

# Amniobed, a Ground-Breaking Medical Device to Save Preterm Infants Lives

PITCH VIDEO INVESTOR PANEL



amnion.life Newport Beach CA  

Hardware Main Street Technology Healthcare R and D

## Highlights

- 1 In Amniobed, the preterm infant is partially submerged in synthetic amniotic fluid.
- 2 Amniobed is intended to prevent hypothermia in preterm infants and decrease environmental heat loss.
- 3 Hypothermia leads to poor medical outcomes and an increased chance of infant death.
- 4 Strong patent portfolio with multiple patents in the US, China, and Japan and pending in Europe.
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- 5 Studies have shown 40% of infants admitted to the NICU from L&D are hypothermic in 1st hour of life.
- 6 Significant calorie loss in the NICU leads to diminished weight gain and longer hospital stays
- 7 3 Years of R&D. Designed, sourced, procured, and assembled Amniobed Golden Hour plus software.
- 8 The project was placed on pause in 2020 due to COVID-19. Raising capital to finish the prototype.

## Our Team



**Amir Fassihi** Founder and CEO

Medical Doctor. Radiologist/Neuroradiologist. Attended UCLA-UCSF-USC/Keck. Author of multiple patents on Amniobed. Founder and visionary behind Amnion Life.

There are shortcomings in medical devices for preterm infants who should be undergoing the third trimester of pregnancy. The current technology is inadequate in replicating a mother's womb, leading to medical complications and death. Amniobed is designed to enhance medical care and give these infants a better chance for a healthy life.



**Michael Druess, PhD** Regulatory Advisor

Dr. Druess is an internationally recognized expert on cutting-edge medical technologies and regulatory affairs. He has worked for and consulted with leading medical device companies ranging in size from start-ups to Fortune 100 companies.



**Molly Ferris** Consultant for Product Rollout, Marketing, Sales

20 years of expertise in device strategic planning, pre-commercial regulatory, market-entry alignment for high-growth medical device startups Experience sales pipelines across medical device verticals.



**Aleksandar Siskovic** Quality Manager

Graduated Engineer of Electronics with more than 12 years of experience in QMS and practical experience in medical areas. Certified Auditor: ISO 13485, ISO 9001, ISO 14001, ISO/IEC 27001, ISO/IEC 20000-1, ISO 37001.

## Giving premature infants a better chance at life



**AmnionLife**

Medical devices for pre-term infants



Amnion Life LLC has the mission to develop novel devices to decrease mortality & complications in preterm infants. As part of its mission, Amnion Life is developing the Amniobed™ - a novel, patent-protected

, neonatal incubator system intended to recreate the core conditions of an in-womb environment. Amniobed can provide a more natural incubator environment for continuous critical organ development, improve preterm infants' thermoregulation and fluid management, and help prevent hypothermia in critical care settings.

#### Reasons to Invest

- Protected by multiple issued patents in the US, China, Japan, and pending in Europe.
- Successful earlier rounds of over \$1.8M in investment and crowdfunding.
- Lead by our founder Amir Fassihi, M.D., an experienced neuroradiologist, our team is made up of experts in regulatory matters (particularly applications to the FDA), medical device commercialization and roll-outs, QMS implementations, and European regulatory affairs.

#### Giving premature infants a better chance at life

At Amnion Life, our mission is to develop novel devices to decrease mortality & complications in preterm infants.

Our patent-protected flagship product, the AmnioBed™[1] is a neonatal incubator system utilizing a proprietary, synthetic amniotic fluid, intended to create an environment that more closely resembles a mother's womb to encourage ongoing, and critical development. The technology is designed to protect, hydrate, and nourish these vulnerable newborns, providing safety and comfort during their most sensitive, vital hours.

