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Modular Incubation System

Delivering infants a better start
Business Plan

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IncuVive

1. Executive Summary

1.1 The Need and Market Opportunity

The majority of worldwide neonatal deaths occur during the first week of life. Hypothermia is an immediate problem because neonates cannot effectively maintain proper body temperatures. Health care facilities in developing nations are unable to afford expensive modern incubators and do not have enough trained health care professionals to effectively combat this issue. Currently, modern neonatal incubators cost over $15,000 and are too complex to be repaired in many developing nations. An affordable, easy to use, and easy to maintain modular incubation system (MIS) providing a warm and safe environment has the potential to substantially improve neonatal care in developing nations.

1.2 Product Research and Development

Our MIS is being developed with a specific focus on the needs of developing nations that have low per capita healthcare expenditures. Our device will:

- Raise an infant's temperature to 37 °C, maintain that temperature, and have a failsafe mechanism.
- Be inexpensive and easy to maintain without requiring specialized parts.
- Be versatile and useable in a variety of decommissioned incubators and cribs with addition of cover.
- Allow for high infant visibility and be sterilizable with ethanol wipes.

IncuVive is currently working with the Mulago Hospital in Kampala, Uganda, to design an MIS to prevent infant hypothermia. The first prototype will be completed by March 2012 and will be tested with a simulated infant. By May 2012, we aim to have a second prototype, with all components integrated into a portable system, for testing at the Columbia University Medical Center (CUMC) neonatal intensive care unit, given Institutional Review Board (IRB) approval. In 2013 we will apply for international device approval and in 2014 we will begin selling our MIS in Uganda.

1.3 Non-Governmental Organizations and Financial Projections

Due to the low healthcare expenditures of the countries we are attempting to help, it is unlikely that we will be able to achieve profitability by relying on device sales alone. By partnering with non-governmental organizations (NGOs) we can recoup the remainder of our production costs. Working with NGOs would allow us to utilize their distribution networks and connections with local governments during expansion thereby making the expansion process more efficient. Furthermore, these NGOs can also pay our customers (e.g., public and private hospitals, Ministries of Health) to buy our product.

In order to generate more operating income, we will begin expansion into the countries surrounding Uganda. Market expansion will be our main source of income due to the large numbers of orders we will need to fulfill. For example, the Mulago Hospital cares for roughly 60 infants on a *light* day and an estimate of 40-60% of these infants are premature and are in urgent need of warmth. With over 80 cribs in each of the three national referral hospitals in Uganda, the number of infants in need of a reliable source of heat compounds. Aside from NGOs and other charitable organizations, our customers include the Ministries of Health of many developing countries and their constituent hospitals with a large need for functional incubators.

1.4 The Team and Our Advantage

IncuVive consists of Indrias Bekerie, Annabelle Chu, Leeanna Hyacinth, Min Ye Shen, and Kiet Vo, seniors in Columbia University's Department of Biomedical Engineering, under the guidance of Dr. Aaron Kyle, Dr. Elizabeth Hillman and Faculty Adviser Dr. Lance Kam. Our medical advisers are Dr. Margaret Nakakeeto-Kijjambu (Head of Special Care Baby Unit at Mulago Hospital in Kampala, Uganda) and Drs. Richard Polin (Head of Neonatology at Columbia University Medical Center), Helen Towers, Yvonne Vaucher and Rakesh Sahni who are all respected physicians in the field of neonatology.

Our Company has many advantages that will allow us to succeed in developing nations. Our MIS will distinguish itself from other incubators by incorporating a reliable feedback mechanism to regulate the temperature output thereby circumventing the use of thermostats, the most common point of failure in other incubation systems. Furthermore, our team has first-hand experience in developing countries such as Vietnam, Ethiopia, and Mauritius and is being advised by leaders in the field of biomedical engineering. Our work as engineering students has given us a strong foundation in math, science, engineering, and the ability to perform critical analysis of multifaceted problems.

