



Amnion Life

MEDICAL DEVICES FOR PRETERM INFANTS



OUR MISSION

Develop novel
devices to
decrease mortality
&
complications
in pre-term
infants

Amir Fassihi, MD

Founder-Visionary-Team Builder

Introducing:

Amniobed™ Golden Hour

Infants incubator with synthetic amniotic fluid intended to prevent hypothermia in preterm infants



**3rd Place (Gold Award)
2019 UCSF/
Stanford Pediatric Device
Consortium Competition**



**2nd Place (Gold Award)
2019 Cleveland Clinic
AMP'D Arena 2019 Medical
Innovation Summit**

**Member: UCSF Pediatric Device Consortium Accelerator
Amniobed™**

The Unmet Need

15 million infants are born prematurely each year across the globe. More than 400,000 of them in the United States.

Pre-Term Births Infants Require

Oxygenation
Thermoregulation
Nutrition
Fluid Management

Hypothermia is a significant risk, particularly in the first sixty minutes of life, referred to in neonatology as the 'golden hour'.



Medical Challenges in Pre-Term Births

Infants

NICU Level 3 & 4 Preemies require:

- Oxygenation
- **Thermoregulation**
- Nutrition
- Fluid Management



The Unmet Need

- Yet despite our best medical efforts
- Per CDC, Premature Birth is the #1 cause of death for infants in the U.S.
- Per WHO, it is the leading cause of death for children less than 5 years globally.
- Today, one preemie is born every minute.
- Preterm birth infants can acquire long-term health problems in their NICU stay creating a lifetime of financial and emotional costs.



Preterm infants at risk for hypothermia:

- Little insulating subcutaneous fat.
- Underdeveloped thin skin leading to significant transepidermal water loss and evaporative heat loss.
- Blood vessels close to the skin increase rate of heat loss.
- Larger skin surface area to mass ratio (3-6x term infants)
- Heat more easily lost from internal organs to skin.
- Poor mechanism for body temperature regulation. (No brown fat/ineffective peripheral vasoconstriction/no shivering mechanism)



Transitional Hypothermia in Preterm Infants

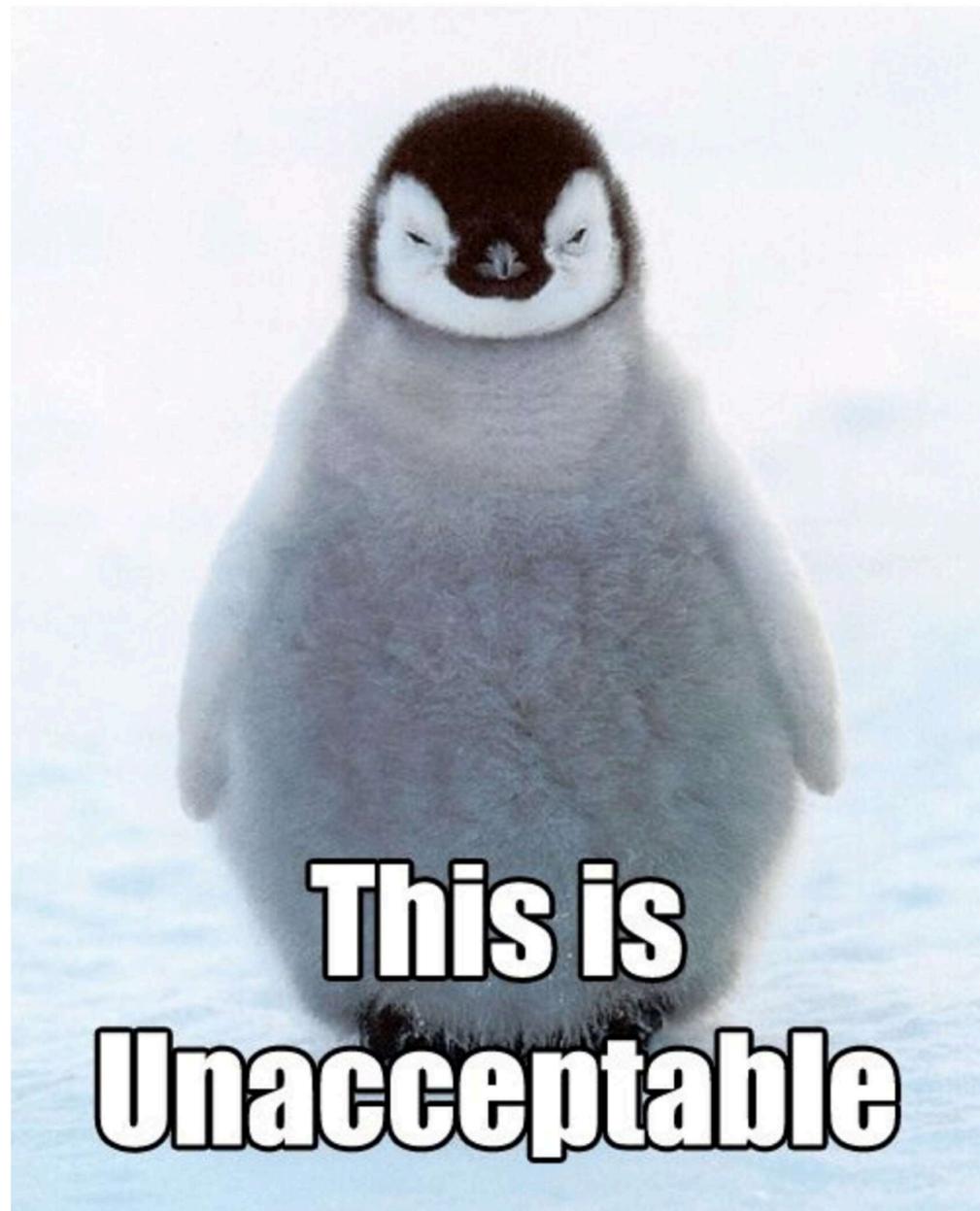
In Europe:

