

Amnion Life

Hardware Technology Medical Device Immigrant R and D

Innovative medical devices for preterm infants - Building an artificial womb

f @ AMNION.LIFE NEWPORT BEACH CALIFORNIA



A little girl in our family was born extreme preterm and spent months in the NICU. Complications from her preterm birth led to life long neurodevelopmental and ocular injuries. Soon after seeing her, I had a dream that preterm infants suffer and need a fluid environment life similar to their mother's womb. I soon became obsessed and passionate.

Amir Fassihi Founder and CEO @ Amnion Life



UPDATES ¹⁵

ABOUT

GRAPEVINE ¹⁵

ASK A QUESTION ¹⁹

Why you may want to support us...

- 1 Raised \$1.44M in previous rounds.
- 2 Key innovation: partially submerging infant in synthetic amniotic fluid that replicates the temperature and environment of the womb.
- 3 3 Years of R&D. Designed, sourced, procured and assembled Amniobed Golden Hour plus software.
- 4 Patents issued in the US [2 patents] and China. Pending in Europe, Japan, India and Australia. US patent issued on artificial placenta.
- 5 25% - 78% of very preterm infants in the US and 53% of very preterm infants in a large European study had hypothermia in 1st hour of life.
- 6 Hypothermia in the first hour of life is associated with increased rate of mortality and morbidity.

Our Team

AND OUR MAJOR ACCOMPLISHMENTS



Amir Fassihi
Founder and CEO



Founder and CEO

Radiologist. MD from UCSF. Author of 2 patents on Amniobed and a patent on Artificial Placenta. Founder and visionary behind Amnion Life



Milos Radovanovic

Lead Engineer

Expert in engineering design, prototyping & initial fabrication, testing, installation, production



Milija Topalovic

Electrical Engineer

8 years experience in designing sensors and electronic components, Expertise in sensor physics



Molly Ferris

Business & Market Development Consultant

Expertise in strategic planning, pre-commercial regulatory, market entry alignment, medical industry



Radovan Bojovic

Mechanical Engineer

Drafting Mechanical Engineer, 30+ years experience in the design of machines/equipment, CAD Design



Evan Fisher

Unicorn Capital - Partner

Advises on strategic issues and capital raising. Raised \$80+ million throughout career.



Brad Ryan

Management Team

Experience managing business operations in tech and entertainment.



Jennifer Knapp

WSGR - Law Firm

Attorney with WSGR who represents life sciences companies.



Sean Mahsoul

WSGR - Law Firm

Sean Mahsoul is an attorney in the Palo Alto office of Wilson Sonsini Goodrich and Rosati.



Mohamed Zitouni

Procurement and Supply Chain Specialist

17 years experience in supply chain, Focus on technology, consumer products, and industrial systems



Joginder Mittal

Risk Management and Analysis, Hazard Identification

Pharmaceutical/Medical Device Consultant, 15 years experience implementing Quality Management System



Mohamed Hamed, M.D., PhD

Neonatologist

PhD Pediatrics and Neonatology from Nagoya City University.



Michael Narvey, M.D.

Neonatologist

Section Head of Neonatology and Med Director of Child Health Transport at Uni Alberta in Edmonton.



Nathan Wolf



Nathan von

Clinical Consultant

Medical technology, regulatory, performance analytics consultant. BS Biomedical Engineering.



Joe Kaur, M.D.

Research Assistant

MD in Physiology and M.D. in Psychology.



Danny Chadha

Regulatory Consultant

18+ years in management of global regulatory risk and small to large teams.



Michael Drues, Ph.D.

Regulatory Consultant

Specializes in bringing medical products to market, Ph.D. in Biomedical Engineering



Hani Sharestan

Accountant/CPA

Partner at Wright Ford Young & Co.

Some of our investors

WE'VE RAISED \$1,636,545 FROM 184+ INVESTORS SINCE OUR FOUNDING



Leonard Helbig

Retired Commercial Real Estate Executive



Babak Kamkar

Inventor, optometrist, expert witness, businessman.



Stephen Persons

Nobody exciting. Just someone looking to invest in some interesting stuff.

SEE MORE

Downloads

 [Amnion Life Pitch Presentation v1.pdf](#)

Premature Birth is the #1 Cause of Infant Death

Current incubators aren't good enough.