2. Company Overview

2.1 Company Mission

The World Health Organization estimated that roughly 38% of all under-5-year-old deaths occurred in the neonatal period, accounting for 4 million annual deaths worldwide in 2001[1]. Once outside the womb, one of the first and biggest problems these neonates face is hypothermia making infants more susceptible to infections and death. UNICEF estimates that 18%-42% of the 4 million deaths result from hypothermia[2]. In addition, babies that become sick at these hospitals and clinics will need to be kept warm.

Furthermore, our Research and Development team finds that the healthcare facilities in many developing countries are unlikely to have the equipment or number of trained personnel to combat infant hypothermia. While elementary solutions exist, such as warming the infant through skin-to-skin contact, these solutions are not feasible in larger settings and in the context of low-resource countries. Incubators eliminate the manpower constraint; however, they are egregiously costly for the budgets of hospitals in developing countries. Additionally, 96% of donated equipment fail within the first five years after donation and stay nonfunctional due to the lack of spare parts and technicians in developing countries. The current utilized methods, such as swaddling, attempt to reduce the inevitable heat loss by these infants but do not address the need to warm them.

IncuVive has an effective and sustainable solution to address infant hypothermia. Our innovative MIS provides heat to infants via a feedback mechanism. Thus, the correct amount of heat is supplied thereby ensuring that hypothermia does not occur. Furthermore, our monitoring system allows caregivers the luxury to attend to the needs of others, freeing up much needed manpower. The ease of use from our System allows usage by caregivers with variable training and educational backgrounds. This, in addition to using parts readily available locally in the third world, makes our system easy to repair. Our MIS is distinctive from the current solutions such as incubators whose manufacturers shy away from the developing countries due to their lack of financial resources. The MIS better suited for them than western technology, and it will be affordable. Furthermore, our creatively versatile design allows the System to be sheltered in decommissioned incubators and can be coupled with a cover and function as an effective incubation device in a crib.

IncuVive, with our strong and diverse team nucleus, tackles head on the constraints in design put forth by the developing world. Our personal ties and first-hand experiences in developing countries (Vietnam, Ethiopia, Mauritius) create a strong commitment from our company to our customers. We believe that through our access to state-of-the art resources and scientists at Columbia University, we can develop viable, affordable, and successful solutions to the problems faced in the developing countries. The breadth and depth of knowledge and experience from our advisers and consultants are second to none. Along with our abilities to think creatively and critically, our strong engineering and quantitative reasoning backgrounds give IncuVive a strong advantage in developing our Modular Incubation System.

Figure 1: Current incubators, such as above from Drager, are too expensive for the health budgets in developing countries. This DRAGER TI500 Globe-Trotter Infant Incubator model was on sale for US$4,450 at dotmed.com.

[1] World Health Organization. Estimates. In: *State of the world's newborns*. Washington: Saving Newborn Lives, Save the Children/USA; 2001: PN1–49.
[2] Wariki WMV and Mori R. Interventions to prevent hypothermia at birth in preterm and/or low-birth-weight infants: RHL commentary (last revised: 1 June 2010). *The WHO Reproductive Health Library*; Geneva: World Health Organization.

3. The Market

3.1 Target Market

Developing countries lack sufficient funding and resources to provide vital neonatal care. Current solutions to infant hypothermia such as incubators are not accessible to the neonatal intensive care unit (NICU) of these health care facilities due to their high cost and high maintenance requirements. Incubators received as donations from developed countries best nonfunctional after a few years. Our MIS must be safe to use because if heating is left uncontrolled then a neonate could be harmed. Our target market will be the hospitals and clinics of these low-resource countries where the health care system is usually governed by the Ministry of Health—such as in Uganda—or jointly with the private sector. The Ministry of Health provides leadership, standards, policies, and financial resources for medical equipment for these hospitals. Through the Ministry of Health, IncuVive hopes to reach as many heath care facilities, from national and regional hospitals to smaller sub-districts hospitals and clinics in these countries.