Study of **5697** very preterm birth infants (<32 weeks of gestation) from 11 European countries found that **53.4%** of the cohort had a body temperature at admission less than 36.5°C, and 12.9% below 35.5°C. (Wilson 2016)

In the United States:

Using data from four Kaiser Hospitals, the incidence of hypothermia on admission to NICU for infants <1500 grams was reported at **31-78%**. (Bhatt et al. 2007)

Hypothermia in preterm infants has been associated with **hypoglycemia** (Elliott 1957), **respiratory distress** and **chronic lung disease** (Boo 2013; Costeloe 2000; Pomerance 1974), **necrotizing enterocolitis** (Yu 1984), **hypoxia** and **metabolic acidosis** (Adamson 1965; Gandy 1964), **coagulation defects** (Chadd 1972), **delayed readjustment from fetal to newborn circulation** (Stephenson 1970), **acute renal failure and intraventricular haemorrhage** (Boo 2013; Miller 2011), **poor weight gain** (Glass 1968), **late-onset sepsis** (Laptook 2007), and **death** (de Almeida 2014; Elliott 1957; Miller 2011).



NICU Level 3 & 4 Preemies are

Subject to:

Hypothermia

Leading To:

Activation of sympathetic nervous system and release of norepinephrine -
Transient hyperglycemia -
Glycolysis (breakdown of sugar)– increase oxygen use – followed by hypoglycemia – lactic acidosis - hypokalemia

Directly Linked To:

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

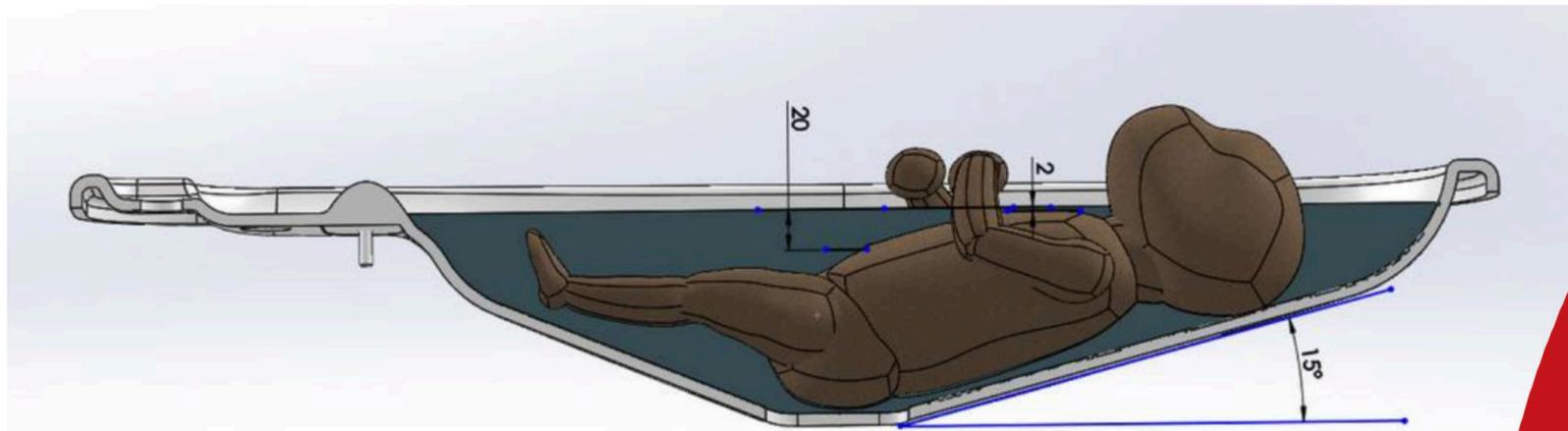


Current standard of care is the use of plastic cover, chemically heated mattress and radiant warmer during the 'golden hour of medical care after birth.



