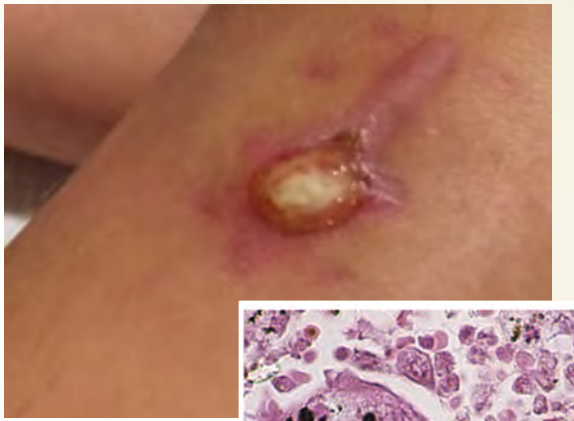

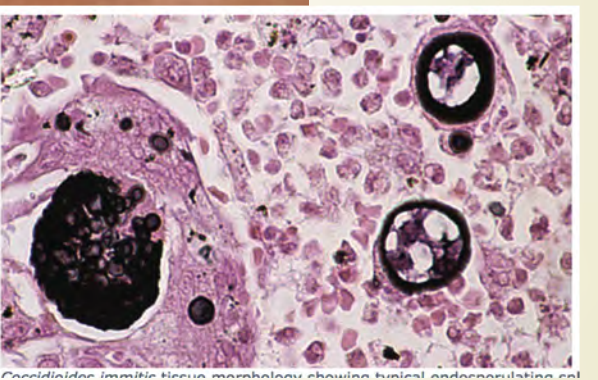

Valley Fever

1,000 patients annually fail current treatments

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David Larwood, CEO, davidl@valleyfeversolutions.com
Steve King, CBO, sking@valleyfeversolutions.com

CLSI FAST
March 22, 2018, 5:30 pm
UCSF, San Francisco, CA

Valley Fever Solutions

FAST Benefits to Reach Market Sooner

- The process of communicating effectively
  - How to make the story more compelling
- We are near "Critical Mass"
  - Key inflection point at 18-24 months Proof of Concept, valuation bump
  - Destination is feasible (drug can be made, should work, approval straightforward)
  - Destination is worthy (save some of 150 lives/yr, help 1K/yr with no therapy options)
- The process of de-risking
  - Committed 3/8/15 to 2 kg pilot scale manufacture, expect 10 kg by 12/31/18
- Sensitivity analysis – leveraging limited resources, manage which to use first
  - Adding key team (pharma MD on BOD; BD) Refining detailed roadmap

