



Amnion Life

MEDICAL DEVICES
FOR PRETERM INFANTS





Amnion Life, LLC.

OVERVIEW

Amnion Life is a medical device company with a mission to develop and market novel devices to decrease mortality & complications in Preterm infants. Amniobed™ Golden Hour is the most advanced infant incubator in 100 years.

Key Highlights:

- 3 Innovative and Game Changing Medical Devices
- 2 United States & 1 China Patent
- 2nd Place, Cleveland Clinic AMP'D Arena 2019 Medical Innovation Summit
- 3rd Place, Gold Award, 2019 UCSF Stanford Pediatric Device Competition
- Member, UCSF Pediatric Device Consortium Accelerator



Industry:

Biotechnology, Medical Equipment, Healthcare,

Market Size:

\$43 Bn

Target Customer:

Top 100 Hospitals in the United States.
Any Hospital Considering Proper Medical Technology and Equipment.

Pre -Term Infants Require:



Oxygenation



Thermoregulation



Nutrition



Fluid Management





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HYPOTHERMIA & PRETERM INFANTS

Today, a Premature Birth occurs Every Minute.

The Golden Hour

- Hypothermia Risk is the Most Significant in the First 60 minutes, Post Birth.
- Neonatology refers to the First 60 minutes Post-birth as the “Golden Hour”.

Hypothermic Consequences

Preterm Birth Infants often acquire Long-term Health Problems in their NICU stay.

Hypothermia in infants is associated with:

Brain Hemorrhage - Sepsis - Convulsions - Respiratory Distress - Anemia - Periventricular Leukomalacia - Apnea - Necrotizing Enterocolitis - Meningitis - Bronchopulmonary Dysplasia - Death

In large European and NA studies, 50% of very preterm infants had hypothermia in the first 60 minutes after birth.





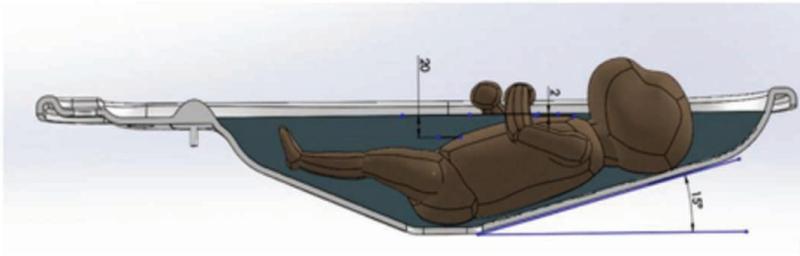
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MOVING POSTNATAL CARE FORWARD

Premature Newborn Existing Procedure

- Plastic Wrap
- Radiant Warmers
- Chemically Heated

Medical Procedure Before
Amnion Life Appears Archaic.



Amnion Life Introduces :
Amniobed Golden Hour

- The preterm infant is immersed in synthetic amniotic fluid.
- An ergonomic harness seat maintains the infant's head above fluid level.
- The synthetic fluid produced by the machine is dialysis grade.
- Similar to Ringer's solution, except that it matches pH and Osmolality of amniotic fluid.
- The amniotic fluid is thermo-regulated and continuously circulated and filtered.





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AMNIOBED EXPLAINED

Amniobed™ is the fluid filled incubator creating a warm and safe environment for growth and development of preterm infants.

Dialysis Grade Water Purification

Five medical grade water purification filters eliminate heavy metals, contaminants, and microorganisms from the hospital water.

Mom is Never Far Away

- Smartapp Delivers Audio and Video to Mother's Phone.
- The Newborn Can Be Comforted By the Mother's Voice.

Amniobed Hardware

- Medical Grade Heating System Keeping Fluid at 98.6 Fahrenheit.
- Computer Operated Electrolyte and Mineral Dosing Pump
- Sterile and Disposable Bath Cover and Medical Grade Infant Harness
- Chest and Pelvic Harness to Prevent Infant Submersion and Drowning
- Ergonomic Infant Bed for Comfortable Positioning
- Fluid Clarity Filter Detects Stool and Automatic Flush Bath Initiates.
- Disposable Cartridges will deliver electrolytes and mineral content.
- Medical Grade UV Filters Continuously Filtrate the Water
- Infant cap with ECG, EEG, Infrared, Skin Temperature, and O2 Saturation Sensors.





