Getting your Venture Ready for Primetime

Mitch Sanders,
Managing Director 3DL

AliraHealth

ENET
The Boston Entrepreneurs’ Network

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Dr. Sanders has over 30 years of experience in preclinical animal models and clinical product development in advanced wound care. With ECI Biotech, he has produced over 13 peer-reviewed publications and 29 worldwide patents in medical device and \textit{in vitro} diagnostics. Mitchell is an expert in clinical and translational research and is a reviewer for the Wound Healing Society, Wounds International, Tissue Engineering, CIMIT, Massventures, MIT, WPI, Tech Sandbox, Piranha Pond, SBANE and the Venture Forum. He has an MS and PhD from WPI in molecular biology and biomedical sciences with 2 postdocs (biochemistry and pathogen genetics) at the Whitehead Institute/MIT.

\texttt{mitchell.sanders@alirahealth.com}
The Drug and Device Discovery Lab (3DL) at Alira Health was built to invent new products and solve bottlenecks for clients throughout the product development life cycle from discovery to commercialization.

3DL has a state of the art biosafety level 2 (BSL2) lab that can support all aspects of product design, development and in vitro testing. The lab specializes in drug, device, and combination products.

3DL has the scientific expertise to design, formulate and prototype products in many different areas of healthcare including advanced wound care, diagnostics, orthopedics, drug delivery, infection control, and prevention.

3DL provides on demand support for technical due diligence of an asset for in/out licensing or strategic planning to accelerate the growth potential of a drug or device indication. 3DL has expertise in nanomaterials and nano drug delivery systems.

3DL is a resource for both large and small companies to ensure that their business strategy is properly aligned with their IP portfolio. 3DL reviews patent portfolios for M&A, investment, and strategic planning activities.

3DL assists clients in developing a regulatory strategy as well as proactively managing their relationships with the FDA and CE Mark. 3DL has been involved in both new drug applications (NDA) and premarket approval of medical devices (510(k) and PMA).
About the Innovation Lab
Alira Health’s Capabilities

**The 3DL Facility**

- 3DL is a state-of-the-art biosafety level II (BSL-2) lab for biochemistry, cell, molecular, and microbiology R&D. 3DL can support clients’ needs for drug, device, and combination product development.

- Through our academic affiliations with top universities and corporate affiliations with CROs, Alira Health can provide preclinical animal models in the areas of advanced wound care, diagnostics, orthopedics, drug delivery, infection control, and prevention.

- 3DL can provide IP portfolio management, technical due diligence, and lab discovery for new product innovations.

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**WOUND CARE**

- 3DL’s areas of emphasis:
  - Wound healing, wound debridement, wound infection, pain reduction, scar removal, and hemostasis.
  - Advanced Wound Dressings

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**POC DIAGNOSTICS**

- 3DL develops prototypes of both cross flow sensors and rapid lateral flow point of care (POC) diagnostics with a specialty in antibody and peptide based diagnostic applications.

- 3DL provides transcriptogenomic profiling for gene expression studies.

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**ORTHOPEDICS**

- 3DL designs, formulates, and produces:
  - Rapid prototype orthopedic devices with a specialization in 3D printing and drug/device combination products.
  - 3DL provides engineering support to assist clients in their rapid device prototyping needs.

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**INFECTION PREVENTION & CONTROL**

- 3DL is an expert in Biofilm Models

- 3DL has a biosafety level 2 (BSL-2) lab for in vitro testing of diagnostics, antimicrobials, and therapeutics for infection control and prevention.
Critical Factors to Securing an Investment

Overview

- Team
- Market Potential
- Innovation
- Strong IP (Novelty and Inventive Step)
- Commercial Partner (Structured Exit)
- Functional Prototypes with strong preclinical data

Understanding of Sales Channels

Competitive Advantage and ROI

Understanding of Sales Channels
Team. Market Potential, & Competitive Advantage

**TEAMS**

- Founders Need:
  - Transparent
  - Coachable
  - Realistic on valuations
  - Ready for growth

**MARKET POTENTIAL**

- With a big opportunity there is greater potential for:
  - Pivoting
  - Platform technologies
  - Lack of focus
  - ROI

**INNOVATION**

- Product must be:
  - Proprietary (IP)
  - Feasible
  - Scalable
  - Sustainable

Alira Health is an international advisory firm providing integrated strategy, execution and innovation services for healthcare and life science companies.

Our strategists, bankers, doctors and scientists collaborate to fully understand every aspect of healthcare.

