Invest in Amnion Life

Hardware Technology Main Street Healthcare Social Impact

Innovative medical devices for preterm infants - Building an artificial womb

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

Why you may want to invest in us...

1. Amniobed is designed to prevent hypothermia in preterm infants.
2. Hypothermia is associated with increased rate of mortality and morbidity.
3. Infant incubator with synthetic amniotic fluid replicating the environment of the womb.
4. Patents issued in the US and China. Pending in Europe, Japan, India and Australia.
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. Raised $1.44M in previous rounds.
7. 3 Years of R&D. Designed, sourced, procured and assembled Amniobed Golden Hour plus software.
8. Invest to help improve lives of millions of children around the world. Preemies need your love.

Why investors ♥ us

WE'VE RAISED $1,781,752 SINCE OUR FOUNDING

I am a past board member of March of Dime and very familiar with the unfortunately high rate of death in babies who were born pre-maturely. The technology being used today to take care of a Pre Term baby is really really outdated. But that's all that is available. In the Golden Hour of birth odd are against the preterm babies. They have no fat on there skin and dehydrate quickly. They have no insolation what so ever. The will lose body heat quickly so they need to be warm. So far the incubator that is being used heats their body, which is further cause of dehydration. &

... *read more*

Hamid Sharafatian General Manager at Start Fresh (early-stage investment fund) and President of Envision Foods

LEAD INVESTOR ? INVESTING $25,000 THIS ROUND

Incredibly accomplished team, tackling a high-demand opportunity to save and improve the lives of preterm newborns. I'm a huge fan and honored to play a part.

Michael Chang

A technologist, I had worked on software and video games for 20+ years. Looking to invest in life-changing products that change the world.

My twin niece and nephew were preemies and I saw how hard it was on the babies and my sister. I think this is a brilliant idea.

Maria C Arevalo

SEE MORE

Our team

AND OUR MAJOR ACCOMPLISHMENTS

Amir Fassihi

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

Hani Sharestan
Accountant/CPA
Partner at Wright Ford Young & Co.

Aaron Reed

In the news

BioSpace No Logo No Logo

Downloads

Amnion Life Pitch Presentation.pptx

Premature Birth is the #1 Cause of Infant Death

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 ™

Current infant incubators have shortcomings

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 respiratory distress, apnea, convulsions, anemia, sepsis, periventricular leukomalacia, necrotizing enterocolitis, meningitis, brain hemorrhage 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)

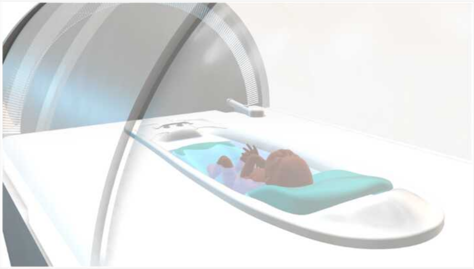
Transitional Hypothermia in the golden hour is linked to increased chance of negative outcomes and increased chance of subsequent infant death. It can be and it must be prevented. Prevention of transitional hypothermia in infants is what Amniobed Golden Hour is being designed to prevent.

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

15M	$43B+	$4,000
Babies born premature every year worldwide.	Spent annually in the U.S. alone caring for premature infants.	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

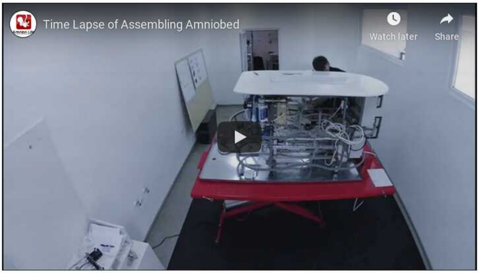
AmnioBed is a new approach to incubation. We submerge the infant partially in specially crafted fluid that mimics a mother's amniotic fluid in temperature, electrolyte balance, pH and minerals. This way, the infant can stay warm upon birth in a fluid environment just like they would in the womb, instead 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 bove 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 three years, we've done tremendous amount of research and development to design and develop our first product, Amniobed Golden Hour. Below is time-lapse video of our engineers in Serbia building the device.



