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Inflatable Fall-Guard System

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by

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I. Acknowledgements

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II. Executive Summary

1. Problem

In General, human beings' health conditions are getting worse and worse as they get older. The phenomenon of aging is characterized by the onset of osteoporosis and other bone degenerative illnesses accompanied by decreased physical stability. Decreased bone integrity could lead to falls or accidents that create a high risk for hip and pelvic-related fractures for the elderly.

According to a hip fracture study, there are an estimated 300,000 elderly individuals suffering from hip fractures per year in the United States ("Majority of Hip Fracture"). Those who suffer from these injuries commonly require hip-nailing or hip-replacement procedures. Not only are these surgeries inconvenient, but they also lead to a significant financial burden on those patients who require them. Additionally, individuals typically suffer a decrease in physiological function even after a successful procedure. It is common for fall-related injuries to correlate with an overall decline in physical health, further leading to a loss of independence and overall quality of life. Long-term institutionalization is a consequence of 25% of elderly fall-related incidents. On the other hand, decreased bone integrity paired with falls or accidents could also lead to death. As shown in figure 1, the age-adjusted fall death rate is 64 deaths per 100,000 older adults according to CDC's older adult fall prevention. The death rate has increased by about 30% from 2009 to 2018 ("Deaths").

Currently, many fall protection devices in the marketplace are neither suitable for daily activities nor cheap enough for the majority of customers. The majority of these products are uncomfortable, bulky, or unattractive for them to be realistic for individuals to wear throughout all daily activities. The rest of the products are comfortable and technological but at a high price.

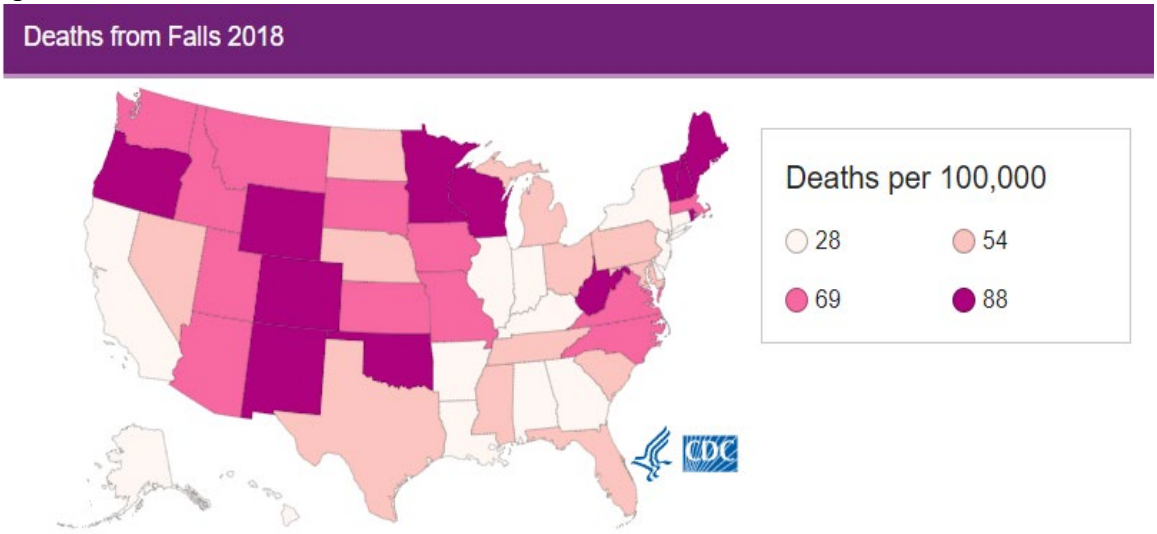

Figure 1. Death from Fall per 100,000 people in 2018

2. Solution

To address these concerns, the capstone team are aiming to develop a product that is comfortable, innovative, affordable, and created with an everyday appeal in mind. To produce a product of this nature, there are several medical and technological considerations necessary to take into account.

On the medical side, the capstone team plans to address data security and maintain product guidelines to meet all HIPAA policies. Data output from the device would only be available to the patient and patient-approved physicians. Furthermore, all technical considerations will be addressed and accommodated, respectively. The first of which is the required pressure differential to maintain an adequate CO_2 output to bags while also maintaining pressure levels in line with the capabilities of the gas routing and solenoid valve. This will be accomplished by downregulating pressure directly from CO_2 canisters to an adequate level. Additionally, the motion analysis system will be designed with a millisecond temporal resolution in mind. A resolution of the accuracy would provide adequate data output to maintain patient safety in all fall-related situations. Reference motion data will be obtained using our motion analysis system to define criteria to differentiate between falls and separate phenomena. This criterion will then be implemented into our prototype system.