Our Solution: Amiobed™ Golden Hour

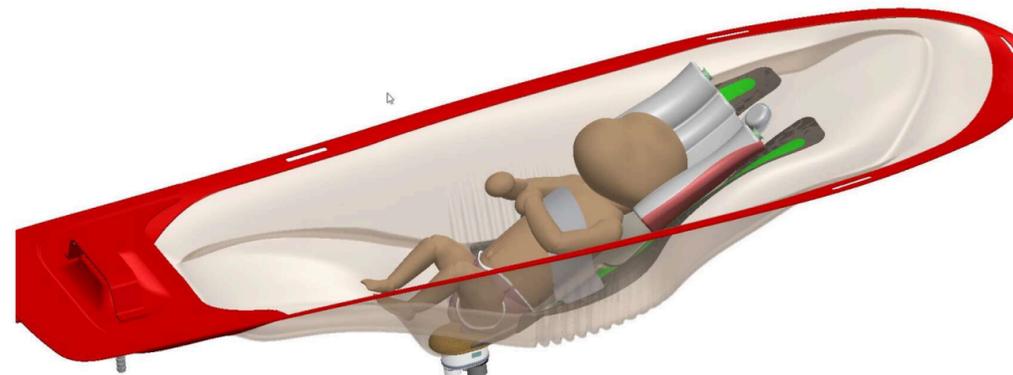
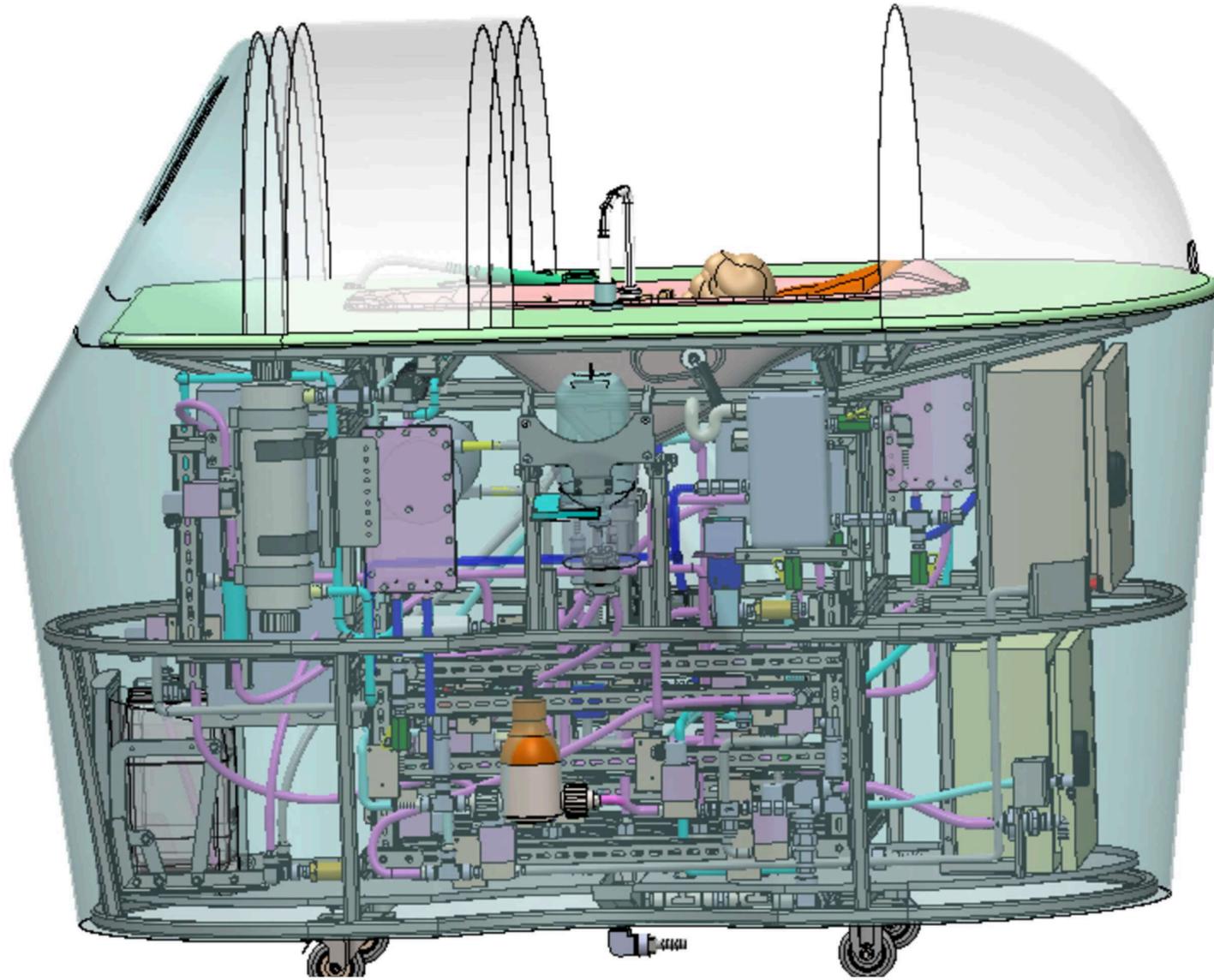
is an infant incubator as close to the mother's womb as possible