Over the next six to 12 months, we plan to do the necessary safety testing of the device. All plastic that come into contact with fluid that comes into contact with infant needs to be tested for safety. All electrical components needs to meet international ISOstandards and

FDA requirements for testing. Software needs to be tested and validated and finally, doctors and nurses need to perform usability testing to ensure the device is safe prior to our first clinical trials.

April 2016

Founded Amnion Life

October 2016

1st Round Seed Funding Secured

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

February 2017

Cleanroom R&D facility built in Pozega, Serbia - Amnion Life Pozega LLC Established

April 2017

US AmnioBed Patent Application Granted by USPTO

International Patent Application Through PCT Approved

July 2017

Proof of Concept Design Completed

February 2018

Parts and Material for Prototype Sourced and Procured

April 2018

2nd Round of Seed Funding Secured

June 2018

Prototype Built and Prepared for Initial Testing

July 2018

Quality Management System in Place

September 2018

Initial Risk Analysis Completed

December 2018

Comprehensive clinical review of device User Needs completed by Clinical Team

Initial Clinical Evaluation Report prepared

January 2019

Artificial Placenta R&D Completed –Patent application drafted and submitted

February 2019

Second Patent on Amniobed obtained - Expanded claims to include adult size patients

March 2019

Awarded 2nd place out of 100 competing companies at Stanford-UCSF Pediatric Device Consortium

April 2019

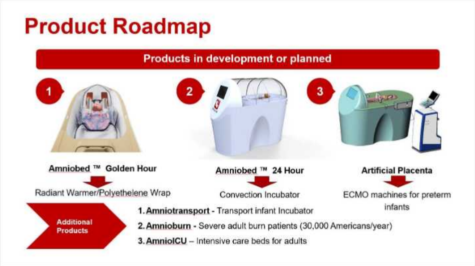
Completed Reg CF Crowdfund Round [raised $305K from 186 investors]

January 2020

Amniobed's Patent Application granted and issued in China.

Other Applications of Our IP

Our patent portfolio now includes multiple patents on Amniobed. Our patent claims on Amniobed were broadened on subsequent application to include adult size patients. In addition, we were awarded a US patent on Artificial Placenta. Below is the roadmap for our future product development:



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

Additional Products

1. **Amniotransport** - Transport infant Incubator
2. **Amnioburn** - Severe adult burn patients (30,000 Americans/year)
3. **AmnioICU** – Intensive care beds for adults

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 that 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 mother's womb. Outside the womb, they cannot survive without great effort to keep them warm, oxygenated 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 tremendous job caring for and nourishing preterm infants until they are safe enough to be discharged home. But the healthcare we currently provide is not enough. There are still too many preterm infants leaving hospitals with life-long disabilities. Others endure lengthy stays in the NICU that can last 110 - 140 days, or more, causing tremendous psychological, social and economic hardship for families. Our goal is to get preterm infants discharged and home – healthier, quicker and with fewer complications.

We as a company feel honored and blessed to shoulder the responsibility to help improve the lives of our preterm infants. I am also honored and excited to be working with a team of individuals from across the world who share the same passion and dedication to this project. As a team, we are determined to build a safe and effective incubator, significantly superior to the 20th-century technology still in use today. We believe the environment found "in the womb" is the gold standard of care at this stage of human development, and progress towards a fluid environment for these infants is natural and expected. We are proud to be at the forefront of that progress.

We realize that our path is long and difficult. Yet we have already come a long way and will remain focused because our goal is too critical for humanity to allow it to go unrealized. We believe that our investors will be financially well rewarded for their support - but the greatest reward for us will be to witness the countless lives improved and saved, and the countless number of families that get to spend a lifetime together because of this new technology.

Sincerely,

Amir Fassihi

Investor Q&A

– COLLAPSE ALL

What does your company do? ⌄

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 mimics 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 the 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 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 counties, 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 healther.

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.

Financials

Amnion Life has financial statements ending December 31 2019. Our cash in hand is $45,830, as of April 2020. Over the three months prior, revenues averaged $0/month, cost of goods sold has averaged $0/month, and operational expenses have averaged $12,000/month.