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AMNIOBED ADVANTAGE



 Lucile Packard
Children's Hospital
Stanford

UCSF

Synthetic Amniotic Fluid

- First Incubator Using Synthetic Fluid.
- Maintains Infant Temperature.

Fluid is Superior to Air as a Heat Capacity and Heat Transference Source.

Amniobed Golden Hour Eliminates or Reduces

- Transitional Hypothermia in Preterm Infants
- Environmental Heat loss and Calories loss.
- Water loss, Skin drying, Scaling, and Breakdown
- Diaper Dermatitis
- Overall Comfort Improvements

Amniobed Golden Hour : Excellence Recognized

- **2nd Place**, Cleveland Clinic AMP'D Arena 2019 Medical Innovation Summit
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AMNIOBED™ PROTOTYPE VIDEO





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TRACTION & ACCOMPLISHMENTS

AmnioBed Directed Patents

- US Patent No. 9,662,257, issued on May 30, 2017
- US Patent No. 10,166,161, issued on January 1, 2019
- China Patent No. 201680064293.7 issued January 8, 2020

Pending Foreign Patent Applications

- Europe, Japan, India, Australia, and Hong Kong.

Press Mentions

November 12, 2018, **Pittsburgh Post-Gazette**

January 23, 2019, **Seeking Alpha**

October 24, 2019, **Pharmacy and Therapeutics**

**Pittsburgh
Post-Gazette®**

Seeking Alpha^α

Pharmacy and Therapeutics

P&T

A Peer-Reviewed Journal for Managed Care
and Formulary Management Decision-Makers



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MARKET OPPORTUNITY

- **15 MM** Premature Births Occur Worldwide Every Year.
- India Leads Premature Births with **3.5 MM** a year on average.
- **6th Worldwide** the U.S. Ranks in Total Premature Births, CDC.
- Premature Birth is the **#1** cause of Infant Deaths in the United States, CDC
- Globally, the leading cause of death for children less than 5 years old, World Health Organization.
- **388,130** Premature Babies Were Born in the U.S., 2016, CDC.
- **\$43 Bn** on Premature Births, in the U.S., annually.
- **\$26 Bn**, direct cost estimation of Preterm Birth care in the NICU.
- Preterm Birth cost **\$280,811** or 9x the average infant birth costs in the United States.





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MEET THE TEAM



Amir Fassihi, MD, Chief Executive Officer

Mr. Fassihi is practicing neuroradiologist in Orange County, California. After obtaining his B.S. in Biology and Ecology from UCLA, Mr. Fassihi obtained his M.D. from UCSF.



Milos Radovanovic, Lead Engineer

Mr. Radovanovic professional experience included managing research and development, testing, production, and overseeing laboratory operations. Mr. Radovanovic maintains a BSc in mechanical engineering with nearly a decade of experience in research and development and production. Additional experience, Mr. Radovanovic has includes QA and QC in system instrumentation and automation.



Danny Chadra, Chief Compliance Officer

Mr. Chadra has 18 years experience in regulatory risk experience with R&D, Clinical Investigation, and Manufacturing. Mr. Chadra has an engineering degree from RMIT University in Melbourne, Australia and an MBA from IE Business School in Madrid, Spain.



Molly Ferris, Business Development

Ms. Ferris orchestrates regulatory and market alignment for high-growth medical device startups. Ms. Ferris is familiar with implementing sales pipelines across medical verticals.



Aleksandar Siskovic

Mr. Siskovic is a quality systems specialist and regulatory affairs consultant and certified auditor for medical device (ISO 13485), QMS (ISO 9001), information security management systems (ISO/IEC 27001), information technology service management (ISO/IEC 20000-1) and environmental management systems (ISO 14001). Mr. Siskovic is proficient in auditing, quality management systems, regulatory requirements, risk management, technical file for CE mark, software validation, ISMS, ITSM, process control, system improving, quality assurance, laboratory devices and medical device production process, in accordance to ISO 9001, ISO 13485, FDA QSR 21, CFR Part 820, ISO 14971, MD.



