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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. IncuVive's Modular Incubation System, priced at $50, is easy to use, and easy to maintain, and provides a warm and safe environment for neonates and has the potential to substantially improve neonatal care in developing nations.

1.2 Product Research and Development

IncuVive, in conjunction with the Mulago Hospital in Kampala, Uganda, has researched and designed an effective MIS to prevent infant hypothermia. Through extensive testing, optimization, and further testing on a biofluid baby model, our system has proven to be as effective, if not more effective, in warming and maintaining the biofluid's temperature as modern incubators.

Our MIS was developed with a specific focus on the needs of developing nations that have low per capita healthcare expenditures. Our collaboration with Mulago Hospital has produced a clear set of functional requirements to meet the needs of our customers. Our device:

- Raises a biofluid temperature by 1 °C in 50 minutes while a modern incubator tested required nearly 85 minutes on average.
- Can raise an infant's temperature to within normal range (36.5 °C - 37.5 °C) and maintain that temperature for over 8 hours
- Has automatic shut-offs, and visual and audio alarms to prevent infant over heating or burning
- Is inexpensive and easy to maintain without requiring specialized parts.
- Is versatile and useable in a variety of cribs and decommissioned incubators.
- Allows for high infant visibility and be sterilizable with ethanol wipes.

1.3 Non-Governmental Organizations and Financial Projections

At the Mulago Hospital, there are 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. We hope to partner with non-governmental organizations (NGOs) so that they may purchase our product in order to provide it at a discount to our customers. 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.

In order to generate more operating income, we will begin expansion into the countries surrounding Uganda. We will use market expansion as an additional source of income due to the large numbers of orders we will need to fulfill. 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.

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 established engineers 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 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, both newborn and non-neonatal babies that become sick at these hospitals and clinics will need to be kept warm.

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 (Kangaroo care) these solutions are not feasible in larger settings and in the context of low-resource countries. Incubators eliminate the manpower constraint with kangaroo care; 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 methods that are used, 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 neither hypothermia nor hyperthermia occurs. 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 developing countries, makes our system easy to repair. Our creatively versatile design allows the System to be sheltered in decommissioned incubators and can be coupled with a dome cover to function as an effective incubation device in a crib. Furthermore, our system can potentially benefit multiple infants at once by allowing the connection of multiple water mats.

Requirement	Kangaroo Care	Incubators	Wrapping infants	Heat Pad	Our Product
Affordable	✓	×	✓	✓	✓
Low maintenance	✓	×	✓	✓	✓
Effective	✓	✓	×	✓	✓
High controllability	×	✓	×	×	✓
High infant visibility	×	✓	×	✓	✓
Safe	✓	✓	✓	×	✓

Table 1: Comparison of our product to other commonly used methods to warm an infant's temperature.

Additionally, our effective technology addresses the limits of current solutions as outlined in Table 1. Our MIS can effectively reduce the number of infant deaths attributed to hypothermia in a cost-effective and sustainable manner. Using our device can help meet the Millennium Development Goal of reducing child mortality. Children from all over the world will be afforded an opportunity to survive and thus grow and fluorish.

Figure 1: Current incubators 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 NICUs of these health care facilities due to their high cost and high maintenance requirements. Incubators received as donations from developed countries often become nonfunctional after a few years. Our company is proposing a robust and safe MIS that is ideal for these areas. Our target market are 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 will be able to reach 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 is cost-effective, durable, sterilizable, and sustainable, and therefore tailored to address the current socioeconomic situations of the developing world. We are working closely with a 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. Current components of our system costs a little less than $50 for our commercial system made in the United States. However, by mass manufacturing in the local economy using local parts will dramatically decrease the cost per unit to an estimated $10/unit. Our initial shipment of 10 Systems will go to Mulago Hospital during our Phase II Development (2014), at a price of US$50/unit. We are using materials that are affordable and available locally and we then intend to produce the device in Uganda. 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. We estimate that Uganda, with over 80 urban and rural hospitals, will need upwards of 400 Modular Incubation Systems. Other countries of similar need will require a large quantity as well. By 2020, well within our Phase III/IV Development, IncuVive plans to sell upwards of 2000 units worldwide (a conservative estimate given that the WHO considers more than 120 countries to be in the third-world).