At a Glance

January 1 to December 31

$0
Revenue

-$568,030
Net Loss

$96,221 +610%
Short Term Debt

$355,892
Raised in 2019

$45,830
Cash on Hand
As of 04/28/20

INCOME BALANCE NARRATIVE

Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this offering. Some of the information contained in this discussion and analysis, including information regarding the strategy and plans for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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 mimics a mother's amniotic fluid environment.

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.

Given the Company's limited operating history, the Company cannot reliably estimate how much revenue it will receive in the future, if any.

Milestones

Amnion Life LLC was incorporated in the State of California in May 2016.

Since then, we have:

- Raised $1.44M in previous rounds.
- Key innovation: partially submerging infant in synthetic amniotic fluid that replicates the temperature and environment of the womb.
- 3 Years of R&D. Designed, sourced, procured and assembled Amniobed Golden Hour plus software.
- Patents issued in the US [2 patents] and China. Pending in Europe, Japan, India and Australia. US patent issued on artificial placenta.
- 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.
- Hypothermia in the first hour of life is associated with increased rate of mortality and morbidity.
- All patents are owned by the company.

Historical Results of Operations

Our company was organized in May 2016 and has limited operations upon which prospective investors may base an evaluation of its performance.

- *Revenues & Gross Margin.* For the period ended December 31, 2019, the Company had revenues of $0 compared to the year ended December 31, 2018, when the Company had revenues of $0.
- *Assets.* As of December 31, 2019, the Company had total assets of $43,608, including $17,050 in cash. As of December 31, 2018, the Company had $56,387 in total assets, including $30,378 in cash.
- *Net Loss.* The Company has had net losses of $568,030 and net losses of $626,723 for the fiscal years ended December 31, 2019 and December 31, 2018, respectively.
- *Liabilities.* The Company's liabilities totaled $570,907 for the fiscal year ended December 31, 2019 and $15,656 for the fiscal year ended December 31, 2018.

Related Party Transaction

Refer to Question 26 of this Form C for disclosure of all related party transactions.

Liquidity & Capital Resources

To-date, the company has been financed with $194,653 in debt, $1,011,000 in convertibles, and $125,000 in SAFEs.

After the conclusion of this Offering, should we hit our minimum funding target, our projected runway is 12 months before we need to raise further capital.

We plan to use the proceeds as set forth in this Form C under "Use of Funds". We don't have any other sources of capital in the immediate future.

We will likely require additional financing in excess of the proceeds from the Offering in order to perform operations over the lifetime of the Company. We plan to raise capital in 6 months. Except as otherwise described in this Form C, we do not have additional sources of capital other than the proceeds from the offering. Because of the complexities and uncertainties in establishing a new business strategy, it is not possible to adequately project whether the proceeds of this offering will be sufficient to enable us to implement our strategy. This complexity and uncertainty will be increased if less than the maximum amount of securities offered in this offering is sold. The Company intends to raise additional capital in the future from investors. Although capital may be available for early-stage companies, there is no guarantee that the Company will receive any investments from investors.

Runway & Short/Mid Term Expenses

Amnion Life LLC cash in hand is $45,830, as of April 2020. Over the last three months, revenues have averaged $0/month, cost of goods sold has averaged $0/month, and operational expenses have averaged $12,000/month, for an average burn rate of $12,000 per month. Our intent is to be profitable in 36 months.

Since December 31, 2019 the spread of COVID-19 has severely impacted many local economies around the globe. In many countries, businesses are being forced to cease or limit operations for long or indefinite periods of time. Measures taken to contain the spread of the virus, including travel bans, quarantines, social distancing, and closures of non-essential services have triggered significant disruptions to businesses worldwide, resulting in an economic slowdown. Global stock markets have also experienced great volatility and a significant weakening. Governments and central banks have responded with monetary and fiscal interventions to stabilize economic conditions.