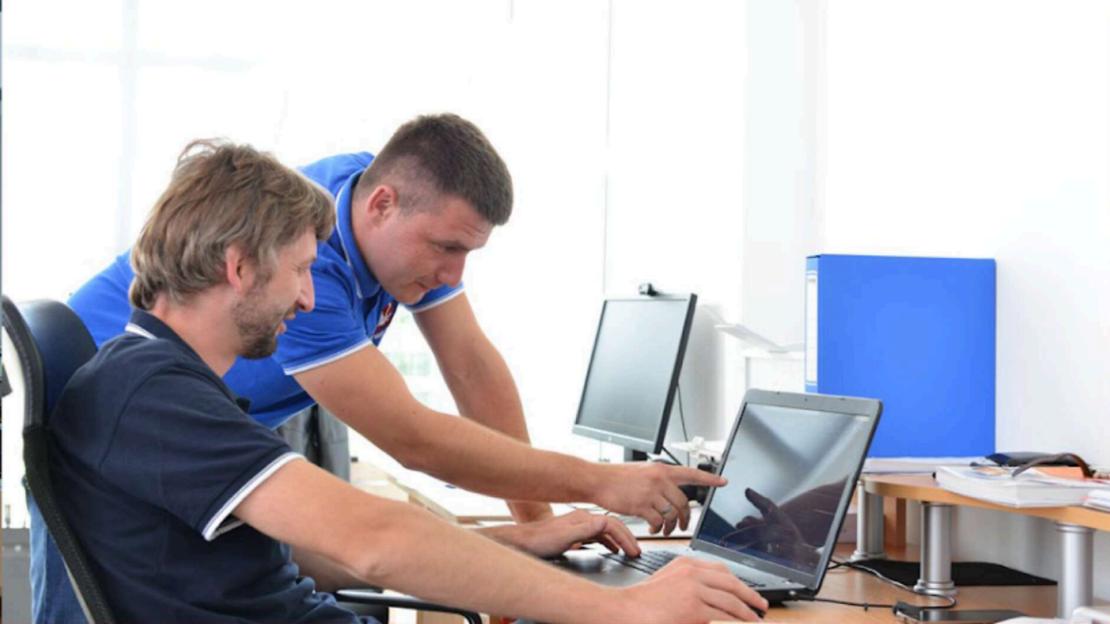
- The preterm infant is immersed in synthetic amniotic fluid and supported by an ergonomic seat with harness so that the head always remains above fluid level. The synthetic fluid produced by the machine is dialysis grade and similar in content as in Ringer's solution, except that it matches pH and Osmolality of amniotic fluid reported in literature . The amniotic fluid is thermo-regulated and continuously circulated and filtered.



Amiobed™ Golden Hour



The infant sits on a single use plastic cover. Head/scalp cap provides access for infant monitoring in addition to a barrier against heat and water loss from head and neck. Fluid level is less than 3 cm from abdominal wall and an anchor mechanism is developed to anchor the tip of umbilical cord above fluid line while central lines with splash proof covers are inserted. Thus the central lines never come in contact with the fluid.



Built an R&D Facility and Team in Serbia





Amnion Life

Amiobed™
Golden
Hour



Executive Management Team



Amir Fassihi, MD
CEO

Practicing radiologist
in Orange County,
CA

Undergraduate
education in Biology and
Ecology from UCLA

Obtained
M.D. from
UCSF



Milos Radovanovic
LEAD ENGINEER

Manager of R&D,
testing, production,
and laboratory

BSc Mechanical
Engineering

Nearly a decade of
experience in R&D
and Production,
as well as QA/QC

Experience in system
instrumentation
and automation



Molly Ferris
BUSINESS DEVELOPMENT

Orchestrates regulatory
and market alignment
for high-growth medical
device startups

Implements sales
pipelines across
medical verticals



Danny Chadra
CHIEF COMPLIANCE OFFICER

18 years experience in
regulatory risk

Experience with R&D,
Clinical Investigation,
Manufacturing, and more

Engineering degree
from RMIT University
in Melbourne, Australia
and an MBA from IE
Business School
in Madrid, Spain



Michael Drues, PhD

Michael Drues, Ph.D., is a medical technology and regulatory strategy consultant specializing in bringing medical products to market in creative and innovative ways and keeping them on the market once they get there. Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis 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. He 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 Medicaid 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. He regularly teaches graduate courses in Regulatory Affairs and Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs and Product Development, Combination Products, Pathophysiology, Medical Technology, Translational Medicine and Biotechnology



Aleksandar Siskovic

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).