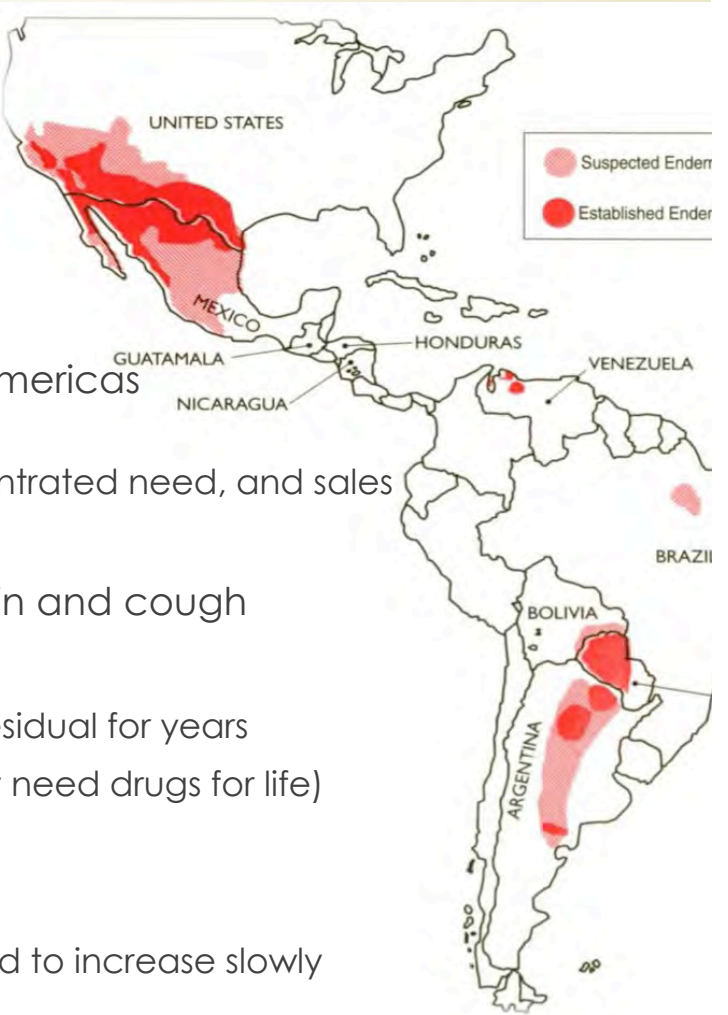
Management Team

- David Larwood, MS, JD, MBA - CEO, BOD
  - First to make two $1B drugs – Iotrolan (contrast agent, UCSD); PEGylated liposomes (UCSF, basis of Doxil)
  - MS=PhD studies – 4 years at UCSF – Medicinal and Pharmaceutical Chemistry
  - 2nd startup as founder after 8 years VP @ 2 strong startups (both NASDAQ), GC for Verisity S1, 4 years public
  - Managed our process improvement and scale up for NikZ to cGMP-ready; organized Trial roadmap; BD
- John Galgiani, MD – BOD Chairman
  - Premier academic in cocci; 40 years research and clinical experience in medical mycology;
    - Post-Doc Stanford University; Professor, University of Arizona College of Medicine
  - Chairman, NIH Mycoses Study Group Coccidioidomycosis Subproject.
  - Founder and Director, UA Valley Fever Center for Excellence (VFCE), University of Arizona College of Medicine
- Consultants, Advisors:
  - David Nix, PharmD, Univ. Ariz – ran Phase I trial center for 10 years
  - Identified: Commercial MD (15 NDAs), BD (30 years in Pharma)
  - Locust Walk – finance and business development

Fungal diseases

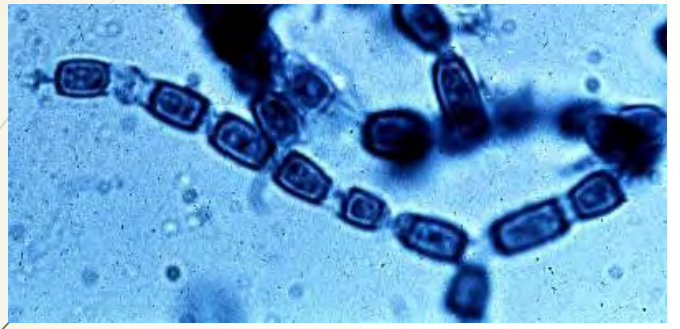
- Current drugs are not helpful to a significant subpopulation of Valley Fever patients
- New fungi are emerging, highly virulent, increasing resistance
  - There is a compelling need for new types of antifungal drugs
- New antifungal candidates: Viamet, F2G, Scynexis (mostly Phase 2)
  - Various MOAs, none interfere with chitin synthase (our MOA)
  - Expect combinations may be needed against new super fungi
- Fluconazole had peak sales > $1B
  - Most widely used drug for Valley Fever, now off patent and much cheaper
- Current drugs used frequently against Valley Fever (recent revenue peaks)
  - Azoles, recent: voriconazole ($800M), itraconazole ($900M),
  - Ambisome ($400M) reformulated Amphotericin B (introduced in 1958)