The Company has taken measures to comply with travel bans, quarantine and social distancing guidelines. As such, the Company's research facility in Pozega, Serbia has limited its operations to comply with the guidelines and requirements for the duration of the pandemic. In addition, the Company canceled two private events in California which were intended to raise capital for the Company. This compliance is expected to add delays in the development of our products. The overall economic slowdown is also anticipated to add additional risks and difficulties in raising money in future rounds due to the volatile financial situation risen from the pandemic.

The Company has determined that these events are non-adjusting subsequent events. Accordingly, the financial position and results of operations as of and for the year ended December 31, 2019 have not been adjusted to reflect their impact. The duration and impact of the COVID-19 pandemic, as well as the effectiveness of government and central bank responses, remains unclear at this time. It is not possible to reliably estimate the duration and severity of these consequences, as well as their impact on the financial position and results of the Company for future periods.

Note: this disclosure is based on management's assumption that there is no significant doubt about the entity's ability to continue as a going concern.

There is no expected revenue over the next six months. The Company's expenses are expected to be further limited to less than $10,000 per month. As a result of the pandemic, the Company took steps to cancel two private fundraising events in California intended to raise capital. The Company intends to reschedule those events once restrictions are lifted in order to raise additional capital. We expect it will take between $2.5M - $5M in total financing for us to reach break even. We hope to begin generating revenues in 2022.

A note from Wefunder. Unlike companies on the NASDAQ, early-stage startups have little operating history. Financial analysis is not as useful when there is limited data. It's more important to predict the size of the future market. If the founder achieves their vision, will enough customers pay the company enough money?

It's also common for fast-growing startups to lose money even faster: they are investing in future growth. In these cases, it's often better to check if the Cost of User Acquisition (CAC) is lower than the Lifetime Value (LTV) of that customer. If one spends $1000 today to make $10,000 over the next five years, that may be a smart bet. Amazon is a famous example of re-investing potential profits to maximize growth over 20 years.

Net Margin: N/A	**Gross Margin:** N/A	**Return on Assets:** -1,303%
Earnings per Share: -$0.44	**Revenue per Employee:** $0	**Cash to Assets:** 39%
Revenue to Receivables: 0%	**Debt Ratio:** 1,309%	

2018-2019 Amnion Life - Financial Statements FINAL.pdf

Risks

1 The medical device being developed may not pass the FDA requirements for safety and efficacy and may not receive the required regulatory requirements

for sales and marketing of the device.

2 The Company may never receive a future equity financing or elect to convert the Securities upon such future financing. In addition, the Company may never undergo a liquidity event such as a sale of the Company or an IPO. If neither the conversion of the Securities nor a liquidity event occurs, the Purchasers could be left holding the Securities in perpetuity. The Securities have numerous transfer restrictions and will likely be highly illiquid, with no secondary market on which to sell them. The Securities are not equity interests, have no ownership rights, have no rights to the Company's assets or profits and have no voting rights or ability to direct the Company or its actions.

3 Our future success depends on the efforts of a small management team. The loss of services of the members of the management team may have an adverse effect on the company. There can be no assurance that we will be successful in attracting and retaining other personnel we require to successfully grow our business.

4 The anticipated clinical trials do not confirm the safety and efficacy of the device. There is considerable harm and danger realized associated with the device which cannot be mitigated.

5 Competitors successfully challenging Company's patent and other intellectual properties and entering the market with similar devices.

6 Clinical Trials for the device do not meet Superiority classification requirements compared to previous devices currently on the market.

7 Amir Fassihi is a part-time officer. As such, it is likely that the company will not make the same progress as it would if that were not the case.

8 We have not commenced commercial operations to date and our future profitability is uncertain.

9 We are primarily dependent on the success of our lead product candidate, AmnioBed, which is still in clinical development, and this product candidate may fail to receive marketing approval or may not be commercialized successfully.

10 We are an early-stage medical device company with no approved products and no historical product revenue, which may make it difficult for you to evaluate our business, financial condition and prospects.

11 We expect that we will need further financing for our existing business and future growth, which may not be available on acceptable terms, if at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. The failure to obtain further financing may also prevent us from capitalizing on other potential product candidates which may be more profitable than AmnioBed or for which there may be a greater likelihood of success.