### As Close To Mom As We Can Get



*The above is a rendering of a future Amniobed. Images are computer-generated demo versions. The product is still currently under development.*

## Increasing Survivability And Thrivability For Preterm Infants





**Amniobed  
Golden Hour**



**Amniobed TM  
24 Hour**



**Artificial  
Placenta**

## **THE PROBLEM**

**Premature birth is the #1 cause of infant mortality across the globe**

In the United States and across the world, one out of every ten infants born is preterm —and each and everyone requires immediate attention.[2]According to the World Health Organization, premature birth is the leading cause of death for children under five years old across the globe.[3]For those who do survive early infancy, inadequate treatment in the first days and weeks of life can put them at risk of long-term health problems, leading to a lifetime of emotional and financial challenges.[4]



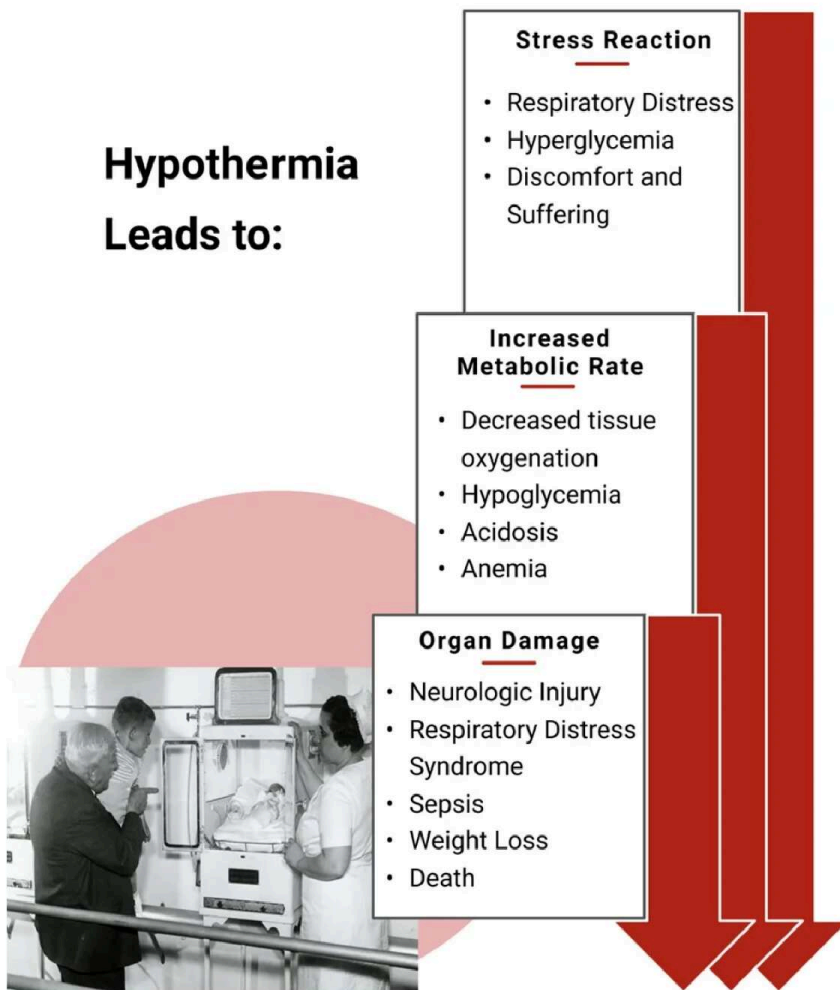
**Premature Birth Is  
The Leading Cause  
Of Death For  
Children Under  
Five Years Globally**

[6]

Preemies, due to their heightened sensitivity, are very susceptible to heat loss, resulting in possible hypothermia and dehydration. This, in turn, can introduce other ailments such as weight loss, brain hemorrhage, hypoglycemia, and sepsis. In the first critical hour of a preterm infant's life, he or she is at significant risk of

what is called "transitional hypothermia." [7]

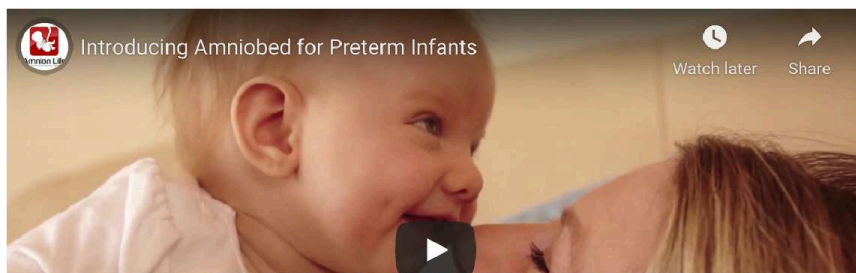
An infant may ultimately end up spending over 100 days in the NICU.[8] The overall impact can be devastating, and current health technologies for addressing the issue are inadequate.