Quality System

Auditing, Medical device, Quality Management Systems, Risk Management, Regulatory Requirements, Technical File for CE Mark, Software Validation, ISMS, ITSM, Process Control, System Improving, Quality Assurance process of production medical devices and laboratory devices in accordance to ISO 9001, ISO 13485, FDA QSR 21 CFR Part 820, ISO 14971, MD

BUSINESS MODEL

Incubator Hardware Sales



\$80K each
or lease option

Recurring Revenue Consumables



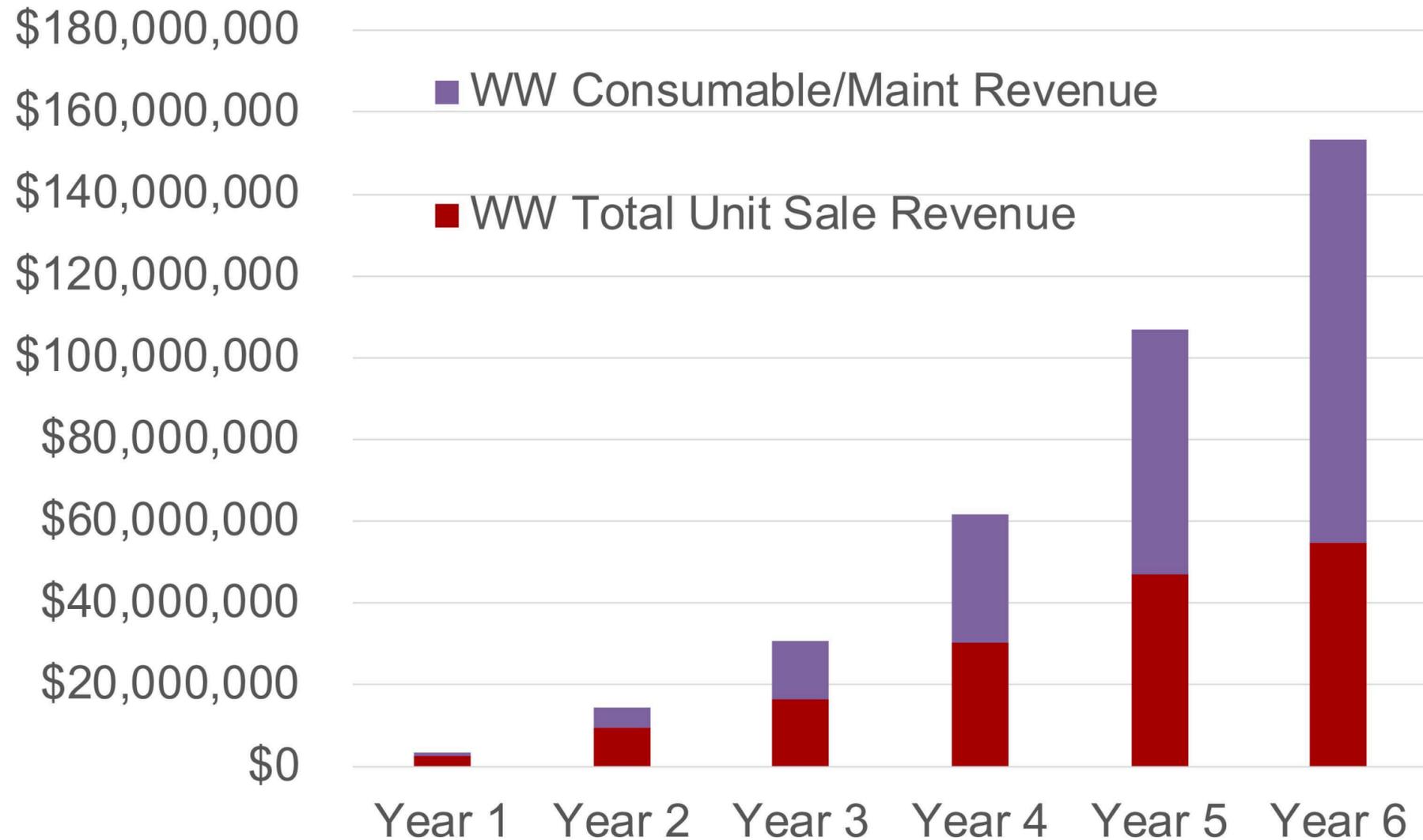
\$300 per day of use
\$55,000 per unit per
annum

This slide contains future
looking projections which
cannot be guaranteed



Future Sales & EBITDA Projection

Worldwide Unit & Consumable Revenue



This slide contains future looking projections which cannot be guaranteed

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 UNITS IN U.S.
2100 UNITS
IN REST OF WORLD