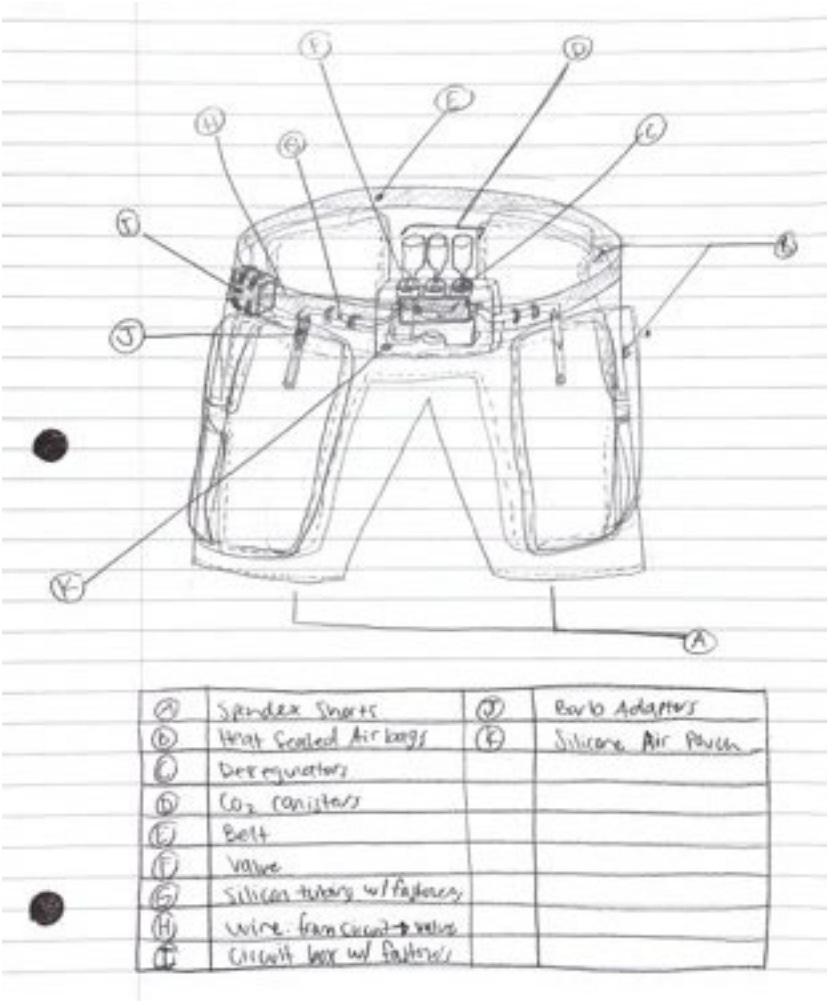

Figure 2. sketch and parts of the Inflatable Fall-Guard system

III. Market Analysis and Marketing Plan

There are lots of different types of hip protectors for the elderly in the market. Common types of padded hip protectors include Medline Hip Protector and Safehip Active Hip Protector shown in Figures 3 and 4. Those products are generally under $100 and can be easily purchased from the internet. However, with the cheap price, those hip protectors can only provide limited protection for the elderly compared to all the other products. At the same time, the tailbone pads are too hard to wear for daily life.

Figure 3. Medline Hip Protector

Figure 4. Safehip Active Hip Protector

There is another type of product, that called Hip'Guard has airbags with hip protectors for the elderly shown in Figure 5 below ("The Airbag Belt"). Those products are designed to be a belt that the elderly could wear and have better protection than the shorts. The belts are simple and user-friendly. The belt will automatically turn on when buckled, and it will indicate the use when the battery is low. The airbags attached to the belt will automatically fill with air when the users fall and give users great protection. The disadvantage of the product is that the price of the belt is around $600-$800, and the cost of replacing the gas canister is $50. Not a lot of people can afford the cost of the product and the replacement cost.