IncuVive will expand its network and will approach 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 developing countries 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. 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 because of cost constraints and lack of trained technicians and available spare parts. The breakthrough of such companies into the low-resource market is not realistic unless they develop a comparable device tailored for the developing world. Often large companies are driven by making a profit; the constraints set forth by the developing world inhibit them from pursuing this option.

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 (~$500) and widely used product is the Van Hemel

[3] Infant Incubator. Medecine Mondiale 2010. Accessed on Nov. 20, 2011. Retrieved from http://www.medicinemondiale.org/.

Incubator, specifically designed and manufactured for low-resource countries since 1968, uses light bulbs and the chimney principle to heat and humidity the infant[4]. Although this device incorporates temperature regulation, our System is superior because it increases and maintains the temperature of the infant based on a feedback mechanism with well-tested fail-safes. We are confident that our versatile design will distinguish itself from others. No other device available in the market has the ability to be sheltered 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

Our award-winning design[5] has been extensively tested and further design optimizations are in the works. Our main obstacle, thus, is to obtain funding to support the production of our device. We have estimated that our current prototype can be sold for $50/unit given its modularity, low repair cost, and inexpensive components but the cost of production and labor amount to be almost twice the cost of the device. We will need to apply for grants, find donors, and attract investors. The Bill and Melinda Gates Foundation offers grants to many global health programs and promising emerging technologies as ours. 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 the Mulago Hospital and the Columbia University IRB before beginning neonatal testing. 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, such as Ethiopia and Haiti, 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] The VAN HEMEL baby incubator. HEBI. Accessed on Nov 20, 2011. Retrieved from http://www.hebi-incubator.org/.
[5] IncuVive's Modular Incubation System won 4th place at Rice University's National Undergraduate Global Health Technologies Design Competition on March 30, 2012.

4. Business Model

4.1 IncuVive in Uganda

We plan to follow a capital equipment model (where we sell a piece of equipment that is meant to last for an extended period of time) and which could 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 for contracts with the Ministry of Health to distribute our products to government run hospitals and clinics. We also market our device to charitable organizations which helps 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 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 upwards of 400 units with the cost of each device at 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 additional staffing and distribution costs. Furthermore, 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 without any needed repairs. At the outset, we plan on exhausting our supplies due to the initial demands upon entering a new market. Meanwhile, we will expand into new markets so that once these large orders have been completed demand will not sharply. 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 Universities. 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

IncuVive's Modular Incubation System mimics the function of conventional incubators. It is composed of a heating unit, pump, an underbelly and fold-over tubular mat that accommodates a warm water circulation system (Fig. 2). Additionally, a feedback system monitors both the temperature of the infant and of the mat.

Our design includes a fold-over heating component to our system. This can act as an additional heating source or the extra space may also be used to warm another infant simultaneously. Our versatile heating unit can be with any type of generic water reservoir. The control panel, which monitors both the infant and mat temperature, houses the microcontroller which prevents the mat from overheating which would lead to burning of the infant. In addition to displaying the infant's temperature, auditory and visual alarms notify surrounding personnel if the infant's temperature deviates too far from the normal range of 36.5-37.5 °C.

Future prototypes will contain adaptors for easy replacement of broken parts and space for a backup battery source. We will replace our current Arduino microcontroller with a cheaper microcontroller ($0.50/unit) with similar functions.

Date	Goal
June, 2012	Optimize our design based on feedback from Dr. Margaret Nakakeeto-Kijjambu
July, 2012	Test optimized design, re-design if necessary
August, 2012	Design/obtain a better infant model for testing
September, 2012	Obtain IRB approval for animal testing

Table 2: Short range plan timeline

Currently, we have a functional prototype with all components integrated into a portable system that is ready to be tested 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 acquired from our R&D team and current contacts in Uganda. The results obtained from the final testing will allow us to make necessary adjustments and prepare our device for the market.