\$73.7M
 ESTIMATED EBIT

\$153.1M
 GLOBAL REVENUE

Product Roadmap

Products in development or planned

1



Amniobed™ Golden Hour



Radiant Warmer/Polyethelene Wrap

2

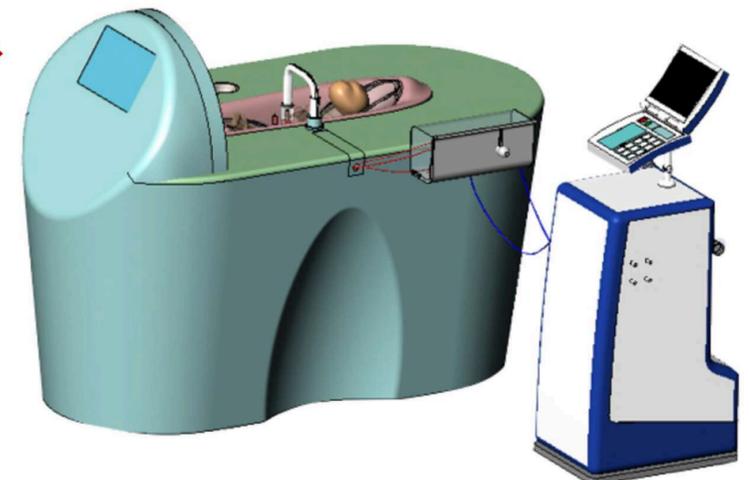


Amniobed™ 24 Hour



Convection Incubator

3



Artificial Placenta



ECMO machines for preterm infants



1. Amniotransport - Transport infant Incubator

2. Amnioburn - Severe adult burn patients (30,000 Americans/year)

3. AmnioICU – Intensive care beds for adults

We are Currently Raising a Seed 3 Round of \$535,000

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

2021

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

2022

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



This slide contains future looking projections which cannot be guaranteed

Our Story

Born from a direct experience with pre-term birth



- A cousin's 3-year-old girl was born very preterm leading to a long NICU stay with complications.
- She experienced ocular and neurodevelopmental injuries.
- As a result, she needs continuing, long term, daily assistance.
- This creates substantial, long term, financial and emotional costs.



Amnion Life

ME

Join us as we proceed to clinical trials and FDA
Application

For investment information, please contact:

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www.amnion.life



Appendix

Join us as we proceed to clinical trials and FDA
Application

For investment information, please contact:

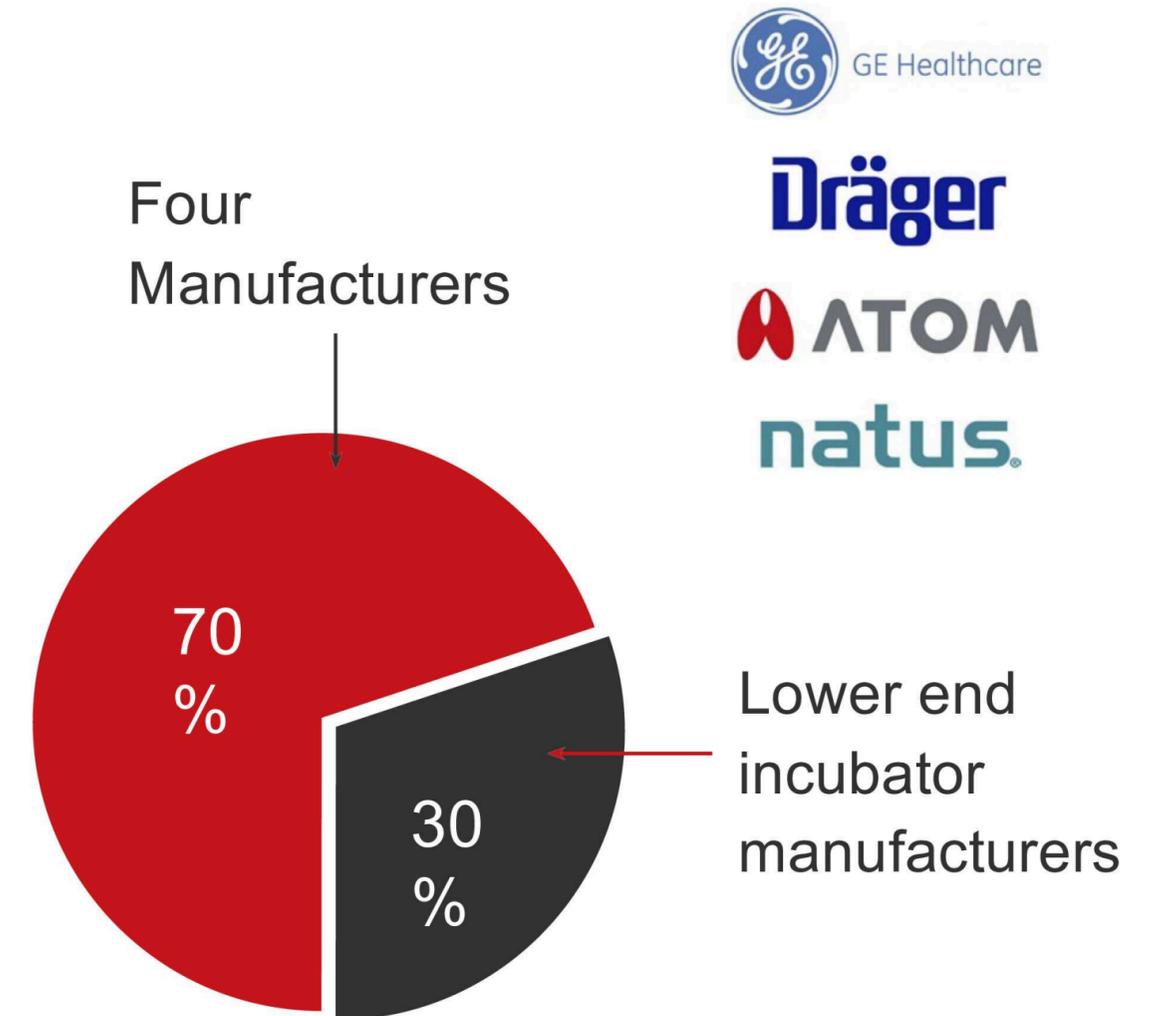
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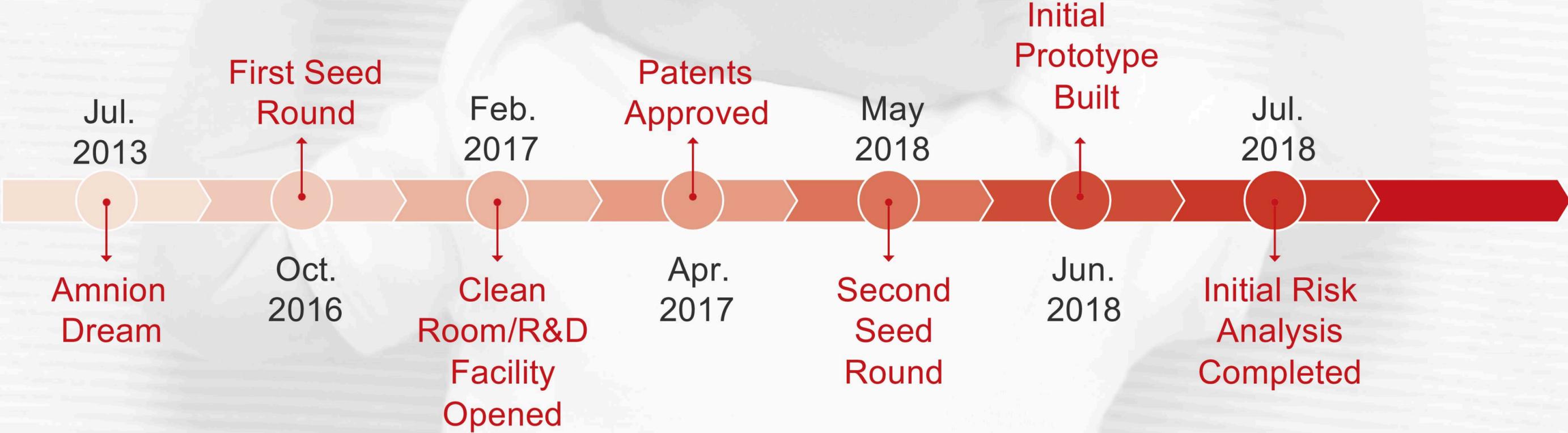
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Competition and Potential Acquisition Partners