Figure 5. Hip' Guard

Tango Belt is device that is designed with airbags protection for hips shown in Figure 6 ("Tango® Belt"). Tango Belt is currently selling for $1500 and can only be used once. The cost of replacing the airbags is an additional $599. With the high price, Tango Belt collects data logging for balance and activity metrics. The belt can automatically contact the caregiver on

fall, and it has high accuracy in fall detection. Even though Tango Belt has great protection for the users, not a lot of people want to buy them since they could not afford the cost.

Figure 6. Tango Belt

With this project, the target customer would be those who are over 60 years old or younger people that are prone to falling due to health conditions. As a goal to saving budget, I would recommend the capstone team create a small number of prototypes of Inflatable Fall-Guard systems that can be tested at local nursing homes such as Katherines Place at Wedington and Superior Senior Care Fayetteville for improvement. After the test, the engineering team can go to large-scale manufacturing and start selling the Inflatable Fall-Guard system at the nursing houses in Northwest Arkansas. As the project moves forward, the capstone team could add a commercial website so that those who have the demand for the product can easily reach out to the right place and purchase the product. The engineering team would like to develop helmet components to prevent head injuries and back inflation for increased safety in the future.

IV. Cost Feasibility Analysis

The following analysis indicates the cost of materials and estimates expenses for labor and the factory. The attached Excel document uses numbers to present the details of the revenue and expenses.

1. Contingency

Based on the current circumstances in the world, the uncertainty of the ongoing conflict between Russia and Ukraine could affect the cost of materials. As the conflict between Russia and Ukraine continues to be a major focus, many economists and investors attach importance to the rising gas price and volatility of the stock market. The oil price rose more than 20% in the past few weeks. On the other hand, a whole host of other commodities rose on supply worries since Russia is such a key producer of wheat, palladium, aluminum, and others. The stock market has also been affected by the Ukraine war ("Russia's Ukraine Conflict"). The S&P 500 fell 1.3% to 4,328, while the Nasdaq lost 2.8% to 13,313 at the beginning of March. The S&P 500 and Nasdaq indicate that the largest 500 and 100 companies did not perform very well in the stock market because of the Ukraine war. The rising gas prices and unstable stock market cause the inflation rate to rise to 7.8%, the highest since 1982. Just like the economists raising their inflation forecasts due to rising oil prices, the capstone team should also get prepared for the upcoming change due to the conflict between Russia and Ukraine. The capstone team used 5.25% for contingency since they started working on the project around the third quarter of 2021. I would recommend the capstone team use 8.54% as the new rate for contingency (US Inflation Rate).

2. Components and Expenses

While working with the senior Capstone team, the biomedical and electronic engineering design team has decided which components would work best for the project. These materials and cost estimations are from the senior Capstone team. There are mainly four parts of the material for the product. All the materials that are required for electronics, hardware, belt, and airbags can be directly purchased from the market. The materials that the Capstone team selected are listed in Table 1.

The amount of $30 includes the costs for all electronic components such as gyroscope, accelerometer, 12v battery, and circuit. The majority of the components only need one to fulfill the need of the product. For the rest parts, in order to give great protection to the users, the products require multiple food storage bags and mattresses on the two sides to protect the users. The strings required for assembling the product may vary based on the different products. However, since the cost of strings is pretty low and almost close to zero, we estimate $0.05 for the cost of strings for each unit of product.

The costs of the materials will decrease if the quantity of the material purchased increases. The price for three men's compression shorts is $35, while the price for one unit is $20. The price for one 12v battery is $30, and eight 12v batteries can be purchased at $160. The price for three regulators is around $60 and $28 for one unit. The price remains at $29 for valve even when the quantity purchased is increased.

Material Component	Quantity	Price	Total Cost
Electronics			
Gyroscope	1		
Accelerometer	1		
Battery(9v)	1		
Circuit	1		
			$ 30.00
Hardware			
Valve	1	$ 29.00	$ 29.00
Regulator	1	$ 28.00	$ 28.00
CO2 Cartridges	1	$ 4.50	$ 4.50
16" Silicone Tubing	5	$ 1.80	$ 9.00
Barb adapters	1	$ 16.00	$ 16.00
			$ 86.50
Belt			
CLC Leather vraft belt	1	$ 4.92	$ 4.92
Silicone food storage bags	3	$ 20.00	$ 20.00
Various Plastic Fasteners	1	$ 10.00	$ 10.00
Small hose Clamps	1	$ 5.00	$ 5.00
			$ 40.00
Airbags			
Air Mattress	2	$ 9.97	$ 19.94
Epoxy glue	1	$ 5.99	$ 5.99
String	Unlimited	$ -	$ -
Men's compression shorts	1	$ 20.00	$ 20.00
			$46.00
Total			$ 202.50