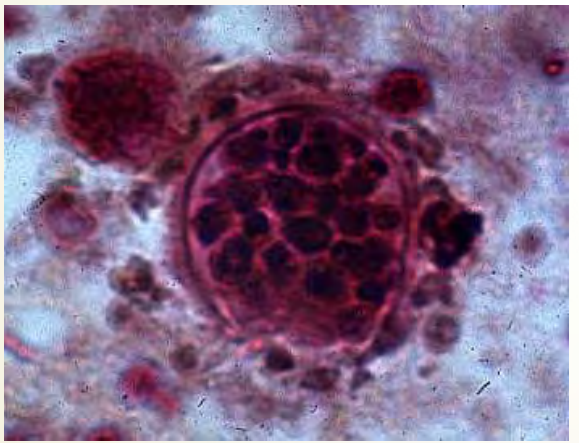
Valley Fever

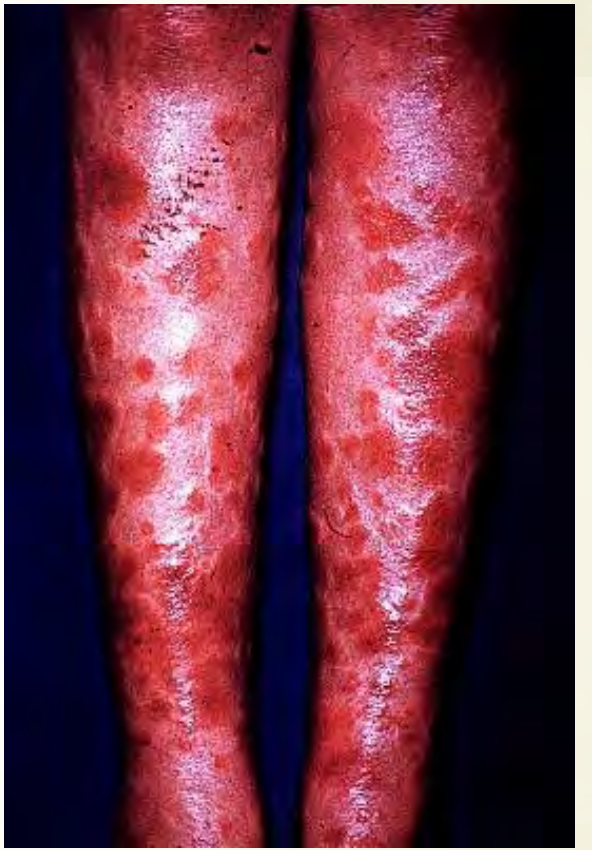


- An orphan disease found in desert regions in the Americas – 50% of known cases in man occur in Phoenix AZ
  - 80% of known cases are in three US counties – concentrated need, and sales
  - Also found in dogs and less commonly in cats.
- Symptoms –pneumonia, night sweats, lethargy, pain and cough
- In the USA, 50,000 new patients each year
  - For 40K, self limiting but miserable for months, often residual for years
  - 8K to 9K helped by azoles and Amphotericin B (many need drugs for life)
  - 1K per year fail current treatments
  - 150 people die every year
  - Natural reservoir of disease – these rates are expected to increase slowly