Every year, 15 million babies are born before their due date. With very thin skin, little

subcutaneous fat, and underdeveloped organs, preterm infants are highly vulnerable to heat loss, which can lead to hypothermia, a drop in their core body temperature of more than one degree Celsius. Hypothermia in preterm infants is a serious concern which can lead to significant stress reaction and is directly associated with subsequent increased incidence of brain hemorrhage, sepsis, convulsions, respiratory distress, anemia, periventricular leukomalacia, apnea, necrotizing enterocolitis, meningitis, bronchopulmonary dysplasia and death.

In the U.S., complications from premature birth is the leading cause of death for infants.

The first hour of care in the field of neonatology and trauma is called the 'golden hour'. Proper medical care in first sixty minutes after trauma or birth is highly consequential in determining the short term and longer term outcomes. Infant hypothermia in the golden hour of care is called 'transitional hypothermia' and is a great medical concern. In large European and American studies, the incidence of 'transitional hypothermia' in very preterm infants has been reported as much as %53 and as high as 78% in extreme preterm infants. (Wilson et al. 2016) (Bhatt et al. 2007)

Transitional Hypothermia in the golden hour is linked to increased chance of negative outcomes above and increased chance of subsequent infant death. It can be and it must be prevented.

Amniobed Golden Hour is the first incubator utilizing synthetic amniotic fluid designed to prevent transitional hypothermia in preterm infants.

15M

Babies born
premature every year
worldwide.

\$43B+

Spent annually in the
U.S. alone caring for
premature infants.

\$4,000

Average cost per day
for an infant in the
NICU.



The Solution: AmnioBed

We believe we can build a better incubator. Our patented solution, the AmnioBed, recreates the natural in-womb environment to nurture critical ongoing development, decreasing the short and long-term complications common in premature births.





How it Works

AmnioBed is a new approach to incubation. We submerge the infant partially in specially crafted fluid that mimics a mother's amniotic fluid in temperature, electrolyte balance, and minerals. This way, the infant can stay warm immediately upon birth in a fluid environment just like they would in the womb, instead of use of humidified incubators or radiant warmers.



5 medical-grade water filters eliminate heavy metals, contaminants, and bacteria.



Heats water on-demand to 98.6°F.



Dosing pump mixes calculated electrolyte solution based on infant's age.



A safety chest and pelvic harness keep the infant's head above water.



Audio and video feed so parents can talk to and monitor the infant.

Caution - Investigational Device, Limited by Federal (or United States) Law to Investigational Use.

Our Journey

Over the last year, CAD drawings were made, parts were sourced and procured, and the first prototype was completed in April 2018. Over the next six to 12 months, AmnionLife plans to heavily test the AmnioBed prototype. It may take more than two years to know if the AmnioBed is a safe, effective, and superior product which may be adopted by the market.

April 2016

Founded Amnion Life

October 2016

1st Round Seed Funding Secured

With funds raised, began R&D and feasibility study.

February 2017

Built R&D Facility in Serbia

April 2017

Secured U.S. and International Patents

April 2018

April 2018

2nd Round of Seed Funding Secured

June 2018

Prototype Built; Initial Tests

July 2018

Initial Risk Analysis

December 2019

Pre-clinical Safety and Device Usability Testing

Prep device for clinical trials.

March 2020

Begin Clinical Trials

December 2020

Apply for FDA Approval and CE Mark

Other Applications of Our IP

We're currently designing a second, complementary device, which will connect to the infant's umbilical vessels to provide nutrition and oxygen, mimicking the way infants are fed in the womb. Later on, we want to build an AmnioBed for adults to address issues nursing, pressure sores, bed sores, and ulcerations in the back in long-term care and burn units.

Dear Investors,

Nothing in the world is as precious as life. When a new infant is born, as a society, we take collective responsibility to protect their lives and ensure the necessary resources for a nourishing and comfortable environment are in place. Our infants and children are vulnerable - they require and deserve tremendous care. Specifically, preterm infants are the most vulnerable, and therefore require the greatest care.

Preterm infants have bodies accustomed to and in need of the warm and nourishing world of amniotic fluid. Often, they cannot survive without great effort to keep them warm and nourished. Virtually any environmental issue during this early stage has the potential to lead to life-long difficulties and disabilities. To date, our health care system has done a

Investor Q&A

What does your company do? ▾

— COLLAPSE ALL

Nearly 15M infants worldwide are born premature. Due to underdeveloped organs, the dramatic shift from amniotic fluid to air puts them at risk for hypothermia, dehydration, and infections which can lead to sepsis, organ injuries, and even death. To substantially improve preterm infants' chances of survival and reduce the time needed in intensive care, we designed AmnioBed, a patented, cost-efficient, fluid-filled solution that can mimic a mother's amniotic fluid environment.