3.2 Market Strategies

IncuVive seeks to provide equal opportunities to all pretermed neonates and infants by ensuring them a comfortable and smooth transition into the world. Our product will be cost-effective, durable, sterilizable, and sustainable and therefore tailored to address the current socioeconomic situations of the developing world. We are working closely with the health personnel of the Mulago National Referral Hospital in Kampala, Uganda. Through initial testing and implementation of our MIS at the NICU at Mulago Hospital, we hope to reach and work in conjunction with the Ministry of Health of Uganda to provide IncuVive's MIS as the standard treatment to hypothermia in every healthcare facility, large and small, in both urban and rural areas in Uganda. Our initial shipment of 10 Systems will go to Mulago Hospital during our Phase II Development (2014), at a subsidized price of US$50/unit. As our product gains acceptance in Uganda, we will reach out to other developing nations in Africa and beyond that face similar situations as Uganda. By 2020, well within our Phase III/IV Development, IncuVive plans to sell upwards of 2000 units worldwide

IncuVive will expand its network and will approach Non-governmental Organizations (NGOs) such as UNICEF, the Red Cross, Doctors without Borders (DWB), and Equipment for Charitable Hospitals Overseas (ECHO), that operate in Uganda and worldwide. These NGOs have extensive global health presence at the national and community levels in the developing nations. By promoting IncuVive's MIS to the NGOs, we will expand our financial and public relations resources as more and more hospitals and healthcare facilities in the third world will be equipped with our MIS to provide essential support to neonates. Our partnership with the NGOs will help us establish a strong global health involvement and allow us to reach even the most inaccessible and ignored communities around the globe. As our product and company become known to the world we will attract more investors and donors.

3.3 Competition

The majority of the infant incubators available on the market are designed for the developed countries. These incubators made by large companies such as General Electric are expensive (>$15,000), consume a lot of power and require extensive maintenance. The breakthrough of such companies into the low-resource market is not realistic unless they develop a comparable device tailored for the developing world. Besides the accessibility of these products through donations from developed countries, the probability for the Ministry of Health to consider such sophisticated and expensive products is minimal.

However, currently in its final stage of testing, Medicine Mondiale's Liferaft Incubator has been specifically designed for the developing world setting and will be manufactured in 2012[3], but its $1,500/unit cost will therefore not present a potential threat to our market. A more affordable and widely used product is the Van Hemel Incubator, specifically designed and manufactured for low-resource countries since 1968[4]. Additionally, there are many other college design projects that focus on more cost-effective incubators made from readily available parts in developing nations.

We are confident that our versatile design will distinguish itself from others as it will incorporate a reliable feedback mechanism. More importantly, no other device available in the market has the ability to be sheltered

[3] Infant Incubator. Medecine Mondiale 2010. Accessed on Nov. 20, 2011. Retrieved from http://www.medicinemondiale.org/.
[4] The VAN HEMEL baby incubator. HEBI. Accessed on Nov 20, 2011. Retrieved from http://www.hebi-incubator.org/.

in decommissioned incubators or can be coupled with some sort of cover to function as an effective incubation device in a crib.

3.4 Risks and Obstacles

Besides achieving a cost-effective and efficient design, our main obstacle is to obtain funding to support the production of our device. We will need to apply for grants, find donors, and attract investors. Although we have secured a stipend from the Department of Biomedical Engineering at Columbia University, it will not be sufficient to fund the device through mass production. Moreover, we need to obtain the approval from Mulago Hospital and the Columbia University IRB before beginning neonatal testing. IncuVive's success will ultimately depend on the Ministry of Health of the developing countries. IncuVive will have to convince the Ministry of Health of these developing countries about the efficacy and essential need of the MIS in their health facilities. Additionally, we have to establish partnerships with the NGOs. With their support, Incuvive will be able to enter the market and reach its customers and end users. Once we have successfully attracted investors and donors, we will be able to subsidize our MIS making it more appealing to customers with few resources.

Once IncuVive has entered the Ugandan market and has implemented the MIS at different locations in Uganda and some other low-resource countries, IncuVive's technology will be exposed to the world. Larger biomedical companies will be attracted by this promising market of the limited-resource countries that extends far beyond the continent of Africa to South-East Asia and South America as well. They may try to develop products that are comparable to ours with even more features within the same price range as our product. We will remain ahead of the competition by ensuring that we build strong relationships with the Ministry of Health of developing countries and the different NGOs from the beginning, thus making it harder for the larger companies to set their foot in those territories.