Images







http://botit.botany.wisc.edu/toms_fungi/jan2002.htm
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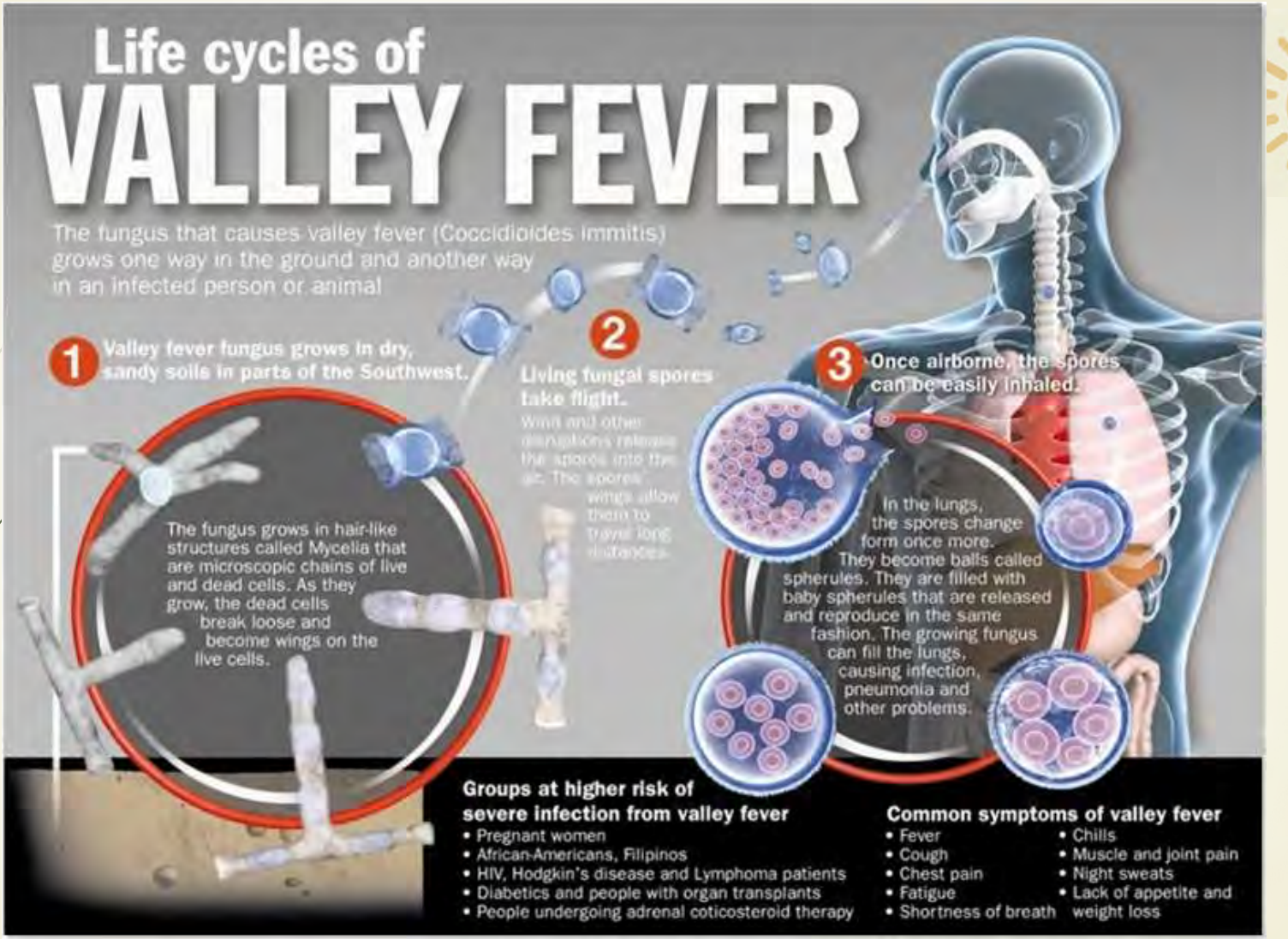


http://diseasespictures.com/valley-fever/ Valley Fever Solutions

https://courses.lumenlearning.com/suny-microbiology/chapter/mechanisms-of-other-antimicrobial-drugs/

