AmphibianSkin™

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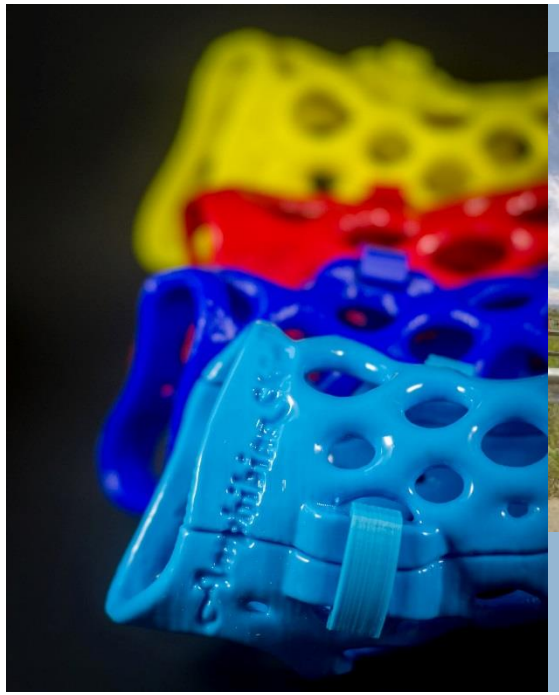

Business Plan – InnovateHER Challege

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Executive Summary (Strategy)

AmphibianSkin™

Vision	Premier niche provider of custom 3D upper extremity splints
Goal	Grow the business to $75M in 5 years with 15% EBITDA ROS
Scope	Provide innovative 3D printed custom splinting solutions to the Medical Device and Sport Medicine Markets
Competitive Advantages	■ Protected Intellectual Property (Patents, Software and Trade Secret Workflows) ■ Unique, Patent-Pending Removable Clip ■ Successful market testing with patients and physicians, positive outcomes ■ Water-safe, lightweight, breathable design with targeted immobilization

Focus Markets	Medical	Sports Medicine
Strategic Key Initiatives	• Custom fit and designed to physician's specifications, designed to be lightweight and breathable • Designed for stability and removability with patent pending clip • Women + families remain more active during recovery with less discomfort and waterproof device	• Custom fit and designed to each individual athlete's unique needs • Waterproof and sweat proof, ice bath and heat therapy safe • Adaptable with EMS and TENS • Increases activity and quality of life options

How we win	Experienced Leadership team with domain knowledge and Protected Intellectual Property

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Background - Overview

- AmphibianSkin, LLC, is headquartered in Pueblo, Colorado and offers custom- designed, custom-fit 3D printed orthoses that fill an unmet need in the medical and sports marketplaces.
- AmphibianSkin, LLC is the first company to produce a commercially available Class 1 splint with medical reimbursements approved by major healthcare insurance companies and Medicaid.
- Our product improves the lives of women and families by easing the difficulties caused by upper extremity injuries, and by providing a more sanitary alternative to traditional casting.
- AmphibianSkin orthoses allow women and families to have less downtime from work and school, and allow speedy resumption of normal activities such as bathing, swimming, cooking and housework. Women who would normally be unable to perform work duties while in a cast can now return to work quickly.

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Experienced Leadership Team

- Diana Hall, ChE MBA – inventor, patent holder, design and fabrication IP, processes and procedures
- Nik Allain, CHT, SFMA, FMS – international hand specialist, clinical expertise, design input for optimal medical application and healing outcomes
- Don Summers – IP and Patent experience and expertise
- Keith McAslan – finance and operations in manufacturing, distribution, technology and healthcare
- Jim Doidge – business and finance experience and expertise, sports application design

Accomplishments To Date

- Completed proof of concept phase in June – distribution process set up, clinical sales begun, fitting of patients and being reimbursed by major insurance carriers including Medicaid. Registered and listed as Class 1 device with FDA.
- Established processes and procedures for distribution, design, fabrication and delivery.
- Currently expanding into clinics across the front range and establishing a center of excellence – successful and reproducible model.

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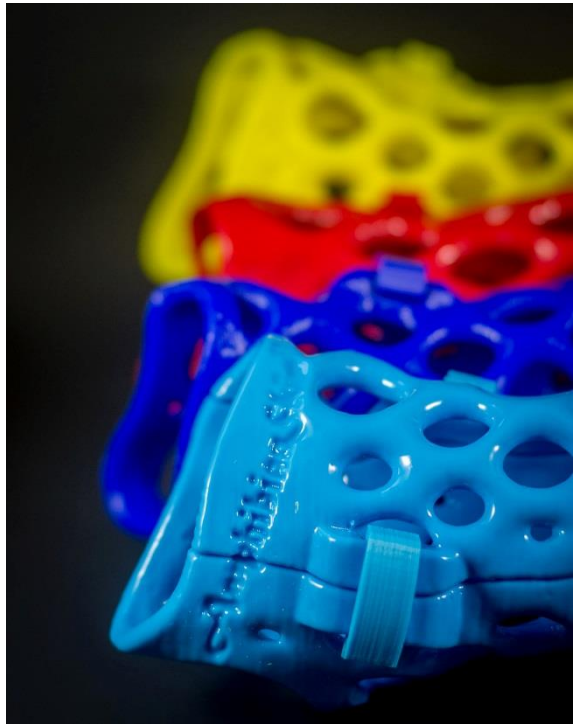
Marketing Plan
Product Overview

