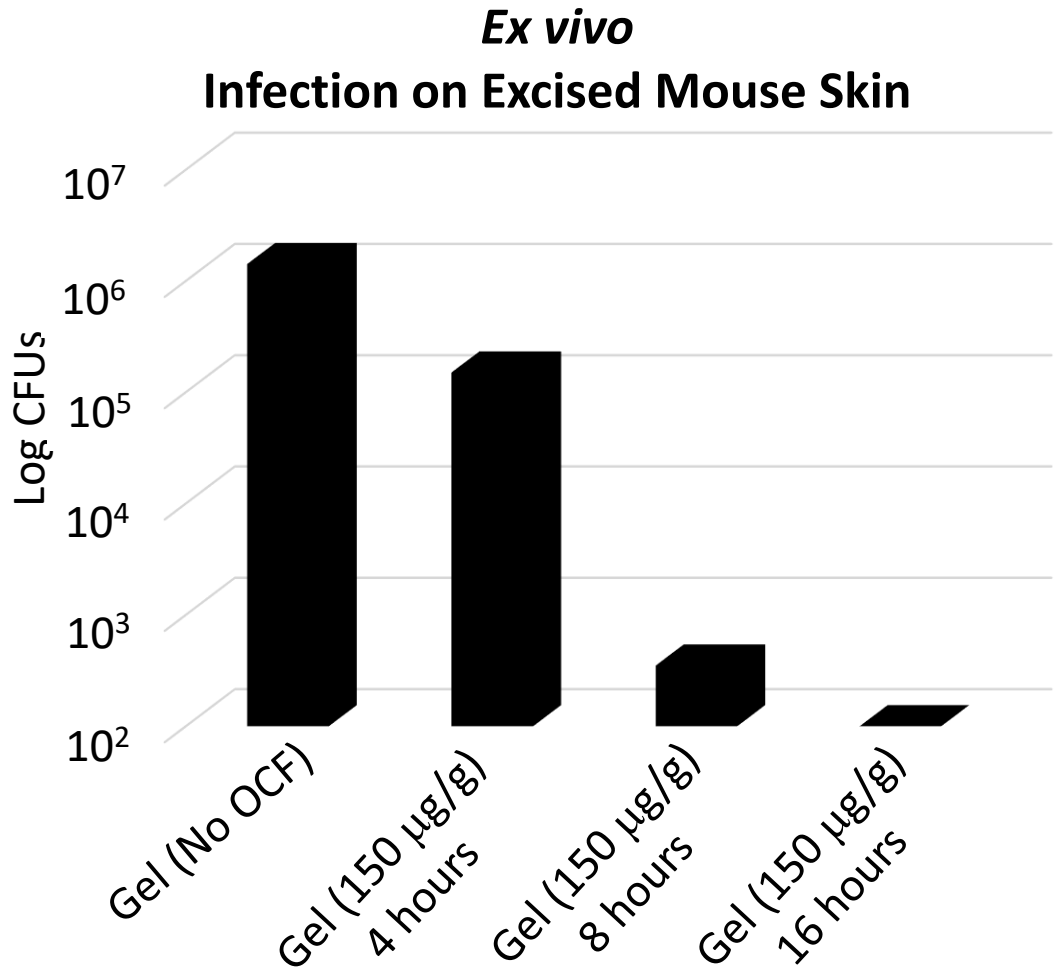
NIH-approved mouse model of vulvovaginal candidiasis

OCF001 demonstrates superior activity compared to miconazole, the current leading treatment for vulvovaginal candidiasis.

OCF001 – Gel Formulation



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



Complete reduction in viable yeast by 16 hours testing the RVVC OCF001 drug product.

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Relevant Publications

1. Previously Uncharacterized Variants, OCF-E-OCF-J, of the Antifungal Occidiofungin Produced by *Burkholderia contaminans* MS14.
Hansanant N, Cao K, Tenorio A, Joseph T, Ju M, McNally N, Kummari E, Williams M, Cothrell A, Buhrow AR, Shin R, Orugunty R, **Smith L.** J Nat Prod. 2024 Feb 23;87(2):186-194. doi: 10.1021/acs.jnatprod.3c00777. Epub 2024 Jan 26. PMID: 38277493 **Free PMC article.**

2. Sano Chemicals introduces Occidiofungin: the fungus killer.
Miles J, Smith L, Nature Biopharma Dealmakers. June 2024 ISSN 2730-6283 (online) ISSN 2730-6275 (print)

3. Intravaginal Gel for Sustained Delivery of Occidiofungin and Long-Lasting Antifungal Effects.
Cothrell A, Cao K, Bonasera R, Tenorio A, Orugunty R, **Smith L.** Gels. 2023 Sep 29;9(10):787. doi: 10.3390/gels9100787.PMID: 37888361 **Free PMC article.**

4. Occidiofungin inhibition of Candida biofilm formation on silicone elastomer surface.
Kumpakha R, Gordon DM. Microbiol Spectr. 2023 Dec 12;11(6):e0246023. doi: 10.1128/spectrum.02460-23. Epub 2023 Oct 10.PMID: 37816202 **Free PMC article.**

5. A Polyketide Synthetase Gene Cluster Is Responsible for Antibacterial Activity of *Burkholderia contaminans* MS14.
Deng P, Jia J, Foxfire A, Baird SM, **Smith LJ**, Lu SE. Phytopathology. 2023 Jan;113(1):11-20. doi: 10.1094/PHYTO-03-22-0106-R. Epub 2023 Jan 13.PMID: 35913221

6. Occidiofungin: Actin Binding as a Novel Mechanism of Action in an Antifungal Agent.
Hansanant N, **Smith L.** Antibiotics (Basel). 2022 Aug 23;11(9):1143. doi: 10.3390/antibiotics11091143. PMID: 36139923 **Free PMC article.** Review.

7. Synthesis and characterization of semisynthetic analogs of the antifungal occidiofungin.
Geng M, Hansanant N, Lu SE, Lockless SW, Shin R, Orugunty R, **Smith L.** Front Microbiol. 2022 Dec 13;13:1056453. doi: 10.3389/fmicb.2022.1056453. eCollection 2022.PMID: 36583054 **Free PMC article.**

8. Formulation, Pharmacological Evaluation, and Efficacy Studies of Occidiofungin, a Novel Antifungal.
Ravichandran A, Escano J, Lee JH, Ross MK, Austin F, Orugunty R, Lu SE, **Smith L.** Antimicrob Agents Chemother. 2020 Nov 17;64(12):e01737-20. doi: 10.1128/AAC.01737-20. Print 2020 Nov 17. PMID: 32958713 **Free PMC article.**

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Relevant Publications

9. Novel Antiparasitic Activity of the Antifungal Lead Occidiofungin.
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10. A Novel Actin Binding Drug with *In Vivo* Efficacy.
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11. Comparative genome-wide analysis reveals that Burkholderia contaminans MS14 possesses multiple antimicrobial biosynthesis genes but not major genetic loci required for pathogenesis.
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12. Toxicological Evaluation of Occidiofungin against Mice and Human Cancer Cell Lines
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Relevant Publications

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