Table 1. Component List and Cost

3. Operation and Manufactured Expenses

Since all the required materials can be directly purchased from the market, there are no additional parts needed for the product. According to the Arkansas manufacturing labor cost, the capstone team estimated hourly labor rate will be $21.03 for each worker to assemble the products. The monthly labor cost of hiring five workers to work 7 hours every day and 21 days a month to assemble the products will be $17,665.20, and it will be $35330.40 if we hire 10 workers. According to the Capstone team's estimates that the worker will need 3 hours to assemble the circuit board, 30 minutes to program the circuit board, and 30 minutes to affix the device to the garment and inflation bags. This implies us that each worker can assemble one unit of product every four hours, and it is only beneficial to have one person hand-soldering components to the board at a time. Hence, we will get 210 units of product per month for 5 workers and 420 units of product per month for 10 workers.

ConStruction Labor	Workers	Wage	Hours per day	work day	Total	Products per month
Labor Cost	5	$21.03	8	21	$17,665.20	210
Labor Cost	10	$21.03	8	21	$35,330.40	420

Table 2. Construction Labor Cost

The total construction cost equals the total materials cost plus the construction labor cost. According to the unit that workers can produce, this will lead to a cost of $60,190.20 or $120380.40 are shown in the table below. The table indicates the monthly total construction costs for 5 and 10 workers.

5 Workers			10 Workers	
Construction Cost	**Total**		**Construction Cost**	**Total**
Materials	$42,525.00		Materials	$85,050.00
Construction cost	$17,665.20		Construction cost	$35,330.40
Total	$60,190.20		**Total**	$120,380.40

Table 3. Total monthly construction cost

On the other hand, the manufactured cost equals direct labor plus direct materials. Costs of materials are listed above as $202.50 per unit of product. We do not know about facilities costs related to the product and we will use 25% additional of the materials as an estimate of facilities cost. For labor cost, we need to figure out how much it will cost to produce one unit of product, which costs $84.12. With direct labor and direct materials costs, we can get an estimate of the manufacturing cost for each unit. The details of cost are shown in Table 4 below.

	Materials cost	Facilities cost	Labor cost	Total
Manufacturing cost	$ 202.50	$ 50.63	$ 84.12	$ 337.25
5 workers				$ 70,821.45
10 workers				$ 141,642.90

Table 4. Total monthly manufacturing costs

4. Price Projections

We probably all have heard about the high profitability of medical devices. However, the priority goal of the project is making the users able to purchase the Inflatable Fall-Guard system rather than making a profit. Hence, it is quite important to charge a reasonable price for our product. The gross profit margin equals net sales minus the cost of goods sold divided by net sales. The gross profit margin for the medical equipment and supplies industry averages 12.1%, according to data from CSImarket.com ("Average Profit Margin by Industry"). The calculations are shown in Table 5 below. This will help us price the product at $384 for every single unit.

Gross profit margin=(Net Sales- Cost of Good sold)/Net Sales
Gross Profit Margin * Net Sales= Net Sales- Cost of Good Sold
Cost of Good Sold=Net Sales - Net Sales*Gross Profit Margin
Net sales = Cost of Good Sold/ (1-Gross Profit Margin)
Net sales = 337.25/ (1-12.1%)
Net sales=383.6746

Table 5. Price Projection

5. Revenue Calculations

With all the information we have right now, we should be able to calculate the revenue for the Inflatable Fall-Guard System. The details of revenue calculations are shown in Table 6 below. Since it is only beneficial to have one person hand-soldering components to the board at a time, the revenue is in direct proportion to the number of workers ("Making Your Medical Supply Business Profitable"). With the available space, the more workers we hire, the more revenue we can make per month.