AmphibianSkin™



- Amphibian Skin is a clean, comfortable alternative to traditional immobilization devices like casts and splints.
- They are precisely fit, using each patient's unique body surface map and custom designed per doctor or therapits' orders for each patient's specific injury or condition.
- AmphibianSkin gives patients and physicians infinitely more treatment options, and allows them to maximize the patient's comfort during the healing phase, to reduce skin irritation issues and improve healing outcomes.

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Market Need

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- A query of the NEISS resulted in 92,601 records of upper extremity injury treated at an emergency department in the USA in 2009

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3280373/

- An estimated total of 3,468,996 such injuries in 2009
- 1,130 upper extremity injuries per 100,000 persons per year
- The average citizen in a developed country sustains an average of 2 bone fractures and multiple sprains in their lifetime
- Up to 7% of the world's adult female population have chronic hand/wrist conditions like carpal tunnel

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- **Market** - Casting is known to be the traditional and the most commonly used method of bone fracture treatment. Globally, it has exhibited a larger market size in different regions of the world. According to a recent market study in the U.S., the casting and splinting market is expected to grow gradually at a CAGR of 5.0% over 2014 to 2020, owing to a number of growth factors, especially in the highly developed regions. Such growth and momentum observed within this market will yield around US $2.3 Billion by the end of 2020. (Transparency Market Research February, 2015)
- **Share** – Amphibian Skin is a disruptive technology and current share of $2B market is not measurable. Year 5 share of $2.3B market is less than 1% with unlimited upside potential
- **Technology** - Utilize 3D printing technology to fabricate custom 3D exoskeleton immobilization devices.

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Product Benefits for Patients and Athletes

AmphibianSkin™

- Hygienic
- Sweatproof / Water safe
- Lightweight
- Breathable
- Comfortable
- Fashionable, colorful or discrete
- Suitable for active lifestyles
- Shower/Bath Friendly
- Immobilization of injured area
- Fits to body-scan contours
- Covered by insurance
- No bulky, unsanitary padding
- Painless, touch-free scanning

Ironman World Championships competitor Elizabeth West wearing AmphibianSkin after wrist surgery

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Product Benefits for Medical Staff

AmphibianSkin™

- Reduces casting time and mess
- No re-casting required
- Easy removal/reapplication for exams and x-rays
- Able to be sterilized for medical staff/food handling positions
- Additional revenue stream with competitive margins
- Scanning/Fitting procedures easy to implement
- Viral demand attracts new patients
- Increase office efficiencies and throughput

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Key Differentiators

AmphibianSkin™

- The unique removable closure mechanism is designed for easy use and allows this orthosis to be put on or removed single-handedly while retaining structural stability in all axes. Our patent-pending design also includes a semi-permanent closure option, more like traditional casts.
- This orthosis is water-safe with functional benefits beyond just swimming or showering. It can easily be cleaned and sanitized making it far more hygienic, versatile and enjoyable to wear. Less bulky, fewer skin irritation issues, fewer restrictions on activity.
- This orthosis is cost effective in multiple ways, by reducing time and costs related to casting, re-casting, skin irritations and a series of doctor's/therapist's appointments

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Process and Costs

Traditional Cast/Custom Splint

1. Visit E.R., receive temporary splint and referral to ortho clinic.

2. At ortho visit, remove temporary splint, perform x-ray and exam, receive traditional cast or fabricate custom splint.

3. At each follow-up appointment, cut off cast, examine and x-ray, and re-cast. Also required if cast becomes wet or skin irritation occurs.

Total Cost in Time and Expense: Casting included in procedure cost code; custom splint and subsequent adjustments is DME custom orthosis code. Multiple castings over course of injury or in-office fabrication of custom splint.

AmphibianSkin™

1. Visit E.R., receive temporary splint and referral to ortho clinic.

2. At ortho visit, remove temporary splint, perform x-ray and exam, perform scan for AmphibianSkin. (e-file uploaded to AmphibianSkin in seconds.) Replace temporary splint for 2-3 business days until device arrives.

3. Office visit (casting room only) for removal of splint and fitting of AmphibianSkin device.

4. At each follow-up appointment, removal and re-application of AmphibianSkin device takes moments. No moisture or skin irritation issues to address.

