

Jake Orville
President & CEO
Cleveland HeartLab, LLC



Inflammation, a key contributor to heart disease and cardiac events

Background

- Bachelor of Arts, University of Massachusetts
- MBA, University of Wisconsin

- 15 years of medical device, diagnostics and life sciences experience within established and emerging medical markets

- Senior Management for two publically traded companies:
 - Third Wave Technologies – Nasdaq
 - NextGen Sciences – London AIM

- Board of Stealth Therapeutics
 - Novel chemotherapy delivery port

Unique Experiences

- SMITHS Medical – global medical device company
 - Grew companies focus product line from \$500,000 to \$30M over three year period
- Third Wave Technologies – novel molecular diagnostics platform
 - Successful technology start up company raised \$110M IPO (2001)
 - Research genomic tools company single customer of \$20M (non recurring)
 - Burned \$70M cash within three year period
 - Hired initiate clinical molecular diagnostics division
 - Grew recurring revenue from \$300,000 to excess of \$25M over 3 ½ year period
 - Company eventually sold for \$580M (2008), was never profitable and burned a total of \$194M over its life

Unique Experiences

- NextGen Sciences – global protein expression research
 - Hired to transition the company away from a one-time capital equipment company (\$1M equipment purchase) to a service orientated recurring revenue model
 - Successful transition within 1 ½ year implementation growing global revenue more than 130% annually
- Created a strong drive and interest for commercialization and revenue generation within both established and emerging markets

How I Arrived in Cleveland?

- Former colleagues at Third Wave and I felt strongly that technology and financing was readily available but that what sparse was:
 - Good management
 - Solid commercialization
 - Focus on expansion of Intellectual Property
- Felt we could leverage our combined skills to create a “professional management team” approach ultimately driving value through our sweat equity
- First time in my career I considered myself and entrepreneur

What we experienced in Cleveland?

- Phenomenal technology, world class researchers, hot bed for invention
- Need for management expertise and a commercialization focus
- Great community for a young family
- Started one company – Tolera Therapeutics (Dr. Seimionow)
 - \$8M investment
 - Currently in Phase II trials
- Shut down another – Prognostix
 - Cardiovascular biomarker company

New Beginning in Cleveland – Cleveland HeartLab

- November 2009, founded Cleveland HeartLab
 - Several term sheets from VC's
 - Seeded the company with \$3M capital from local “Cleveland investors”
 - \$8.5M of capital to date
- Rapid growth since inception
 - Started with 9 employees now 60 plus
 - Won a key appeal of Medicare reimbursement for our lead test
 - Set testing records
 - Jan 2010 – 200 tests
 - Dec 2010 – 8,000 tests
 - Jan 2011 – 50,000 tests
- Book approximately \$14M in revenue in 2011

Key Learning's from my experience

- Everyone should try and raise money at some point in their career, it is a very humbling experience
- You don't have to be a doctor or a scientist but you do have to be connected to one if you aren't
- You will be on the brink and you have to push through it
- You must be able to build and work a network of investors
 - Choose board, advisors, counsel very wisely

Key Learning's from my experience

- Many times a viable commercial product/test/technology is not the best invention, but has the best (many times simplest) story
- Must map out the commercial side of your invention
 - What is the addressable market
 - Has to include reimbursement, regulatory and distribution
 - Must be show benefit for all stake holders in order to achieve true adoption beyond early adopters
 - Doctor, Hospital, Patient, Payer
- Intellectual property is a must
 - Only thing that protects your invention before commercialization and beyond early adoption
 - Try and build an IP portfolio versus a single patent

Thank you!

“Innovation distinguishes between a leader and a follower.”

- Steve Jobs

“Entrepreneurs average 3.8 failures before final success. What sets the successful ones apart is their amazing persistence”

- Lisa Amos

"My son is now an 'entrepreneur'. That's what you're called when you don't have a job."

- Ted Turner



ABOUT 50% OF HEART ATTACKS AND STROKES OCCUR IN PEOPLE WITH *NORMAL* CHOLESTEROL LEVELS¹

Did you know that *inflammation* in the arteries contributes to heart attacks and strokes?

Have you checked your inflammation levels lately?