12 We depend on third parties for clinical and commercial supplies, which could affect our business. We also rely on third parties to conduct our preclinical studies and clinical trials.

13 If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

14 We may be exposed to claims and may not be able to obtain or maintain adequate product liability insurance.

15 We depend on skilled labor, and our business and prospects may be adversely affected if we lose the services of our skilled personnel, including those in senior management, or are unable to attract new skilled personnel.

16 Our employees and our independent contractors, principal investigators, CROs, consultants or commercial collaborators, as well as their respective sub-contractors, if any, may engage in misconduct or fail to comply with certain regulatory standards and requirements, which could expose us to liability and adversely affect our reputation.

17 We may acquire businesses, products or product candidates, or form strategic alliances or create joint ventures, in the future, and we may not realize the benefits of such transactions.

18 System failures may disrupt our business operations and delay our product development programs and commercialization activities.

19 The marketing approval processes of the FDA and comparable regulatory authorities in other countries are unpredictable and our product candidates may be subject to multiple rounds of review or may not receive marketing approval.

20 We may be unable to continually develop a pipeline of product candidates, which could affect our business and prospects.

21 Our preclinical studies and clinical trials may not be successful and delays to such preclinical studies or clinical trials may cause our costs to increase and significantly impair our ability to commercialize our product candidates. Results of previous clinical trials or interim results of ongoing clinical trials may not be predictive of future results.

22 We are planning to pursue the FDA De Novo pathway for all of our current product candidates. If we are unable to rely on the De Novo regulatory pathway to apply for marketing approval of our product candidates in the United States, seeking approval of these product candidates through the PMA pathway would require full reports of investigations of safety and effectiveness, and the process of obtaining marketing approval for our product candidates would likely be significantly longer and more costly.

23 We may encounter difficulties in enrolling patients in our clinical trials, which could be detrimental to business.

24 We have conducted, and may in the future conduct, clinical trials for our product candidates outside the United States and the FDA may not accept data from such trials.

25 Our facilities are subject to extensive and ongoing regulatory requirements and failure to comply with these regulations may result in significant liability.

26 Our current pipeline product candidate, AmnioBed, requires extensive clinical data analysis, regulatory review and additional testing. Clinical trials and data analysis can be very expensive, time-consuming and difficult to design and implement. If we are unsuccessful in obtaining regulatory approval for AmnioBed does not provide positive results, we may be required to delay or abandon development of such product, which would have a material adverse impact on our business.

27 Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

28 Even if we obtain marketing approval for our product candidates in the United States, we or our collaborators may not obtain marketing approval for the same product candidates elsewhere.

29 The terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

30 Our products may not achieve market acceptance, which would be essential to our company's success. Furthermore, We may not be able to respond effectively to changing consumer preferences and demand.

31 The commercial success of our medical device products depends on the availability and sufficiency of third-party payor coverage and reimbursement.

32 Our products may be subject to reduced prices negotiated by certain group purchasing organizations that could adversely impact our product revenue.

33 We may not be able to build our marketing and sales capabilities or enter into agreements with third parties to market and sell our medical device products.

34 The off-label use or misuse of our products may harm our image in the marketplace, result in injuries that lead to costly product liability suits, or result in costly investigations and regulatory agency sanctions under certain circumstances if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

35 Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review.

36 If our product candidates are approved for commercialization outside of the United States, we may be exposed to a number of risks associated with international business operations.

37 If the FDA or comparable regulatory authorities in other countries approve generic versions of our product candidates, or do not grant our product candidates a sufficient period of market exclusivity before approving their generic versions, our ability to generate revenue may be adversely affected.

38 Our medical device products may be subject to recalls, withdrawals, seizures or other enforcement actions by the FDA or comparable regulatory authorities in other countries if we fail to comply with regulatory requirements or previously unknown problems with our medical device products are discovered after they reach the market.

39 We may not be able to engage third-party CMOs to manufacture our approved medical device products on a commercial scale to meet commercial demand for our medical device products.

40 Our commercial success depends largely on our ability to protect our intellectual property.

41 If we are unable to protect our trade secrets, the value of our AmnioBed technology and product candidate may be negatively impacted, which would have a material and adverse effect on our competitive position and prospects.