Fungi: NikZ Inhibits Chitin Synthase

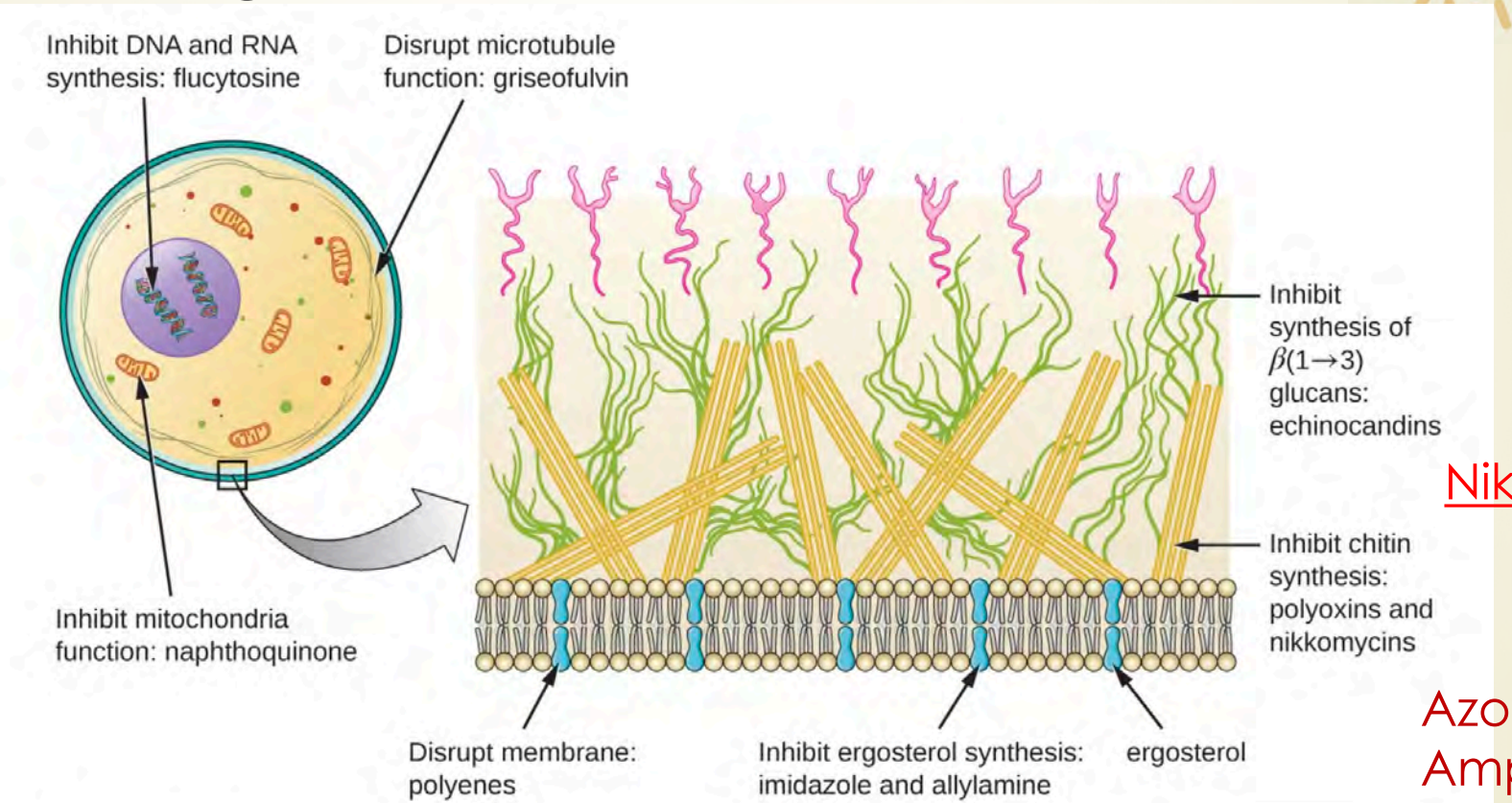


Figure 2. Antifungal drugs target several different cell structures. (credit right: modification of work by "Maya and Rike"/Wikimedia Commons)