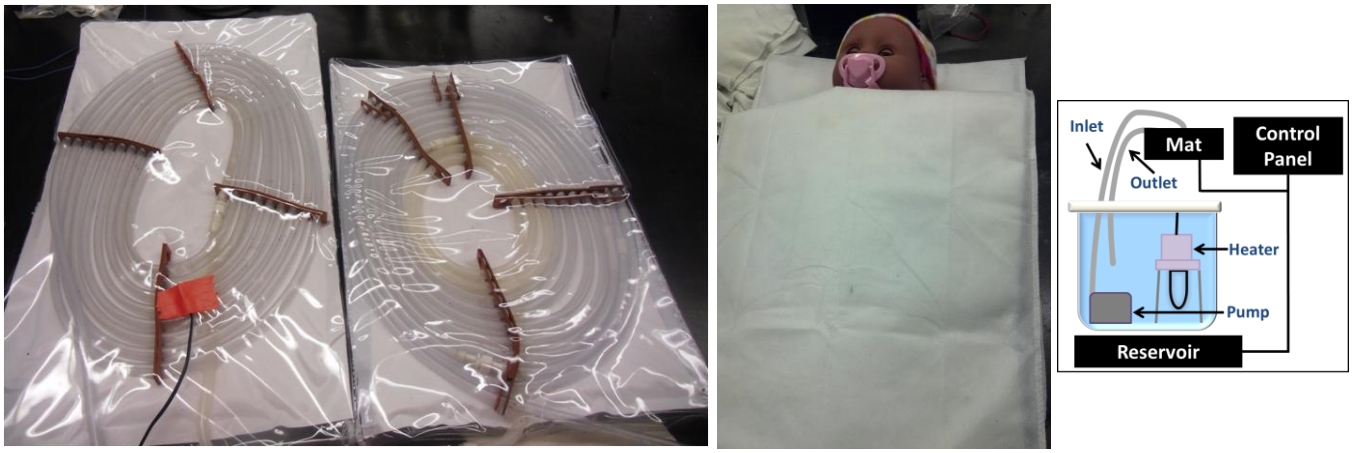

Figure 2: Our R&D team is hard at work testing and refining our designs to find the most appropriate solution for the developing world. Left – Picture of the design which uses a warm water circulation system made of biocompatible materials such as PVC tubing and plastic to provide heat to the infant. Middle – Prototype, including fold-over component, in use. Right – System diagram.

Item	Vendor	Prototype Cost US$	Commercial Cost US$
1000W Water heating element	Amazon	11.00	11.00
Tubing and Mat	McMaster	14.36	14.36
Bucket and Pump	Amazon	33.32	
Electronics & Misc.	Miscellaneous	39.33	16.94
Total Cost		***98.01***	***49.31***

Table 3: Components and Costs of the prototype as of 4/4/2012. As we optimize the design, we will be able to minimize the cost of most of the components. We also hope to have some components that can be modulated to be used with materials that are available on site such as the reservoir and pump, and to utilize cheaper components such as the microcontroller and have calculated our commercial cost to be $50.

6. Financial Projections and Long-Range Plan

6.1 Phase 1: Clinical Testing (2012-2013)

The application of the device on a biofluid infant model demonstrates 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 animals and under different conditions that may not have been achieved with the biofluid baby model. 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. In addition to conducting our own fundraising, we can encourage NGOs to fund further progress of our proposed solution with contributions such as grants. With results demonstrating the efficacy of our system on animal tests to raise and maintain their temperatures, we hope to obtain IRB approval to conduct tests on neonates.

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.

6.3 Phase III: Market Availability (2015-2021)

We will continue to request funds from various NGOs in order to mitigate some of the expenses associated with producing and distributing our product 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 also continue to reach out to developing countries nearby.

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.