Where will your company be in 5 years? ▾

The world is in desperate need of more sophisticated infant care. Despite ongoing technology advancements, current incubators and radiant warmers have many deficiencies that put preterm infants at risk for hypothermia. We believe our patented AmnioBed design can prevent hypothermia and save lives, reduce complications, improve short- and long-term outcomes, and decrease costs for millions of infants born preterm every year.

Why did you choose this idea? ▾

A little girl in our family was born extreme preterm and spent months in the NICU. Complications from her preterm birth led to life long neurodevelopmental and ocular injuries. Soon after seeing her, I had a dream that preterm infants suffer and need a fluid environment life similar to their mother's womb. I soon became obsessed and passionate.

What is Amnion Life? ▾

Amnion Life is a medical device company developing novel and innovative products to decrease morbidity and mortality in preterm infants, particularly very preterm and extreme preterm infants. Upon preterm birth, these infants are vulnerable and susceptible to hypothermia and organ injuries due to oxygenation and nutrition difficulties. We aim to create medical devices that are closer to the environment they resided in before birth to eliminate hypothermia and ultimately replicate the oxygenation and nutrition mechanism in the womb through an artificial placenta.

What is your background? ▾

I'm a medical doctor. I went to UCLA for my undergraduate work and to UC San Francisco for medical school. I went to Keck USC to do a specialty in radiology, and later a sub-specialty in neuroradiology. I am a practicing radiologist.

Why did you create Amnion Life? ▾

On a long family trip, after visiting a family with preterm infant, I had a dream where an imaginary medical school classmate told me that his daughter was born preterm and she suffered in the NICU and should have been in synthetic amniotic fluid. He said in the dream that he is developing a device for it. I told him, "that's great, I wish I had thought of it, I would have pursued it. what are you calling it?" He said Amnion and I woke up.

I couldn't ignore the dream and it eventually led me to design the idea on paper for patent application followed by starting the company. We have come a long way since then and now the dream is getting closer to reality.

What complications can arise after preterm birth? ▾

During the last month of pregnancy, significant organ development and change is happening to prepare the fetus for the outside world. In very preterm and extreme preterm infants, organs such as skin, brain, lungs and GI tract are underdeveloped. Underdeveloped skin is particularly very significant because that's their connection to the environment.

Preterm infants have very little subcutaneous fat that insulates them and protects them from heat loss. Their skin is permeable to water, so they're also losing insensible water to evaporation, with which a tremendous amount of heat is also lost. They don't have shivering mechanisms to reregenerate heat. They have limited muscular-skeletal movement compared to term infants. They also don't have storage of brown fat that is used to regenerate heat.

Thus they are very vulnerable to hypothermia which is a significant risk and reported from 25%-78% in the first hour (golden hour) of life. Hypothermia in the golden hour of care is associated with brain developmental injuries leading from mild intellectual disability to severe cerebral palsy. Hypothermia is also associated with injuries to lungs and GI tract in preterm infants as well as sepsis and death.

How many babies suffer from preterm birth complications? ▾

15 million infants are born preterm each year across the world. About 400,000 infants are born preterm every year in the United States, and about 110,000 of them are very preterm, which is less than 32 weeks. About 30,000 of them are extreme preterm, which is less than 28 weeks.

Hypothermia at birth is unfortunately very common in very preterm infants. In a large European study involving 11 countries, 53% of very preterm infants had hypothermia in the first hour of life. In a Kaiser hospital study of 4 major centers, 25% to 78% of very preterm infants had hypothermia upon admission to the NICU. Hypothermia at birth is associated with negative outcome for the infants.

First hour of care in neonatology is called 'the golden hour', a concept used in both trauma and neonatology to signify the importance of care in the first sixty minutes of care. Hypothermia in the golden hour is associated increased chance of death as well as complications leading to organ injuries, including life-long neurodevelopmental injuries leading to mild intellectual disability to severe cerebral palsy.

By reducing or eliminating heat loss and thus hypothermia, we are hoping for a more comfortable stay for the preterm infant as well as reduction or elimination of negative outcome associated with hypothermia.