Revenue	Sales	Price	Costs	Total
5 workers	210	$ 384.00	$ 70,821.45	$ 9,818.55
10 workers	420	$ 384.00	$ 141,642.91	$ 19,637.09

Table 6. Revenue Calculation

6. Tax Rate

Since the Capstone team only has nine people, I would recommend they create a limited liability company to enjoy all the benefits, including tax benefits. A limited liability company is a legal form of business other than a corporation or partnership in which the company files Articles of Organization and pays a fee in the state where the company wants to do business. In return for forming a limited liability company, the company could avoid double taxation, which means that the business is taxed on its income and the shareholders are taxed on dividends. Other than avoiding double taxation, a new deduction called qualified business income deduction allows small limited liability company owners to get a 20% deduction from the amount of the net income they filled.

The table below shows the related costs of filing a limited liability company in Arkansas. The Arkansas Online limited liability company filing fee will be $50 and the Registered Agent fee will either be $39 or $99 depending on the agent that the capstone team might choose. Those fees are one-time payments. Another fee related to the limited liability company is the Arkansas Franchise Tax fee, which is $150, which a limited liability company has to pay every year. There is a $25 late fee punishment if the limited liability company does not pay franchise tax on time ("LLC Arkansas Cost - Cost to Form an LLC in Arkansas: Truic").

Arkansas Online LLC Filing Fee	$50
Arkansas Franchise Tax	$150/yr, $25 late fee
Registered Agent Fee	$39or 99
Business Permits and Licenses (optional)	$50
Limite Liability Company Name Reservation	$22.50 online/$25 mail or in person
Certificate of Good Standing	$25
Certified Document Copies	$5+0.50 per page

Table 7. Filing limited liability company costs

The way that limited liability companies file their tax returns is similar to S Corporations. Other than the annual Franchise Tax fee, the limited liability company does not need to file any other corporate income taxes. The individual limited liability company will pay federal and state taxes on the amount of revenue distributed to them.

7. Patent Cost

For the best protection of innovation and technology, it is important for the engineering team to file a patent application for their design product. There are nine members on the engineering team, and they will share the ownership of the patent. Each of them will own 11.11% of the patent. According to the Forsgren Fisher's research on patent cost, the medical product patent will cost around $10,000-$25,000 depending on the process of the application. ("Bitlaw Guidance"). The details of the cost are shown below. The fee of a patent attorney is around $275-$400 per hour. This fee will depend on how many hours the engineering team needs the attorney's help.

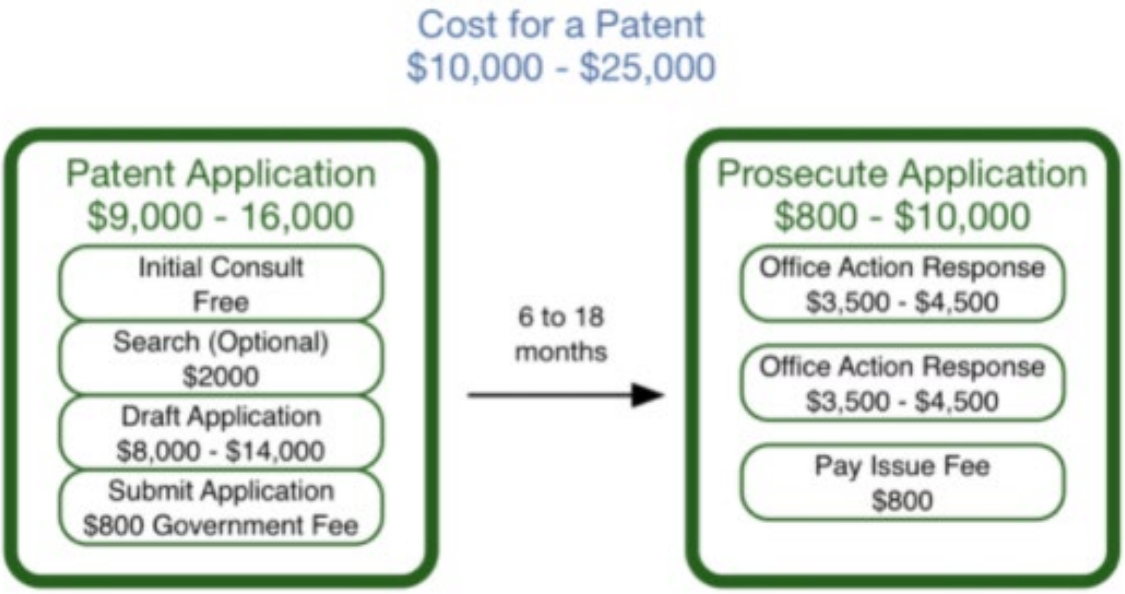

Table 8. Patent Cost

V. University Incentives

As we all know, the University of Arkansas has tremendous influence in Northwest Arkansas. The capstone engineering team could seek some help from the University of Arkansas at the early stage of their business.