4. Business Model

4.1 IncuVive in Uganda

We plan to follow a capital equipment model and be profitable with each device sold. The capital equipment model allows for high margins; however, we would not want to price our device outside of our desired market. Many hospitals in developing countries such as Uganda do not purchase their own equipment. The National Medical Store operating under the Ministry of Health is in charge of the purchase and distribution of medical supplies in Uganda. With our low cost and efficient device we believe we can place a low enough bid to be distributed to the government run hospitals and clinics. We would also market our device to charitable organizations which could help sustain a low margin of operation. Disposable and service contracts are not ideal for developing nations with limited health care expenditures so they are not incorporated into our modular incubation system. Our main source of income is going to come from market expansion as we plan on generating revenue when fulfilling large orders for governments and NGOs.

4.2 Strategic Partnerships

Strategic partnerships with NGOs will allow us to continue to subsidize the production costs of our MIS prior to transitioning to a new market. Uganda has three national referral hospitals with about 80 cribs each. In addition to the government run hospitals and clinics, there are NGOs and private for-profit hospitals. We estimate that we can sell 3,000 units total with an initial shipment for 1,500 units. Each device will cost US$50. The remaining production costs will be paid for through NGO and sponsor donations.

Due to the sustainable nature of our device, after initial shipments have taken place we expect to see a decline in sales and distribution as the market in Uganda becomes saturated. Donations and the profits we have accumulated so far will allow us to expand into other developing nations in Africa. International demand will be high therefore the amount of profits we can generate will be limited to how fast we can expand into new markets. After expanding to new countries a partnership with an NGO such as WHO and UNICEF would help pay for addition staffing and distribution costs. Furthermore, by partnering with an NGO that already has a presence in a new market will allow us to quickly establish operations by utilizing their distribution channels.

4.3 Expansion and Distribution

Our product will be manufactured regionally in order to ensure that all components needed are available locally. The device will need to be durable and last for 3 to 5 years. At the outset, we will not need a warehouse for storage because we plan on exhausting our supplies due to the initial demands upon entering a new market. Once these large orders have been completed demand will sharply decline prior to entering a new market. Our system is designed to be easy to maintain and repair. Components that need to be replaced more often will be accessible. Repairs will take place locally potentially with students from a local partnered university. In addition, our device will be intuitive and easy to use with clear labeling for the medical professionals and caregivers. The transport of our device to the local hospitals will be contracted out to a third party. Once we have expanded into the surrounding countries we will utilize air freight to distribute our product.

5. Design and Development Plans

5.1 Short Term

Our Modular Incubation System mimics the function of conventional incubators. IncuVive's system is composed of a heating system and a feedback system that will monitor both the temperature of the infant and of the ambient air. Currently, IncuVive has narrowed down to three ideas that have the most potential and is conducting our Proof of Concept (PoC testing), which will help us decide on which idea to prototype. Our PoC consists of examining the feasibility of phase change material as source of heating (PCM) as our R&D team has found the PCM to be a viable heating source in other applications. We are in the process of testing how much heat needs to be inputted for the PCM to liquify and how long the material will keep a constant temperature. Furthermore, we are testing different temperature sensors for one that is most suitable for our application. We aim to have this done by December 1st and will use our results to start our preliminary prototype ideas. We will explore and test other avenues of heating. The design for our first prototype will be completed in December, 2011. Our decision on the optimal heating method and temperature sensor will depend primarily on power consumption, cost, availability of materials in Uganda, and maintenance needs.