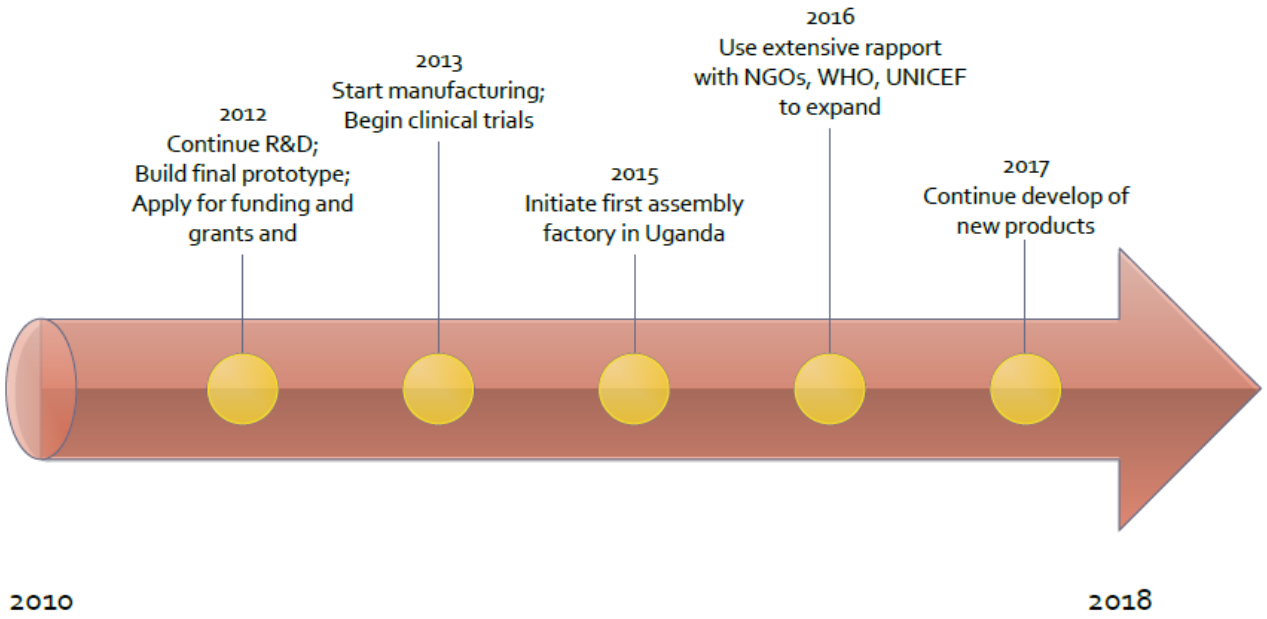

Figure 3: Graphical representation of our long range plan showing some of our key performance indicators. Financial performance indicators follow in *5.3 Financial Projections.*

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. 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 an amount of $500/unit for the cost of goods sold (COGS) which includes the cost of product and labor and anything used to the produce product, 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 4), 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					
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
# of Units	0	0	10	150	300	500	1200	1500	2000	2500
Sales ($)	0	0	500	7500	15000	25000	60000	75000	100000	125000
Funds from NGOs & Grants ($)	500	0	3500	10500	21000	34000	72000	89000	116000	145000
Fundraising ($)	500	0	5000	10000	15000	20000	30000	40000	50000	60000
Revenue ($)	**0**	**0**	**9000**	**28000**	**51000**	**79000**	**162000**	**204000**	**266000**	**330000**
R&D ($)	100	1000	700	700	500	500	400	500	2000	3000
Int'l Device Approval ($)	0	2000	5000	1000	500	500	500	500	500	500
SGA Expense ($)	0	0	10000	30000	50000	50000	50000	50000	50000	50000
COGS Expense ($)	400	200	500	7500	30000	50000	120000	150000	200000	250000
Transportation ($)	0	0	15	225	450	750	1800	2250	3000	3750
Total Cost ($)	**500**	**3200**	**16215**	**39425**	**81450**	**101750**	**172700**	**203250**	**255500**	**307250**
Net Income ($)	**-500**	**-3200**	**-7215**	**-11425**	**-30450**	**-22750**	**-10700**	**750**	**10500**	**22750**

Table 4 Financial projections given that the device can be sold for $50/unit.