The engineering could potentially ask the University of Arkansas for space to assemble their products to save facility costs in the early stages of their business. The University of Arkansas has several off-campus labs that might work for the team to rent. Hiring future engineering students would benefit the product and create job opportunities for students. Another good resource is the University of Arkansas start-up village located in downtown Fayetteville. The UA Startup Village supports seed-stage companies created by faculty, students, and alumni. The UA Startup Village has partnered with Faytown Designs and Mercery Collective, which will be helpful for the capstone team. Faytown Designs is a company that offers promotional products, wholesale products for retail, product design, engineering, and manufacturing for any size business. The capstone team could let Faytown Designs help with improving the Inflatable Fall-Guard system. On the other hand, Mercery Collective could provide assistance to meeting the needs of manufacturers while abiding by ethics and sustainability goals.

The engineering team could also introduce the Inflatable Fall-Guard System to the University of Arkansas specifically, the Eleanor Mann School of Nursing, in order to let them introduce the products to the customers and allow the customers to try the products. After the trial, the engineering team could ask the users to provide feedback so that they can use the data to further modify the products.

Furthermore, the engineering team could potentially get funding from the University of Arkansas if they would like to exchange part of their patent. Right now, there are nine members on the engineering team and each of them owns 11.11% of the patent. The Capstone team will need to discuss and negotiate with the university to figure out how much percentage of patent they are willing to exchange for certain amounts of funding. Another apt way to obtain funding is by participating in competitions that are organized by the University of Arkansas Office of Entrepreneurship and Innovation. The winners of competitions could obtain funding of$2,000 up to $100,000 (“Heartland Challenge”).

VII. Analysis

There are many factors to consider before considering whether to invest in this project. The gross profit margin for the Inflatable Fall-Guard system is 12.1%, similar to all the others profit margins of product in the medical device industry ("Average Profit Margin"). The operating profit margins are equal to the operating profit margin divided by net sales. The operating profit margin was 11.48% for the Inflatable Fall-Guard system. For net profit margin, we will use net income divided by net sales and end up getting 10.53% for the Inflatable Fall-Guard system. Overall, the net profit margin for our product is considered average in the industry since the Capstone team is aiming to give up part of their profit to exchange for customer satisfaction. The detailed calculations are shown in Table 9 below.

Gross Profit Margin	12.10%
Operating Profit Margin	$ 222,093.50
Net Sales	$ 1,935,360.00
Operating Profit Margin	11.48%
Net Income	$ 203,823.50
Net Sales	$ 1,935,360.00
Net Profit Margin	10.53%

Table 9. Gross Profit Margin, Operating Profit Margin, and Net Profit Margin Calculation

There are several other incentives for the University of Arkansas to invest in this project. These incentives, such as job opportunities for engineering students to operate and assemble, collaborate with the Sam Walton college of business to let students navigate the real-world of business. These are all factors the university must consider before investing. The weight of these non-monetary incentives must be taken into account.

With all calculations and other incentives considered, I recommend the University of Arkansas invest in this Inflatable Fall-Guard system. There is potential for monetary gain. I believe this project has the potential to be very impactful for the University of Arkansas.

VIII. Appendix

1. Net Income Statement

The net income statement can be found in the excel document below. The example assumes the company will hire 10 workers to work on the products. Therefore, the example uses 10 workers for the salaries estimates. Net income is calculated by taking gross profit and subtracting all of the operating and non-operating expenses. The details are shown in the Table 10 below.

Inflatable Fall-Guard System	
Income Statement	
Sales Revenue	$ 1,935,360.00
Cost of Goods Sold	$ 1,020,600.00
Gross Profit	$ 914,760.00
Operating Expenses	
Facilities	$ 255,175.20
Wages	$ 437,491.30
Total Expenses	$ 692,666.50
Operating Income	$ 222,093.50
Non Operating, Other	
Patent Application	$ 18,000.00
Arkansas Onlice LLC filiing	$ 120.00
Profit befor tax	$ 203,973.50
Franchise Tax cost	$ 150.00
Net Income	$ 203,823.50

Table 10. Income statement calculation

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