Total Cost in Time and Expense: Single DME custom orthosis code, 1 additional casting room visit, no cast removal or re-casting at each follow-up appointment.

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Background – Fabrication

- Utilize 3D printing technology to fabricate custom 3D exoskeleton devices.
- Utilizing Fused Filament Fabrication printers with a low total cost of ownership (acquisition of machine, materials and on going maintenance)
- 3D Printers are compact and scalable with a short learning curve (due to our propriety process) and global service and maintenance.

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SWOT – AmphibianSkin™ (Pueblo, CO)

STRENGTHS:

- 1st to market with a commercially viable product
- FDA registered Class 1 device
- Painless fitting
- Insurance reimbursements
- Positive feedback
- Proprietary processes
- No inventory required
- New physician revenue stream
- Experienced multi-disciplined leadership team
- Availability for use with ultrasound and electromagnetic and monitoring devices

WEAKNESSES:

- Few clinical studies
- Increased cost compared to traditional casting/splints
- Turn around time compared to traditional casting and splints
- Training required for clinical staff
- Labor intensive to fabricate
- Funding

OPPORTUNITIES:

- Take market share in next 6 months
- International Licensing
- Scanning/printing technology becoming more cost effective
- Utilize process in adjacent markets (sports, military, prosthetics, etc.)

THREATS:

- Funding
- New Medical Device Fabrication process
- Speed of competition
- Competition well funded
- Litigation potential

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SWOT – Fiberglass Casting

STRENGTHS:

- Estab. Global market Millions+ 20 yrs
  - Good availability
- Rapid fitment- low temp (wet)
- Reliable closure- no opening
- Resilient
- Cost
  - $15.00 materials
  - labor approx: 20mins@$15/hr(*3 for ben) = $15
  - Total $30.00

WEAKNESSES:

- Need to store inventory
- Generates heat when applied, skin risk
- Unable to remove without saw
- Not waterproof
- Not able to monitor wound sites, pins, skin
- Spontaneous EPL tendon rupture rate 0.3-2%
- Required skill to apply- frequently immobilize unnecessary jts
- Unable to regulate temperature in cast
- Prefabricate cast if too tight, too loose or damaged

OPPORTUNITIES:

- Newer materials coming into play
  - polyester fiber and resin (Delta cast)
- Incidence of fractures increasing
  - increased sales in existing market

THREATS:

- Alternative products on market
- EXOS, BSN Delta-cast, Amphibian Skin
  - More hygienic products
  - More resilient
  - Tolerant of heat and moisture
  - No and low heat molding processes
  - Better asthetics

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Competition – Market Availability Timing

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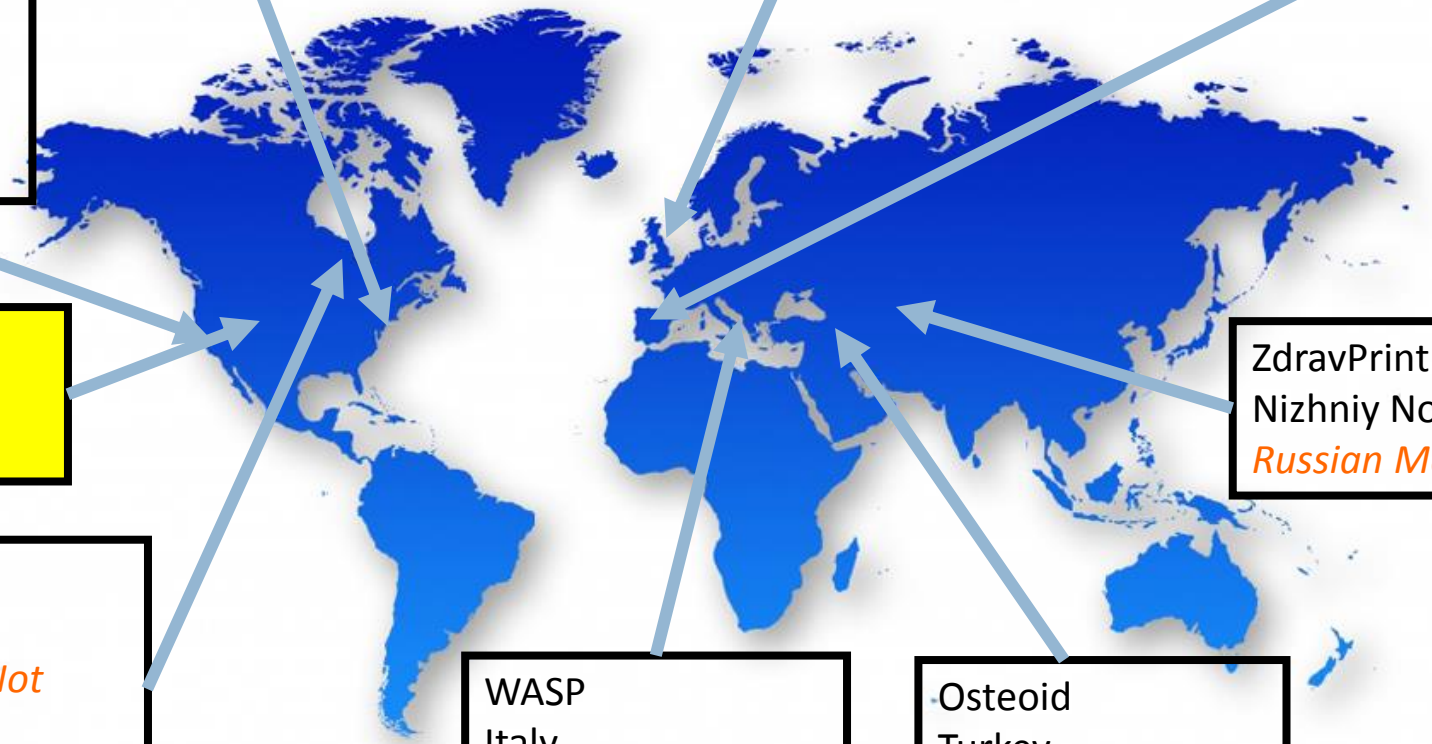