42 We may become involved in litigation to protect our intellectual property or enforce our intellectual property rights, which could be expensive, time-consuming and may not be successful.

43 We may be subject to claims that our employees or consultants have wrongfully used or disclosed to us alleged trade secrets of their former employers or other clients.

44 We may be subject to claims from third parties that our products infringe their intellectual property rights.

45 Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

46 If we fail to comply with various procedural, document submission, fee payment or other requirements imposed by the USPTO or comparable patent agencies in other countries, our patent protection could be reduced or eliminated.

47 Changes in patent laws or interpretations of patent laws in the United States or elsewhere may diminish the value of our intellectual property or narrow the scope of protection of our patents.

48 Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

49 Healthcare laws and regulations may affect the pricing of our medical device products and may affect our profitability.

50 We may not be able to enforce our intellectual property rights throughout the world, which may be problematic.

51 We need to protect our trademark, trade name and service mark rights to prevent competitors from taking advantage of our goodwill.

52 We are subject to various laws and regulations, such as healthcare fraud and abuse laws, false claim laws and health information privacy and security laws, among others, and failure to comply with these laws and regulations may have an adverse effect on our business.

53 Legislative or regulatory reform of the healthcare system in our target markets may affect our operations and profitability.

54 Our management has broad discretion in using the net proceeds from the initial public offering and may not use them effectively

Details

The Board of Directors

DIRECTOR	OCCUPATION	JOINED
Amir Fassihi	CEO @ Amnion Life	2016

Officers

OFFICER	TITLE	JOINED
Amir Fassihi	CEO	2016

Voting Power

HOLDER	SECURITIES HELD	VOTING POWER
Amir Fassihi	1,000,000 Class A Units, Voting	100.0%

Past Equity Fundraises

DATE	AMOUNT	SECURITY
	$144,107	SAFE
12/2018	$116,226	Loan
04/2020	$42,893	Loan
04/2020	$35,534	Loan
04/2019	$305,892	SAFE
03/2020	$25,000	SAFE
03/2020	$50,000	SAFE
11/2019	$50,000	SAFE
09/2018	$250,000	Convertible Note
04/2018	$761,000	Convertible Note

Outstanding Debts

LENDER	ISSUED	AMOUNT	OUSTANDING	INTEREST	MATURITY	CURRENT?
Amir Fassihi	12/01/2018	$116,226	$118,794	5.0%		Yes
Bank of America	04/09/2020	$42,893	$42,893	17.74%	04/30/2025	Yes
American Express	04/09/2020	$35,534	$35,534	29.24%	04/30/2025	Yes

Related Party Transactions

Name	Amir Fassihi
Amount Invested	$116,226
Transaction type	Loan
Issued	12/01/2018
Outstanding principal plus interest	$118,794 as of 04/2020
Interest	5.0 per annum
Outstanding	Yes
Current with payments	Yes
Relationship	CEO/Founder

The amount owing to officers and directors relates to a shareholder loan which is due on demand, unsecured and carries an annual percentage rate of 5%. No guarantees have been given.

Use of Funds

$125,000	50% R&D facility costs for ongoing engineering and pre-clinical safety testing, 25% legal, 17.5% IP and accounting fees, 7.5% Wefunder intermediary fee
$535,000	50% R&D facility for ongoing engineering and pre-clinical safety testing, 20% ongoing regulatory and risk management, 10% clinical trial draft and preparation for initial safety early feasibility human trial, 12.5% company debt, 7.5% Wefunder intermediary fee

Capital Structure

CLASS OF SECURITY	SECURITIES (OR AMOUNT) AUTHORIZED	SECURITIES (OR AMOUNT) OUTSTANDING	VOTING RIGHTS
Class A Units	1,000,000	1,000,000	Yes
Class B Units	292,812	292,812	No

The Funding Portal

Amnion Life is conducting a Regulation Crowdfunding offering via Wefunder Portal LLC.
CRD Number: #283503.

Form C Filing on EDGAR

The Securities and Exchange Commission hosts the **official Form C** on their EDGAR web site.