We provide our clients with a continuum of support to achieve success at any and every point in their business lifecycle.
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### IP Position

**IP Considerations:**
- Novelty
- Independent Step
- Country Coverage
- Competition
- Competitive Advantage

### Commercial Partner

A partnership will:
- Validate the Investment
- Set a Higher Valuation
- Improve Scale
- Ramp Sales

### Prototypes

Prototypes must be:
- Robust
- Low COGS
- High Gross Margins
- Commercial Ready
**Case Study: Expansion Strategy in Healthcare and Implementation**

**Our Expertise in Advanced Wound Care**

*Alira Health provided corporate strategy development, business development and M&A advisory for Z-Medica, which contributed to the company's annual growth of 62.4% from 2008 to 2012 before its sale to DW Healthcare Partners.*

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**Z-MEDICA**

- **Website:** http://www.zmedica.com/
- **Headquarters:** Wallingford, CT
- **Sales:** ~$30M in 2012
- **Employees:** 77
- **Z-Medica Corporation** is a medical device company that manufactures and distributes hemostasis agents. It offers sterile nonwoven gauzes, hemostatic bandages, hydrophilic roll dressings, and hemostatic sponges impregnated with kaolin. The company also offers specialty hemostasis products for use in the fields of podiatry, emergency medicine, cardiology, critical care, orthopedics, obstetrics/gynecology, and dermatology.

**PROJECT OBJECTIVE**

To Maximize Z-Medica's Value By Providing Strategy Consulting for Expansion into New International Markets and Business Development Advisory

**ALIRA HEALTH'S ACTIVITIES**

**PHASE I STRATEGY**

Developed a Market Access Strategy to Penetrate the European Market

Provided Strategic Advisory to Shift the Company From the Military Market and Penetrate the Hospital Market

Identified Emerging International Markets For Entry

**PHASE II EXECUTION**

Executed Partnerships With >20 Distributors Internationally Including:

- Italy
- France
- Germany
- Spain
- Japan
- China
- Korea

Sold the Company to DW Healthcare Partners in 2012

**OUTCOME**

Alira Health contributed to Z-Medica's expansion before its sale. The company grew at a CAGR of over 62% from 2008 to 2012.

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Source: Z-Medica, Alira Health.
Case Study: Bringing a Novel Wound Care Technology to Market

Our Expertise in Advanced Wound Care

By performing a wide range of consulting services, Alira Health helped an advanced wound care company make tremendous progress towards bringing their product to market in a very short amount of time.

**PROJECT OBJECTIVE**

A client had an innovative concept that addressed a significant clinical need in advanced wound healing. However, the company had a slow start in bringing the product to market.

**ALIRA HEALTH ACTIVITIES**

- Alira Health began the engagement with the client in December 2016 and has helped the company make tremendous progress towards bringing the product to market.
- **August 2017:** 510k application submitted
- **Q4 2017:** Start of sales for the product in an initial pilot run.
- **Q2 2018:** CE Mark Registration for the product.
- **Q4 2017:** Company will apply for reimbursement Q code for the product.
- **June 2017:** Determined the mechanism of action (MOA) for the product
- **October 2017:** Clinical studies expected to begin.

2008:
- Company founded.

2010:
- Product was invented.
- Product patent was filed.

2011:
- Product pre-clinical studies conducted.

2012:
- Product patent was filed.

2013:
- Product pre-clinical studies conducted.

2014:
- Product patent was filed.

2015:
- Product patent was filed.

2016:
- Q1 2018: Start of sales for the product in an initial pilot run.
- Q2 2018: CE Mark Registration for the product.
- June 2017: Determined the mechanism of action (MOA) for the product
- October 2017: Clinical studies expected to begin.

2017:
- Q4 2017: Company will apply for reimbursement Q code for the product.

2018:
- Company will apply for reimbursement Q code for the product.

2019:
- Company will apply for reimbursement Q code for the product.

2020:
- Company will apply for reimbursement Q code for the product.
THANK YOU

USA
BOSTON
1 GRANT STREET, SUITE 400 FRAMINGHAM, BOSTON, MA, 01702 USA
TEL +1 (774) 777 5255
BOSTON@ALIRAHEALTH.COM

FRANCE
31 RUE DE MONCEAU, 75008 PARIS, FRANCE
TEL +33 (0)1 44 54 96 23
FAX +33 (0)1 44 54 90 20
PARIS@ALIRAHEALTH.COM

SPAIN
CASAFRANCA 38, 08017 BARCELONA, SPAIN
TEL +34 (93) 406 71 71
BARCELONA@ALIRAHEALTH.COM

USA
SAN FRANCISCO
101 MONTGOMERY ST, SUITE 2300, SAN FRANCISCO, CA, 94104 USA
TEL +1 (650) 457 3854
SANFRANCISCO@ALIRAHEALTH.COM

GERMANY
KURFÜRSTENSTRASSE 22, 80801 MUNICH, GERMANY
TEL +49 (89) 416 14 22-0
FAX +49 (89) 416 14 22-99
MUNICH@ALIRAHEALTH.COM

ITALY
VIA CARLO OTTAVIO CORNAGGIA 10, 20123 MILAN, ITALY
TEL +39 (02) 36680198
FAX +39 (02) 94 19 50 07
MILAN@ALIRAHEALTH.COM

mitchell.sanders@alirahealth.com