NikZ

Azoles, Ampho

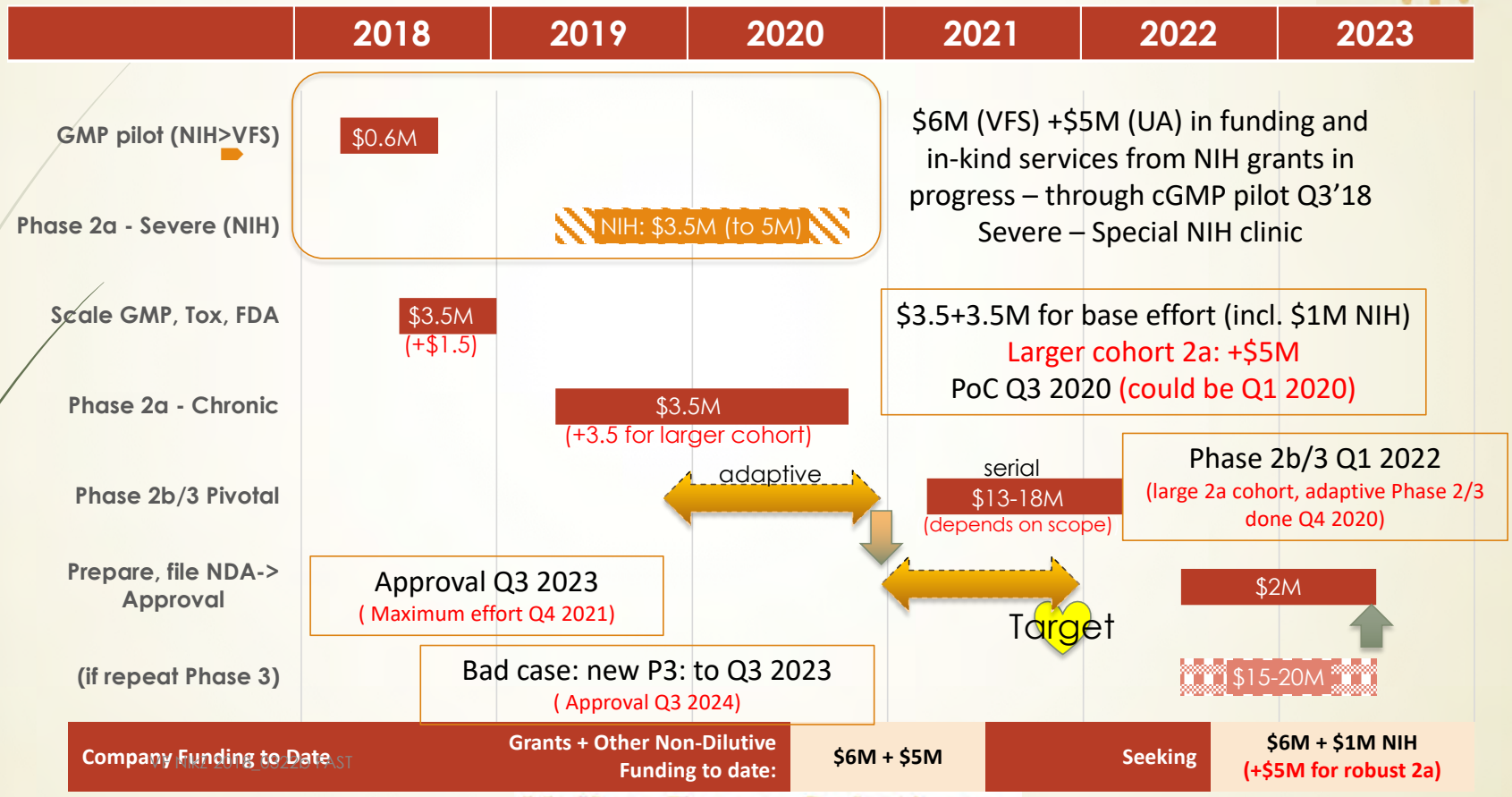
Drug History - Nikkomycin Z

- Discovered in late 1970's, developed at Bayer,
  - Novel mechanism of action, interfering with chitin synthase, initially pesticide
  - Human use discovered 1986 (effective vs. high chitin fungi, esp. cocci, histo, blasto)
  - Potentiator in treating "bigger" fungi – aspergillus, candida
- Developed by Shaman Pharmaceuticals, Phase 1 started,1994-2000
- Acquired by University of Arizona in 2005
- Valley Fever Solutions formed in 2007 to drive commercialization.
  NIH support to VFS has enabled
  - completion of Phase I trial (grant to Univ. Az, also FDA support)
  - improvement of API production
  - preparation for Phase II
- We have started pilot scale API production (2 kg)
  - Expected late 2018 – cGMP 10 kg trial material

Clinical Trial Strategy

- Phase 1
  - Does not interact with mammalian physiology (anticipated, now shown)
  - 36 patients; blinded Nikkomycin Z and placebo
- Phase 2a:
  - focus on patients not responding to current therapies
  - 25-36 patients, open label, dose ranging, 1 and 4 month readouts with an option to add blinding in a larger trial
  - Study bioavailability, look to improve through formulation
- Phase 3:
  - Broaden enrollment criteria
  - 75-100 patients, blinded, traditional, well controlled trial

Development Timeline



Valley Fever Solutions

Market Opportunities

- Veterinary Indications
  - Dogs - can be on human time frame, or sooner. Estimate $3-5M market
  - Cats – less common
- Dosage Form
  - Improve bioavailability – expands market opportunities
  - Injectable – for acute use
  - Oral liquid : Pediatric / geriatric
  - Inhalation
- Clinical Indications
  - Other fungi, some known;
  - Drug combinations for Aspergillus and emerging treatment resistant fungi

Intellectual Property

- OOPD Office of Orphan Product Development – Orphan Designation
  - Seven years US market exclusivity after approval
  - USA is the primary world market
- QIDP Qualified Infectious Disease Product
  - Additional five years US market exclusivity
- Patents
  - In preparation – initial filings 3/23/18
    - improved product,
    - improved API, improved use, formulation, more,

Summary

Valley Fever Solutions has a clearly defined clinical development plan which could lead to approval in 2023 of Nikkomycin Z.

As an orphan, there is a likely path to conditional approval in 2020.

Most drugs used for VF have had peak sales > $800M