3D Systems
Rock Hill SC
Conceptual Stage

University of
Loughborough, UK
Research

Exovite
Spain
Europe Market Concept

Exos Fracture Brace
Vista, CA
Custom fit splint, inventory item

AmphibianSkin LLC.
Pueblo, CO
Currently Available

ZdravPrint
Nizhniy Novgorod, Russia
Russian Market - 1 hospital

HEALx
Toronto, Canada
Elite Athletes only, Not Medically approved

WASP
Italy
Conceptual Stage

Osteoid
Turkey
Conceptual Stage

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Competitive Barriers to Entry

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Barriers to entry are: securing FDA approval (time/cost), expense and adaptation of scanning equipment/distribution, difficulty in effectively combining hardware/software for efficient and effective reproducible system (scanner/CAD/fabrication), lack of consistency/strength of fused filament fabrication, man hours required for custom design and fabrication, etc.

AmphibianSkin LLC is the first company to produce a commercially available product with medical reimbursements market tested and approved by most major healthcare insurance companies and Medicaid. The nearest competitor is not directly competing in the traditional casting/splinting market.

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Distribution Growth Strategy

- Near Term -
  - Local Proof of Concept - growth and adoption of product in key markets (PT and sports medicine clinics) across the front range receiving referrals from Colorado-based orthopedic surgeons, hospitals and athletic trainers.
  - Establish procedures and efficient model of operations while utilizing consumer-driven marketing to drive demand.
  - Broaden out with demand to include orthopedic, GP and family medicine clinics, hospitals, and emergicare centers.

Capital required for purchase of design and fabrication equipment and infrastructure for growth.

- Mid-Term - Partner with vertically integrated health providers, national or international medical device distribution firm or sports medicine clinics to expand quickly and manage growth.
- Long Term - License internationally - distribution and fabrication on-location with design kept in-house.

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Design and Fabrication

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- **Centralized Design**
  - Located in Pueblo, CO with trained 3D CAD designers in office environment, oversight provided by Inventor.
  - Developed design operations manual with standardized workflows.
  - Action - Keep trade secret software and workflows in-house to assure consistency and quality control.
- **Centralized Fabrication**
  - Using standardized print/finishing operations manual, outsource fabrication/finishing work/shipping
  - Increase capacity using current outsourced manufacturing company for ease of standardization, maintain proprietary hardware/software/settings/workflows in-house as trade secrets, and ensure quality control.
  - Overnight ship across the U.S.

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Financial Summary

	2015	2016	2017	2018	2019	2020
Sales	$ 11,250	$ 162,500	$1,457,500	$3,437,500	$7,000,000	$14,250,000
Cost of Sales	$ 5,250	$ 68,250	$ 632,500	$1,437,500	$3,125,000	$ 6,250,000
Gross Margin	$ 6,000	$ 94,250	$ 825,000	$2,000,000	$3,875,000	$ 8,000,000
Gross Mrgin %	53.3%	58.0%	56.6%	58.2%	55.4%	56.1%
S,G & A Expenses	$ 35,000	$ 75,000	$ 575,000	$1,250,000	$1,650,000	$ 2,250,000
Income from Operations	-$ 29,000	$ 19,250	$ 250,000	$ 750,000	$2,225,000	$ 5,750,000
ROS %	-257.8%	11.8%	17.2%	21.8%	31.8%	40.4%

2015 – Proof of Concept

2016 – Front Range Expansion, development of Center of Excellence

2017 – 2020 – Growth and expansion of model across the country and internationally

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