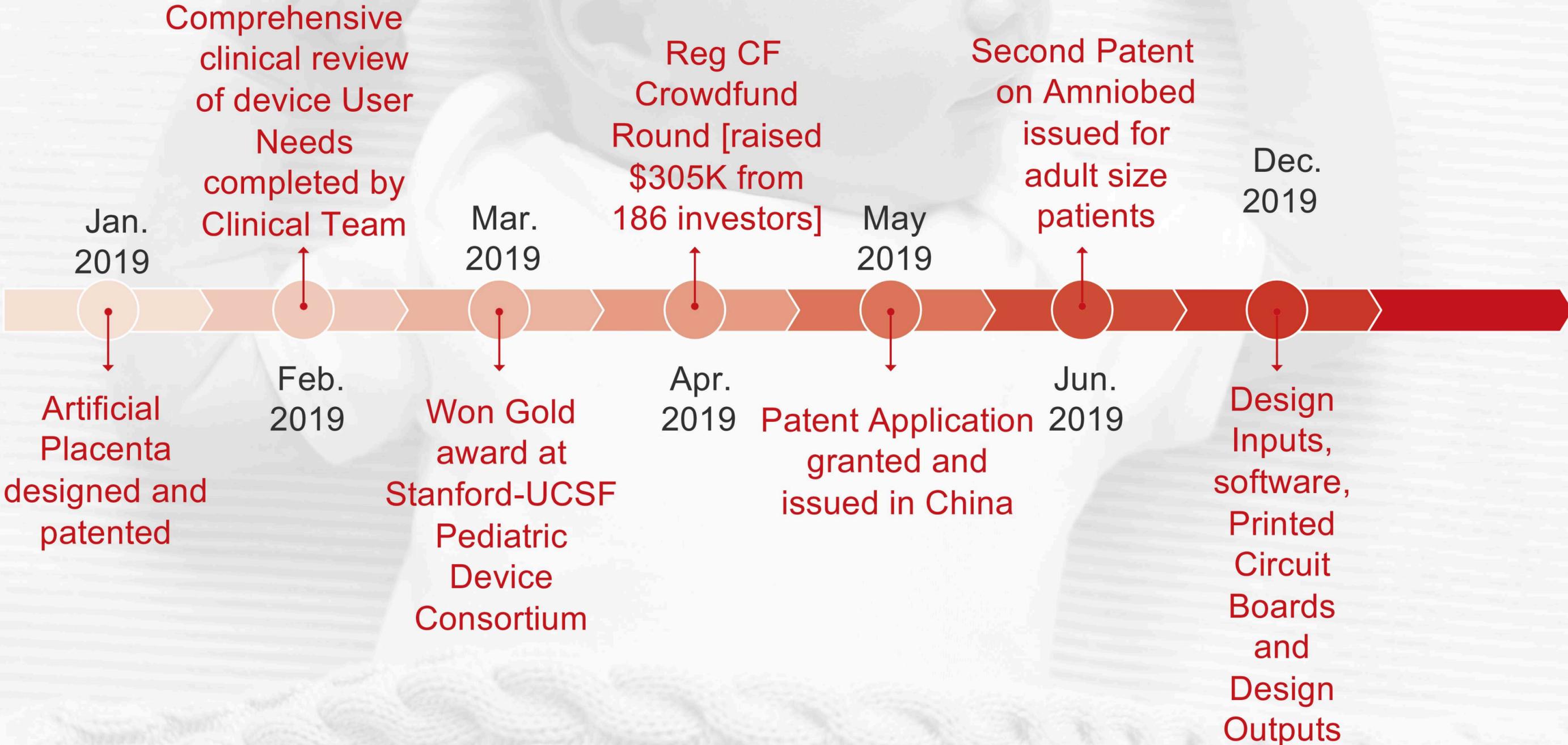
Incubators currently on the market are outdated (100+ years old)