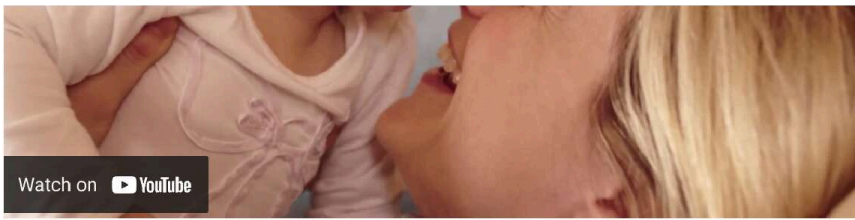


#### THE SOLUTION

Patent-protected technology that keeps preemies safe, warm, and stabilized after birth

The Amniobed is designed to improve health outcomes for preterm infants while also reducing their time spent in the NICU. We've created a revolutionary proprietary medical technology that leverages the power of fluid as a source of heat regulation, transfer, and hydration. Designed to replace current incubators, wraps, and warmers, the Amniobed partially surrounds a preterm infant in synthetic amniotic fluid to simulate the womb, thereby easing their transition into the world.





**Amniobed™ Golden Hour** - is intended to replace the use of radiant warmer/plastic wrap in the labor and delivery room to allow optimal temperature regulation of the infant immediately upon birth and to prevent transitional hypothermia very preterm and extremely preterm infants).



**Amniobed™ 24Hour** - is intended to replace convection incubators for use in the NICU for up to 28 days. It is intended to improve temperature regulation, fluid management, skin protection and general comfort for preterm infants.

This leads to healthier babies and substantial reductions in both short-term and long-term emotional and financial stress for everyone involved.

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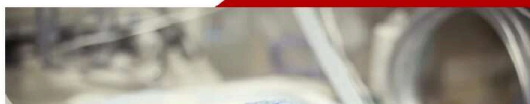
## THE MARKET

### Billions of healthcare dollars are spent on preterm infants

The US spends over \$26 billion each year on costs associated with premature births.[9]The average cost per day for an infant in the NICU exceeds \$3000. [10]Extremely preterm infants can spend 110 days or more in intensive care[11]—earning them the nickname “million-dollar babies.”[12]

There are 985 NICU facilities in the US[13]with 22,721 total beds[14], serving the hundreds of thousands of preterm infants in the US each year. The US is in the world’s top 10 based on its number of premature births, with the overall global estimate for premature births per year tallied at 15 million.[15]

The U.S. Spend On



Premature Births

**\$26 Billion  
Per Year**



[16]

#### OUR TRACTION

Award-winning medical innovations

Amnion Life has been thrilled to receive multiple Gold Awards for our flagship Amniobed, including second place in the 2019 Cleveland Clinic AMP'D Arena Medical Innovation Summit and third place in the 2019 UCSF/Stanford Pediatric Device Consortium Competition. We've secured multiple issued U.S. utility patents, with several foreign patents pending.