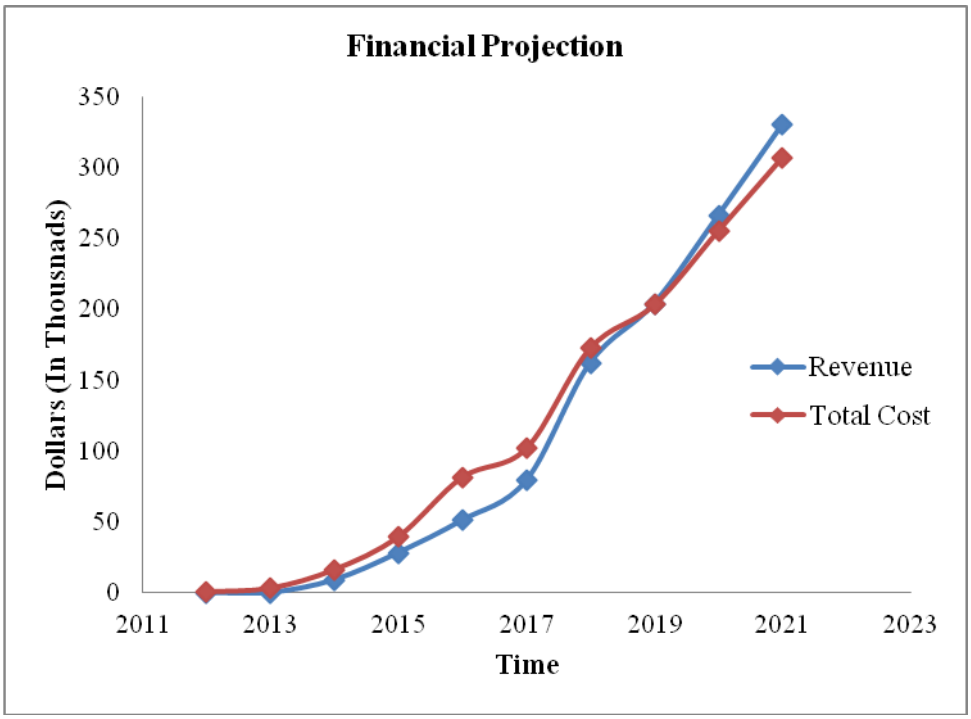

Figure 4: Cost and revenue plot of dollars vs. year. That being said, IncuVive expects to be profitable by roughly the first quarter of 2019.

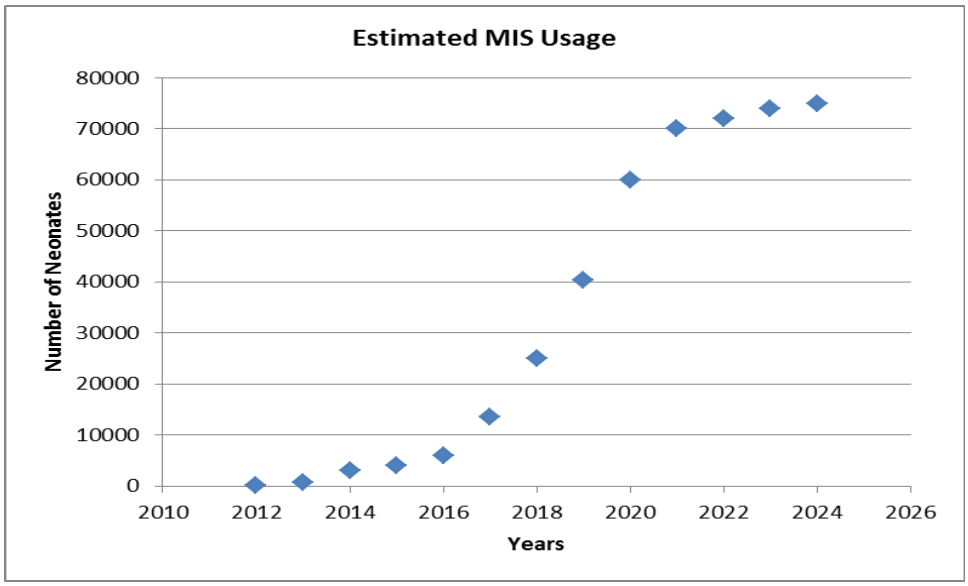

Figure 5: Estimated MIS Usage projection based on a conservative 10% outreach to all neonatal deaths from hypothermia. A more in-depth explanation is in DS 2: *Basic summary of problem*. As you can see, the curve is sigmoidal and saturated at roughly 72,000 neonates per year.

IncuVive is building a timely product with broad appeal, 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 is well positioned to capture a large market share and become highly profitable. 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 developing world.