Milestones



Milestones 2



What is Amniotic Fluid?

- Amniotic fluid is the protective liquid bathing the fetus during pregnancy. Amniotic fluid serves as heat reservoir for thermoregulation, a reservoir for absorption of water by the fetus (intramembranous pathway) and creates an environment for fetal movement and comfort.
- Amniotic Fluid helps to maintain fetal environment temperature.
- Amniotic fluid contains electrolytes, proteins, peptides, lipids, lactate, pyruvate, enzymes, hormones and amniotic stem cells.
- Source of amniotic fluid is through combination of excretions from fetal kidneys, respiratory system, gastrointestinal system and surface of the placenta.
- Several growth factors or cytokines have also been discovered within amniotic fluid.

Benefits:

- Reduction or eliminate of transitional hypothermia in very preterm infants (Up to 50% global incidence).
-
- Reduction in environmental heat loss/calories loss.
- Reduction of water loss, skin drying, scaling and breakdown as well as diaper dermatitis.
- Improvement of overall comfort.



Extent of Problem

- **Transitional hypothermia in preterm newborns** D R Bhatt *Journal of Perinatology* volume 27, (2007)
- Using data from four centers, we documented an incidence of hypothermia on admission to the neonatal intensive care unit from the delivery room of 31–78% for infants <1500 g birth weight.
- **Admission Hypothermia in Very Preterm Infants and Neonatal Mortality and Morbidity** E Wilson *The Journal of Pediatrics* Volume 175, August 2016 - Effective Perinatal Intensive Care in Europe (EPICE) Research Group
- In this cohort study from 19 regions in 11 European countries, we measured body temperature at admission for infants admitted for neonatal care after very preterm birth (<32 weeks of gestation; n = 5697) who were followed to discharge or death.
- A total of 53.4% of the cohort had a body temperature at admission less than 36.5°C, and 12.9% below 35.5°C. In the adjusted model, an admission temperature <35.5°C was associated with increased mortality at postnatal ages 1-6 days, (risk ratio 2.41; 95% CI 1.45-4.00), and 7-28 days (risk ratio 1.79; 1.15-2.78)

Physiology of Thermal Response in Infant

Thermal response in infant prematurely exposed to cold nursery environment mediated primarily through the sympathetic nervous system and release of norepinephrine.

Vasoconstriction in deep dermal layers is the earliest response reducing blood flow to the skin creating a insulation between the core and the environment.

Reduced subcutaneous fat in preterm infants diminishes this effective insulating property.

Brown fat provides a source of non-shivering thermogenesis in newborns.

However preterm infants have little to no brown fat and may not be capable of any more than 25% increase in metabolic rate despite the most severe cold stress.

Control of voluntary muscle tone, posture and increased motor activity may serve to augment heat production in skeletal muscle but this mechanism is limited in preterm infants.

Glycolysis (breakdown of sugar) may also be stimulated during extreme cold stress from epinephrine release from adrenal glands which may result in transient hyperglycemia.

Overall, thermal response in preterm infants is extremely limited and these infants are particularly vulnerable to cold stress.