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

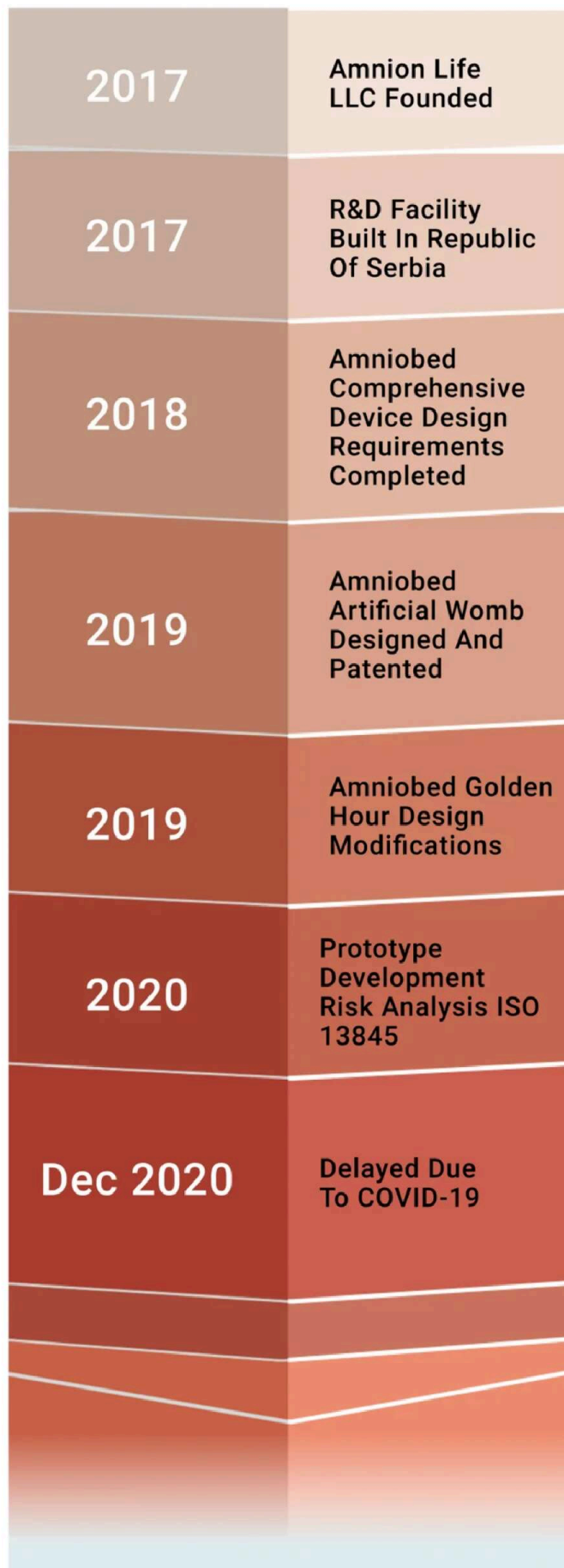
Member: UCSF Pediatric Device Consortium Accelerator  
Amniobed™

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This round of funding will enable us to perform pre-clinical verification, usability testing, and pilot studies. The Amniobed will then be ready for clinical trials, FDA and CE mark approval, and from there, manufacturing and commercialization.



## Raised \$1.8M Through Accredited Investors And Crowdfunding

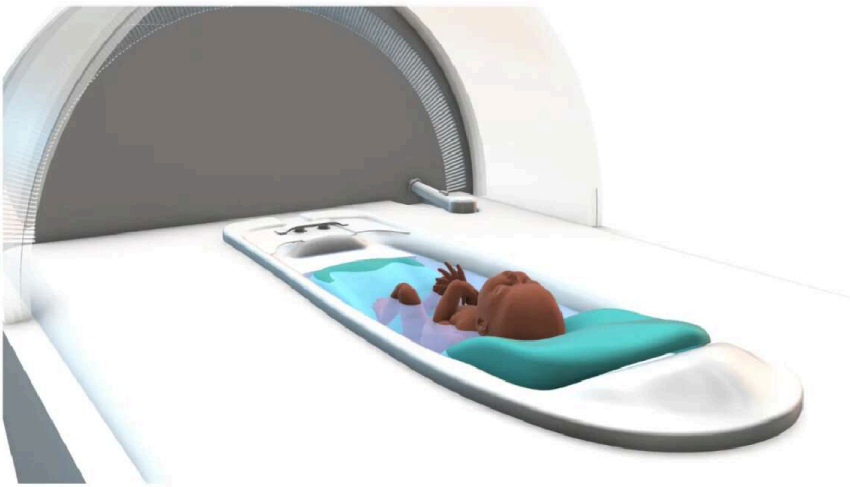




## WHAT WE DO

### We're building a much better incubator

The Amniobed™ is a rigorously researched and carefully designed incubator that partially submerges the infant in fluid. Our uniquely crafted synthetic fluid mimics a mother's amniotic fluid in temperature, electrolyte balance, pH, and minerals. The Amniobed was conceived with particular consideration to an infant's first hour of life, at which point they are especially vulnerable. As premature infants make the dramatic transition from amniotic fluid to air, they are at elevated risk of hypothermia and dehydration. Negative outcomes during this first "golden" hour of life are associated with higher incidences of mortality, as well as the development of comorbidities and long-term disabilities.