What is being done now to care for preterm infants, and where did you see a need for improvement? ▾

The very preterm and extreme preterm infants, immediately upon birth, rely on a radiant warmer as a heat source together with use of polyethylene bags or caps and thermal mattresses, and are then transferred in a warmed incubator. With the above, there has been tremendous improvement in decreasing incidence of hypothermia on admission to the NICU. However, the the incidence of hypothermia is consistently reported in double digit percentages across multiple studies with large European and US studies citing as high as ~50% average incidence in very preterm infants. That's too high and cannot be ignored. These infants need more advanced solutions to keep them warm and prevent hypothermia upon their admission to the NICU. Amniobed Golden Hour is our solution.

Once the infant is in the NICU . He/She is placed in convection/humidified incubators with portholes to access the infant. These incubators have shown to have fluctuations in temperature inside. At times, these infants are accessed once an hour. Upon access through the portholes, drafts of cold air come in, and can take up to 20 minutes for the incubator environment to re-balance to the desired temperature. Kangaroo care is also used and is often quite effective. Unfortunately, in the very preterm and extreme preterm, this method may not be adequate and the infant can lose a significant heat during handling.

How does Amnion Life improve preterm infant care? ▾

First and foremost, we want to eliminate hypothermia in preterm infants. Initially, we are working on Amniobed Golden Hour to prevent hypothermia in the first hour of care (golden hour), prior to their admission to the NICU. There is a considerable need for this market. In addition, testing and regulatory approvals will be far easier for an incubator intended for up to 60 minutes as opposed to 24 hours or up to 28 days which is our ultimate goal.

We believe that if we can decrease the episodes of hypothermia, we can increase the velocity of growth for these infants and thus decrease the length of their hospital stay. Hypothermia is also linked to organ developmental injuries and is directly linked to brain hemorrhage, sepsis, convulsions, respiratory distress, anemia, periventricular leukomalacia, anea, necrotizing enterocolitis, meningitis, bronchopulmonary dysplasia, death

We think that we can build a device that's safe, effective, and superior that will keep the infants warmer and eliminate hypothermia and thus will eliminate one cause of any of the above morbidities in preterm infants and ultimately discharging them home sooner and healthier.

Other potential advantages of our device would be fluid management for these infants. Right now, they receive IV fluid to replace the water they lose to the environment losing. However, high administration of IV fluid relative to body size has been associated with bronchopulmonary dysplasia, a form of lung disease. Injury to the lung is thought to be due to changes in plasma content from the fluid administration. In our solution, the infant is in a fluid bath and is not losing water as they currently do. In addition, the osmotic difference between infant serum and amniotic fluid creates a natural gradient which leads to absorption of water by the fetus across their skin and membranes in the womb. This absorption of water is called 'intramembranous pathway'. In Amniobed, there is the same osmotic gradient difference as is found in the womb, thus the infant would be absorbing water across their skin and membrane as they do in the uterus. This may eliminate the use of IV fluids which can be harmful at high levels.

What is the history of incubator development for preterm infants? ▾

The first incubator was invented in Paris in 1882 by Stephane Tarnier. Before then, about 90% of preterm infants died. He showed that we can decrease the mortality of these infants from 90% to less than 20%. The incubator was taken to world fairs and to Coney Island. They'd put these preterm infants on display for people to see. There are actually a lot of historical photographs of them.

In the 1930s, they tried to humidify these incubators, and then realized there is a risk of bacterial colonizations which were at times very dangerous to the infants. So, by the 1950s, incubators weren't incubated more than 50%, which is right now the current standard. In the late '90s, more computerized and sophisticated radiant warmers and convection incubators were created. Right now, the top of the line incubator, GE incubator, Giraffe OmniBed, is a combination of a humidified convection and radiant warmer. Other main companies manufacturing infant incubators are Drager in Europe and Atom Medical in Japan. There are also smaller Chinese and Indian manufacturers.

When water is known to transfer heat much more efficiently than air, why has nobody else done this? Were you the first to think about actually incubating a baby in an environment similar to the womb? ▾

There have been attempts at the university level to successfully incubate preterm goats and sheep in sythetic amniotic fluid, but no one had taken the step to do a commercial version. Perhaps for the bigger companies like GE, it is too risky to invest in such a radical idea and for entrepreneurs, too complex and difficult.