Michael Drues, PhD

Dr. Drues is a medical technology and regulatory strategy consultant specializing in bringing medical products to market. Dr. Drues expertise includes next step development strategies, maintaining the products are well marketed. Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. Mr. Drues has assisted, founded, and consulted leading medical device, pharmaceutical and biotechnology companies. Companies ranging in size from start-ups to Fortune 100 companies. Dr. Drues regularly consults for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world. Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. Dr. Drues conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicare Services (CMS) and other regulatory and governmental agencies around the world. Finally, Dr. Drues is an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology at several universities and medical schools.

Future Sales & EBITDA Projection

Current Market:

Total US Incubators: >20K
Total US Radiant Warmers: >30K
Rest of World Incubators: >40K
Rest of World Radian Warmers: >50K

BY YEAR 5 OF U.S. COMMERCIALIZATION

1,400 OPERATING UNITS IN U.S.
2100 OPERATING UNITS
IN REST OF THE WORLD

This slide contains future looking projections which cannot be guaranteed

\$73.7M

ESTIMATED EBIT

\$153.1M

GLOBAL REVENUE

MEDIAN EBITA TRANSACTION MULTIPLE IN MEDICAL DEVICE INDUSTRY IS 10-14X



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BUSINESS MODEL & REVENUE



Revenue Sources

- Equipment Sales to Hospitals
- On-going Revenue from Single-Use Items for Daily Bed Functions

Equipment Retail Prices

Amniobed

- Approximately \$300 Daily Revenue per Device (Single-Use Items, Maintenance Fees and Lease/Rental Fees)
- Each Bed is expected to generate \$55,000 per year in Recurring Revenue.

Amniotic Fluid Cartridge

- \$35 per Unit or per Day of Use

Sterile Bath Cover and Infant Harness

- \$145 per unit, per Day of Use

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OUTDATED RESPONSE MEASURES

100 Years.

Amniobed Provides the Most Innovative Incubator for Preterms in 100 Years. **Amniobed** Will Reduce Preterm Birth Costs Through Efficient Response. Reducing Preterm Births Demand on NICU Staffing Needs.

Aiming to Reduce Preterm Baby Deaths

- **Amniobed** Delivers a Clean, Controlled, and Post-birth Environment.
- **Amniobed** Technologically Controlled Amniotic Fluid Reduces Hypothermia Risk.

Hospital Will Purchase AmnioBed Because

- They Will Reduce Preterm Death, Hypothermia, and Other Complications.
- Will Reduce Overall Preterm NICU Staffing Demand and Associated Costs

AmnioBed is the Next Frontier in Proper NICU Care.





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PRODUCT OFFERING & DEVELOPMENT



Amniobed Golden Hour

Radiant Warmer &
Polyethylene Wrap



Amniobed TM 24 Hour

Convection Incubator



Artificial Placenta

ECMO machines for
Preterm infants

Additional Products

Amniotransport

- Infant Transport Incubator

Amnioburn

- Severe Adult Burn Patients

AmnioICU

- Adult Intensive Care Beds



Please join us as we move toward FDA Application and Europe's CE Mark.

How long is it going to take and how much is it going to cost?

2020

Preclinical Safety, Biocompatibility, Electrical, Software and Device Testing - Need \$500K-\$1M

2021

Device Ready for Clinical Trials
Clinical Trials Commence
Application for FDA and CE Mark Ready For Submission
\$1.5M to \$2.5M

2022

Manufacturing and Commercialization
\$5M-\$8M raise.



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INVESTMENT OPPORTUNITY

Raise Information

Capital Raise	\$500K - \$1MM
Funding Type	SAFE
Valuation Cap : First \$250,000	\$7.5MM
Valuation Cap : Post \$250,000	\$12.5 MM
Discount Rate	10%
Previous Raise Amount	\$1.44 MM

Funding Milestones

- Complete Pre - Clinical Device Safety
- Obtain Investigational Device Use (IDU)
- FDA Approves Clinical Trials

Use of Funds

R&D Facility for Ongoing Engineering and Pre-Clinical Safety Testing	50%
Ongoing Regulatory and Risk Management	20%
Initial Safety Clinical Trial Draft and Prep. / Early Human Trial Feasibility	10%
Company Debt	12.5%
WeFunder Intermediary Fee	7.5%



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WHY AMNION LIFE?

Nothing Matters More Than Your Children.

- Amniobed adapts
- Cutting Edge Innovation
- Decreasing Preterm Mortality and Complications in a Remarkable & Novel Way.



Additional Information

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