## Amniobeds Provide Infants With



Thermoregulation



Fluid Management

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The infant is safely supported by an ergonomic seat and harness, which ensure the head is always above the level of fluid and allow movement of the arms and legs. The infant is also outfitted with a cap that tracks skin temperature and contains an electrocardiogram. A 24/7 audio and video feed connects to a smartphone app for remote observation at all times, allowing the mother and/or other caregivers to talk directly to the baby.





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## **THE BUSINESS MODEL**

### **Equipping hospitals across the world with our state-of-the-art Amniobed**

We are pursuing a model that enables hospitals access to Amniobed either for purchase or lease. We project an average selling price of \$150,000 per unit in the US and at a discount in Rest of World, and will also offer a leasing option accompanied by lower upfront costs.

Our model plans to have recurring revenue through a \$150-\$250 price per use fee for supplies such as the amniotic fluid cartridge and sterile cover. Each Amniobed can be used >300 times per year meaning we can generate greater than \$60,000 revenue per device.

Cost of Goods Sold is estimated at \$45,000 for parts and \$1600 for labor for assembly. The Company estimates approximately \$25,000 to \$37,500 in costs associated with sales and distribution of each unit and \$5000 for shipping and installation.. The costs of goods sold for daily supplies is estimated at \$50 per unit use. Total cost for each unit is estimated at \$76,600 to \$89,100 per unit. Thus the Company estimates margins of 40% on capital equipment costs and margins >70% for supplies.

### **Regulatory Strategy**

We have developed a network of medical device professionals and resources in the Republic of Serbia, Macedonia and Bulgaria. Bulgaria is part of European Union and has a Notified Body. As such, we intend to seek CE Mark approval for marketing and sales of Amniobed Golden Hour and Amniobed 24Hr in Bulgaria.

Once we have regulatory approval for Amniobed Golden Hour in the European Union, we plan to seek distribution partnerships in the EU, followed by distribution partnerships and regulatory applications in U.K, Canada and Australia, followed by Israel, UAE and SA the Middle East and China, S. Korea

and Japan in the far East. We also intend to design and develop a lower cost Amniobed for India and developing countries.

We intend to submit a Presub Application to the FDA upon reaching Design Freeze and will be in close coordination with the FDA as Amniobed is approved and utilized worldwide. The Real World Data generated is intended to be used to prove safety and efficacy of the device for our application to the FDA.

Similar to Amniobed Golden Hour, Real World Data (ROW) from use of Amniobed 24HR will be used to prove safety and efficacy of the device to the FDA. Thus, it is expected that FDA approval will lag ROW approval by at least one year.

#### **HOW WE ARE DIFFERENT**

**Amniobed will be the incubator that recreates a fluid environment**

Convection-warmed incubators, which rely on artificial humidification, can take up to one hour to reach optimal temperature and humidity levels. Their incubator ports are opened and closed as often as once an hour, allowing in drafts of cold, dry air and subsequent temperature fluctuation. The box-like design can result in pressure sores and skin injuries, and is not well suited for keeping infants with very low birth weights warm. Radiant warmer beds, on the other hand, distribute heat unevenly across an infant's body parts and can result in excess evaporative water loss in addition to skin injuries.

Our Amniobed replaces humidified incubators, plastic wraps, radiant warmers, and chemically heated mattresses with a holistic system that reduces the risk of hypothermia and dehydration. Our fluid-based technology regulates temperature, reduces friction, and enables body movement, all in a safer, more comfortable, and more comforting way.



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## **THE VISION**

### **The new standard for intensive care**

Amnion Life is ready to revolutionize modern intensive care. Stationed in hospitals across the world, the Amnionbed will transform the quality of care and patient outcomes in the NICU, improving the immediate and long-term health of preterm infants. In doing so, we will be reducing the time, cost, and intense emotional distress associated with drawn-out hospital stays for families and their preemie newborns, as well as hardworking healthcare workers.