Somebody had to take on the challenge. I had this dream that woke me up one night more than four years ago and I could not ignore the dream. A couple of years of thinking about it, I finally told myself, "Okay, I can take this through the FDA . I can create a business model, and I can make a company from it." There was passion inside me that was a driving force to make me do it, where others were too afraid to take a step, perhaps. That's the best explanation I can think of.

Can you explain the details of the AmnioBed? ▾

AmnioBed is a complex medical device with more than 13 subsystems and specially designed software.

Amniobed Golden Hour will be placed in the Labor and Delivery suite next to the mother and is intended for up to 60 minute of use during resuscitation and stabilization of the infant.

The device is connected to the hospital water supply and waste line. The device purifies the hospital water by taking it through five or six medical grade filters to eliminate all harmful substances, bacteria, and viruses that may be in the water supply, including any

hard minerals and heavy metals. The purified water is dialysis grade. That water is warmed to the proper temperature, and using a dosing pump, it is mixed with a solution that is a concentrated electrolyte and mineral solution. The concentrate electrolytes come in plastic cartridges which are one of the consumable product and a source of revenue.

The prepared fluid is pumped into the basin covered by a biocompatible and sterile disposable cover which has a built in pelvic and chest harness to keep the infant in place. The infant is placed on the sterile cover and secured in place using the pelvic and chest harness. The disposable cover is another consumable and source of revenue. The infant sits at a 15 degree angle and fluid line rises to just above the shoulders and below the chin.

A specially designed cap is placed on the the infant. It covers most of the scalp and has a strap that goes around the chin. The cap is used to prevent heat loss from the scalp but also serves as a scaffold for multiple sensors for infant vitals. In addition, there is a fluid

sensor on the the infant's chin to make ensure the fluid in the bath does not go above the chin level.

Are you planning to create other products as well? ▾

Amniobed Golden Hour is considered our first device. Once we gain regulatory approval for this device, we intend to work on Amniobed 24 Hour. Amniobed 24 Hour is the device we initially built the company around. We worked on it for nearly two years. It is more sophisticated than Amniobed Golden Hour. It has dome with a dual air and fluid environment. The air above the infant is purified, warmed and humidified. The device also required a stool detection mechanism for the amniotic fluid to allow the computer to automatically discharge and replace the fluid upon infant defecation. This mechanism was not needed for the one-hour use of the device. But once we get the one-hour use through the market, we intend to build Amniobed 24 Hour, an incubator which can allow incubation of the infant from 24 hours to 28 days.

In addition, our company did significant research and development of artificial placenta and we are proud to have been able to have its US patent issued. We intend to develop the first commercial artificial placenta for preterm infants in order to improve their oxygenation and nutrition upon early birth and eliminate negative outcomes associated with their underdeveloped lungs and GI tract.

In addition, in our continuation patent application for Amniobed, we broadened our claims to allow our technology to be used on adult size patients who may benefit from being in a fluid bed. Such adult patients may include patients with severe burn or patients in recovery prone to bed sores leading to decubitus ulcers who can benefit from resting in fluid bath for a number of hours or even days to help them recover faster. The automated stool detection in Amniobed can also eliminate significant nursing challenges related to adult defecation such as the use of rectal tubes or adult diapers.

When would you expect for investors to see a return on investment? ▾

We are less than 2 years away from gaining regulatory approvals with FDA in the US and CE mark in Europe. That would be the first potential for exit for the company. After that, we will be in the commercialization phase which could last 3-6 years before we exit.

What is the economic benefits of having better medical devices for preterm infants? ▾

On average, very preterm infants are staying in the hospital 46 days and 110 days for extreme preterm infants.

The cost of NICU is high. The average cost is estimated to be about \$3,500 to \$4,000 a day, but it can range anywhere from \$2,000 to \$8,500 a day. The economic cost for society is tremendous. We've realized that if we can reduce the length of stay for these infants by just three days, about \$1.1 billion will be saved. That's just the savings on the short-term care. That's not including all the long-term chronic injuries that require health and social care in the future. As far as the complications with these infants, the highest cause of cerebral palsy in society is preterm infancy. It can cause cerebral palsy, infant death, chronic lung injuries, and chronic developmental injuries in the brain that are less severe but still debilitating. Therefore, the device creates not only an economic positive aspect, but also a social positive aspect that could be priceless.
