



# Sustaining Your Early Stage Life Science Company during the Covid-19 Pandemic Crisis

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# Brief Bio

- ▶ 25+ years industry experience
- ▶ Early Stage Start-Up
  - ▶ Former Founder, CEO, President ImmusanT – 2010-2019
    - ▶ Reverse Merger, December, 2019
  - ▶ President & CEO: Ventaira Pharmaceuticals – 2003-2009
  - ▶ Director of Marketing & Sales: INO Therapeutics – 1996-2003
  - ▶ Founder, Bdev: OptimizOR
- ▶ Venture Capital – Battelle Ventures
- ▶ Large Pharma/Commercial Experience: Merck, GSK, Datex-Ohmeda, BOC
- ▶ Board of Directors: Multiple: Public, Private, Non-Profit companies
- ▶ Clinical Experience: Duke, MCV, University of Iowa
- ▶ Education: MBA, Wash U; Chemistry/Physics, VCU; BS Honors Nursing/Biology U of Iowa

ImmusanT,  
Inc.  
subsidiary of  
BNC Pharma

- ▶ Focused on discovery and development of tolerizing antigen-specific immunotherapies for auto-immune diseases
- ▶ Lead program in Celiac Disease – developed through Phase 2B
- ▶ Failed to meet primary endpoint in Phase 2B
- ▶ Follow on program in Type 1 Diabetes
- ▶ 18 team members
- ▶ Founded in 2010
- ▶ \$90M capital raised
- ▶ Reverse merger December, 2019

# Focus on People: Employees, Board, Patients, Suppliers, Vendors



- ▶ Safety first
- ▶ Regular communication is critical
  - ▶ Employees
    - ▶ Err on the side of overcommunication
    - ▶ Weekly calls with entire team/opportunity to highlight team members
    - ▶ One-on-one discussions
    - ▶ Team Zoom gathering – Happy Hour
    - ▶ Actions speak – follow your own advice



# Communication



- ▶ Board of Directors
  - ▶ Focused regular discussions (milestones/burn/runway)
- ▶ Vendors/Suppliers
  - ▶ Communicate anticipated need and sensitivity to supplies diverted to COVID research
  - ▶ Delays in delivery
- ▶ Employee Families – be creative with children
  - ▶ Study hours
  - ▶ Projects
  - ▶ Reading hours

# Work Environment



- ▶ Flexibility is key
- ▶ Adjust work environment
  - ▶ Masks/face covering for everyone
  - ▶ Regular cleaning
  - ▶ Instill shifts and limit number of people in lab and office
  - ▶ Rearrange office – 6 feet apart; create zones
  - ▶ Minimize public transportation – reimburse parking passes; pay for UBER
  - ▶ Testing: temperature taken; diagnostic testing before come to work
  - ▶ Minimize group areas- break rooms etc.
  - ▶ Restrooms: develop protocol: mask/wipe down
  - ▶ Wash hands!
- ▶ Other
  - ▶ Support home office setup

# Financing



- ▶ Double down on burn rate - scrutinize every dollar (as always)
- ▶ Analyze what you can and cannot control – renegotiate contracts if possible
- ▶ Focus on lead programs
  - ▶ Consider regions of the world to conduct trials
  - ▶ Scenario plan – incorporate delays and potential for a future outbreak
- ▶ Aggregate portfolio
  - ▶ Delay/put “on hold” other programs
- ▶ Funds are available
  - ▶ Investors will focus on their portfolio first and then selectively look at new opportunities
  - ▶ Several funds with capital to deploy to new investments
- ▶ PPP Loan – close tracking of expenses

# Focus & Prioritize Operations

- ▶ Mission Critical Programs
  - ▶ Clinical trials underway
  - ▶ COVID-19 work – if appropriate
  - ▶ Discovery/Lab
- ▶ Considerations
  - ▶ Shift work to minimize number of people in lab
  - ▶ Modify work space in lab
  - ▶ Testing
- ▶ Zoom meetings will be here for awhile - efficiency
- ▶ Productivity improvements – use technology to your benefit
  - ▶ Monitor what works/what does not
  - ▶ **Flexibility**



# Programs: Clinical Trials

## Challenges

- ▶ Patients enrollment delays
  - ▶ Inability to attend site visits for treatments, follow-up visits
  - ▶ Decline to attend study visit
- ▶ Delay investigational product shipments
- ▶ Sites suspending research activities
- ▶ Study deviations

## Company

- ▶ Focus on patient safety first and trial data integrity
  - ▶ Telemedicine
  - ▶ Nurses go to patients
  - ▶ Private car service for those that must come to site
- ▶ Protocol deviations
  - ▶ Work closely with CRO's
  - ▶ Eliminate non-essential patient visits
- ▶ Communicate with CRO/Vendors, PI's, Patients
- ▶ Reconsider geographic areas

Learnings from Halloran Consulting Group

# Programs: Regulatory



- ▶ CDER/CBER continue to meet 30-day IND review cycle
- ▶ No face-to-face meetings and teleconferences are downgraded to WRO (written response only)
- ▶ FDA and EMA are communicative
- ▶ HOWEVER, focus is on COVID-19 programs and reviewers reallocated
- ▶ CRO's are focused on safety for their staff thus limitations in critical functions
- ▶ Access to nonhuman primates (NHPs) is limited and costly



**ALL GREAT CHANGES ARE  
PRECEDED BY CHAOS.**

//DEEPAK CHOPRA

We will be better on the other side of  
this



Thank you!

Leslie J Williams

Former President & CEO ImmusanT

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