In March 2012 we will construction our first prototype; it will be composed of the heating unit and feedback system. The device will contain adaptors for easy replacement of broken parts and space for a backup battery source. A unique MATLAB algorithm, which will interface with an Arduino, will be used to measure, display, and correlate the infant's temperature and ambient air temperature to decide whether to increase or decrease the heat setting. There will be an alarm to notify surrounding personnel if the infant's temperature deviates too far from the normal range of 36.5-37.5 $^{\circ}$C. We will test the prototype initially on a bag containing saline solution to mimic an infant body. For this phase, we will test the effectiveness of heat transfer to the saline bag and the sensitivity of our feedback system. Initial testing will allow us to target weak areas of our device and improve our design.

A more refined prototype will be made based on the results from the initial testing phase. By April 2012, we aim to test our prototype on an infant simulator to determine the optimal placement of the temperature sensor for the most accurate reading. We can model an infant with a similar-mass saline bag. Our main objectives are to ensure the accuracy of our temperature sensor and to determine the optimal configuration to deliver the most comfort and safety for the infant.

By May 2012, we aim to have a second prototype with all components integrated into a portable system to test at the CUMC neonatal care unit, given IRB approval. We will evaluate the accuracy, comfort, and safety of our device. We will optimize our unit for neonatal use and ready our unit for shipment and testing in Mulago Hospital, Uganda. We will determine the compatibility of our device with the incubators and cribs in the hospital and see if the parts available in Uganda, such as temperature sensors, will be compatible with our device. The device will come with a training manual on how to use and maintain, with a list of places to buy the parts. The results obtained from the final testing will allow us to make necessary adjustments and prepare our device for the market.

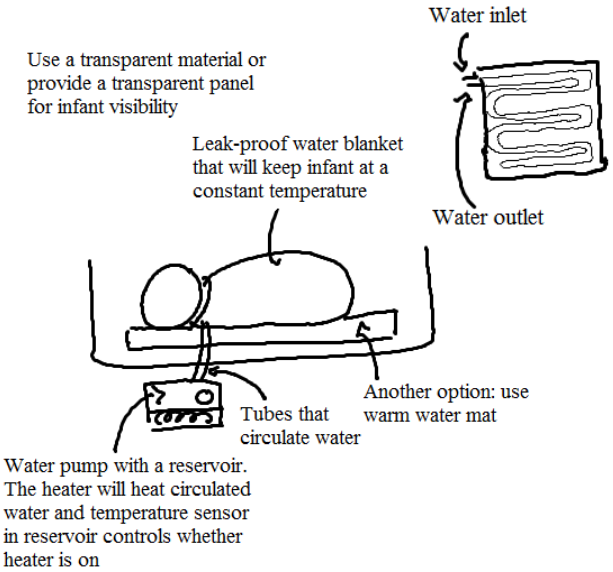

Figure 2: A design utilizing a warm water circulation system providing heat to an infant. Our R&D team is hard at work testing and refining our designs to find the most appropriate solution for the third world.

Date	Goal
December, 2011	Complete Proof of Concept; Finalize preliminary prototype idea
January, 2011	Complete research and testing of different heating mechanisms Start first prototype; Start circuitry and code for feedback system
February, 2012	Complete circuitry and Matlab program for feedback system
March, 2012	Complete construction and testing of first prototype on small animals; Test durability, power efficiency, and feedback/fail-safe mechanism; Use results from testing to start second prototype
April, 2012	Test refined prototype on an infant simulator Construct a monitor, composed of a central processing unit and temperature display
May, 2012	Construct second prototype with integrated heating unit and feedback system; obtain IRB approval for field tests in Uganda; create user manual

Table 1: Short range plan timeline

Item	Vendor	Cost US$
Nichrome Wire	Fisher Scientific	14.00
Various Electronics	Sparkfun	55.00
Circuitry Accessories (ex. wires, batteries)	Miscellaneous	80.00
Housing and Displays	Miscellaneous	150.00
Contingency	Miscellaneous	75.00
Total	-	374

Table 2: Budget, as of 11/20/2011 and is subject to change as we obtain more funding. The developmental phase of the project will be funded by a $500 stipend from Columbia University's Department of Biomedical Engineering.

6. Financial Projections and Long-Range Plan

6.1 Phase 1: Clinical Testing (2012-2013)

The application of the device on a bag of saline solution will demonstrate the feasibility of the device. After review from the IRB at Columbia University, clinical studies will be done to illustrate how our system functions with infants and under different conditions that may not have been achieved with the saline bag. This will be accomplished by having at least two units at the Mulago Hospital in Uganda in August of 2012. After this testing phase minor modifications, within IRB limits, can be made to the device. Furthermore, during this time, we will be accumulating data that could be used to develop awareness to the problem of neonatal hypothermia in the developing world. With our proposed solution, we can encourage NGOs to fund further progress with contributions such as grants, thereby giving us more leverage to be of interest to potential investors.

6.2 Phase II – Final Product Development and International Device Approval (2013-2015)

Using an incubator as the predicate device, we will apply for International Device Approval in 2013 after sufficient clinical testing and any improvements to the device have been made so that the device may be developed and sold in Uganda. This incorporates some research and development to build the final prototype of the device as well as taking into consideration any special requirements that may be necessary for approval. In this time we will continue to house approximately 10 units in the Mulago Hospital at a cost of $50/unit until we accumulate enough funds to develop the product for greater distribution. We would like to modify any non-functional incubator with our MIS in health facilities which will significantly improve the neonatal health care of infants with hyperthermia.

6.3 Phase III: Market Availability (2015-2021)

We will continue to request funds from various NGOs in order to subsidize the existing products and to continue to manufacture the product such that it can be distributed to hospitals and clinics throughout Uganda by the end of 2015. The device can be produced with both labor and materials in Uganda which will allow us to decrease the cost of shipping and production. We will then be able to reach out to developing countries nearby. During this time we expect to sell upwards of 1000 devices/yr.

6.4 Phase IV: Expansion (2016-2021)

Our MIS is a product developed specifically for the hospitals in the developing world to combat infant hypothermia. Hence, our primary market will not include developed countries. The main functional requirement of our device is to warm the infant, and therefore our device has room for improvement such as adding humidification. We hope to develop new technologies to address the needs of neonates in the developing world. By this phase, we should be profitable from our device and should therefore have enough funds to contribute to the research and development of new devices.

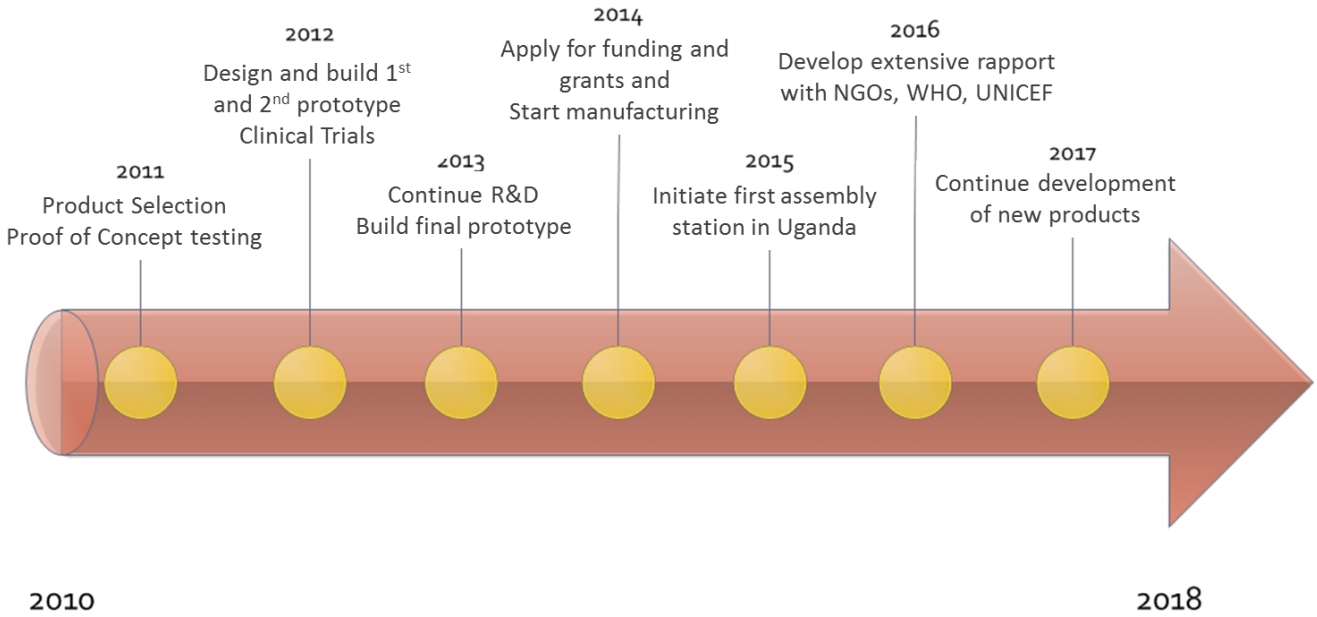

Figure 3: Graphical representation of our long range plan showing some of our key performance indicators. Financial performance indicators follow in *5.3 Financial Projections.*

6.5 Financial Projections

Since IncuVive's goal is to address the need of the developing world, most of the cost of the device will be subsidized by NGOs, such WHO and UNICEF, and grants. We expect that clinical trials and International Device Approval will bring attention to the importance of the device in the lives of infants in the developing world. We project that we would need ~$50/device in addition to > $3000/yr after clinical trials. Our revenue will be based on the projected number of products sold at a price of $50/unit and funds and grants.

Continued research will be underway to improve the product and make development more efficient. The cost of research and development will decrease once the product is manufactured in Uganda hence eliminating the cost of shipping and decreasing some of the cost of labor. We estimate a cost of $700/unit until the product can be built in Uganda and we will see a decrease in cost. In the same respect, the production cost and wages will start at a certain value then would be expected to decrease as more of the device is built and distributed in Uganda and other developing countries in Africa. As is depicted in the financial projections graph (Fig 1), our expenditures will exceed our revenue for the first seven years of the development of the device. These values are primarily influenced by the number of devices sold and the cost of expanding to the developing world. As is shown in Table 4, once the cost of transportation and having a facility levels off and the number of products sold increase, IncuVive will then begin to make a profit.

	Phase I	*Phase II*			*Phase III / Phase IV*					
$ in thousands	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
# of units ($)	0	0	10	150	300	500	1000	1500	2000	2500
Unit Sales ($50/unit)	0	0	500	7500	15000	25000	50000	75000	100000	125000
Funds from NGO ($50/unit) and	500	0	3500	10500	18000	28000	53000	78000	103000	128000
Revenue ($)	500	0	4000	18000	33000	53000	103000	153000	203000	253000
R&D ($)	0	1000	700	700	800	900	1000	1100	1350	1500
Internatiional Device Approval ($)	0	2000	5000	1000	500	500	500	500	500	500
Material cost ($)	150	500	600	300	15300	15500	16000	16500	17000	17500
Production Cost ($)	350	500	500	100	19400	19000	18000	17000	16000	15000
Wages ($)	0	0	1500	22500	30000	60000	85000	120000	145000	160000
Transportaton ($)	0	0	100	200	300	400	1000	1000	1000	1000
Total Cost ($)	500	4000	8400	24800	66300	96300	121500	156100	180850	195500
Net Income ($)	**0**	**-4000**	**-4400**	**-6800**	**-33300**	**-43300**	**-18500**	**-3100**	**22150**	**57500**

Table 4: Financial Projections. Wages are based on the average weekly wages of Ugandan (~US$6)[5].

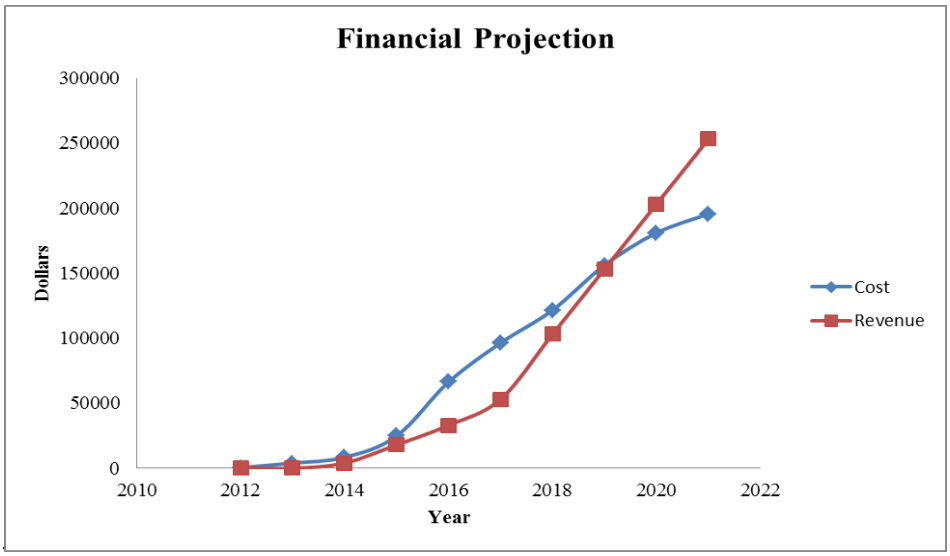

Figure 4: Cost and revenue plot of dollars vs. year. We are in it for the long haul because we expect great returns both in saved lives and in profit. That being said, IncuVive expects to be profitable by roughly the first quarter of 2019.

[5] Stoker, N. Ugandans desperately seeking education. *BBC News*. 21 June, 2005. Retrieved from: http://news.bbc.co.uk/2/hi/africa/4112560.stm.

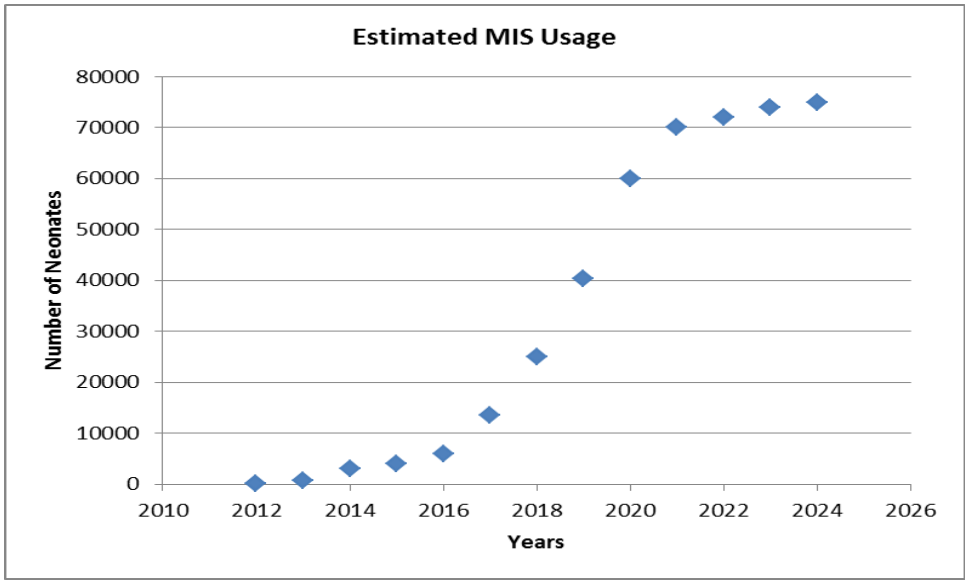

Figure 5: Estimated MIS Usage projection based on a conservative 10% outreach to all neonatal deaths from hypothermia. A more in-depth explanation is in DS 2: *Basic summary of problem*. As you can see, the curve is sigmoidal and saturated at roughly 72,000 neonates per year.

IncuVive will prove to be profitable as the demand for an affordable and effective heating system to combat infant hypothermia is at an all time high. With few established competitors, our company will indubitably capture the majority of the market. While saving thousands of lives, we are committed to being a sustainable business as well. We hope you will join us in leading the development of technology to address the needs of the third world.