



*baby*ation

Business Plan

November 2015

Proprietary and Confidential

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Glaring Need

Any mother will tell you that the breast pumps currently on the market are severely outdated and drastically underserve the needs of the women who purchase and use them. Despite the fact that the pumps leave much to be desired, consumers buy them because they have no viable alternative. Women often use a breast pump to allow them to return to the workplace; 85% of breastfeeding moms have tried a pump, with 25% continuing to use them regularly¹.

In the past two years, the shortcomings of breast pumps have been highlighted by mainstream media in unprecedented detail. Dozens of articles were written by outlets such as *The New York Times*, CNN, *The Huffington Post*, *The Los Angeles Times*, *The Atlantic* and *Newsweek*. Much of this recent attention has centered around a MIT Hackathon in September of 2014 that was dedicated to “Making the Breast Pump Not Suck.” While a modicum of new thinking emerged from the Hackathon, opportunities to innovate still abound.

The most popular portable breast pump currently on the market is based on a patent from 2003 – 12 years ago. These pumps are loud, clunky, lack discretion, and are “dumb.” These clear deficiencies caused *The New York Times* to pose the following question in a headline: “Shouldn’t the breast pump be as elegant as an iPhone and as quiet as a Prius by now?”

Breast Pump Primer

According to the FDA, “All breast pumps consist of a few basic parts:

- a) Breast Shield: a cone-shaped cup that fits over the nipple and the circular area surrounding the nipple (the areola).
- b) Pump: creates the gentle vacuum that expresses milk. The pump may be attached to the breast shield or have plastic tubing to connect the pump to the breast shield.

¹ <http://www.ncbi.nlm.nih.gov/pubmed/18829833>

- c) Milk Container: a detachable container that fits below the breast-shield and collects milk as it is pumped. The container is typically a reusable bottle or disposable bag that can be used to store the milk or be attached to a nipple and used for feeding a baby².”

There are three different types of pumps: electric (plugs into a wall outlet), battery-operated (runs on batteries, can sometimes be plugged in) and manual (operated by the mother). All of them operate on a similar premise of creating a seal on the breast and using suction to express breast milk. Pumps can be single (one breast at a time) or double (both breasts simultaneously). Most pumps have to be held at the breast unless a consumer purchases a separate bra specially designed for pumping.

Because breast pumps are considered Class II medical devices, they are regulated by the FDA and require 510k clearance. Unlike the process required for more invasive devices, the 510k submittal simply has to demonstrate that the device is “substantially equivalent” to others already on the market. We have worked with several FDA consultants who have all assured us of a very straightforward regulatory process since this is a well-understood space.

Babyation’s Product and Company History/Awards

We have taken a clean-sheet approach in order to optimize our product for the working mom. It is quiet, discreet, innovative, smart, easy to clean and closest to baby. Babyation’s patent-pending product isn’t just an evolution of pumps that are presently available; its design is revolutionary. Our pump is quiet and our re-imagined form-factor allows a woman to keep her shirt on while pumping. Our goal is to allow a woman to be able to pump inconspicuously – wherever she is. The user experience is integrated with the user’s cell phone, allowing seamless control while multitasking, as well as an opportunity for “smart” data logging.

Our pump features low-profile breast shields that more closely mimic a baby’s mouth. The shields are held in place and concealed by a proprietary bra. Milk is pulled through to a separate bottle that is not

² <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BreastPumps/ucm061584.htm>

located on the breasts. The user is able to control the pump and track various metrics via an app on her phone. Babyation's pump is optimized to reduce cleaning time at the end of a long workday.

Babyation has secured a provisional patent on this innovative pump. As of Fall 2015, we are finalizing the pump prototype; upon completion, we will begin independent lab testing and the regulatory process. Our regulatory consultant has indicated that this will be straightforward, and she advises that this process should take less than six months from the time of submission.

The company was organized in March 2015, following a year of R&D. In June 2015, Babyation received an Entrepreneur Innovation Award from CTNext, and in October 2015, we were named a "Tech Company to Watch" by the Connecticut Technology Council. We recently relocated from Branford, Connecticut to St. Louis, Missouri and are proud to be a 2015 Arch Grants recipient.

Breast Pump Industry Analysis, Market Opportunity and Target Consumer

The breast pump industry is quite robust, and it continues to grow. Transparency Market Research has projected the breast pump industry will be valued at **\$2.61 billion**³ globally in 2020, with the U.S. market comprising the largest segment. A report from Global Industry Analysts estimates that the market is expected to reach **5.63 million units** in 2015⁴.

The number of women breastfeeding in the United States has increased over the last decade, and upswing is continuing. The CDC has published the following statistics on the uptick in breastfeeding⁵:

³ <http://www.transparencymarketresearch.com/pressrelease/breast-pumps-market.htm>

⁴ http://www.strategyr.com/Breast_Pumps_Market_Report.asp

⁵ http://www.cdc.gov/breastfeeding/data/NIS_data/index.htm

	2001	2011	2020*
Started Breastfeeding	71.6%	79.2%	81.9%
Still Breastfeeding at 6 months	37.3%	49.4%	60.6%
Still Breastfeeding at 12 months	18.5%	26.7%	34.1%

*Targets were set as part of the Healthy People 2020 Initiative⁶

For the breast pump industry, those women still breastfeeding at six and 12 months are the most compelling potential customers. Most working mothers' maternity leaves will have concluded at that point (at least in the US), and they will generally need a pump to assist in milk expression during working hours. The steady increase in working mothers is part of the reason for the considerable year-over-year sales growth. Also, all major health organizations continue to espouse the benefits of exclusive breastfeeding for at least six months⁷, and The World Health Organization recommends breastfeeding for as long as two years⁸. Lastly, most commodity pumps are marketed as single-use devices, precluding reuse of pumps between mothers.

Following the implementation of the Affordable Care Act (ACA), "the health care law requires most health insurance plans to provide breastfeeding equipment and counseling for pregnant and nursing women⁹." Coverage varies significantly among plans, so it's difficult to draw a conclusion as to the full impact on the market, but it is widely expected that the new provisions will increase pump sales even further. Unfortunately, there is no regulation around the type and quality of pump covered. Many women still buy pumps directly from retail stores if the pump offered by insurance isn't sufficient.

⁶ <http://www.healthypeople.gov/>

⁷ <https://www2.aap.org/breastfeeding/faqsBreastfeeding.html>

⁸ http://www.who.int/nutrition/topics/exclusive_breastfeeding/en/

⁹ <https://www.healthcare.gov/coverage/breast-feeding-benefits/>

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Babyation is targeting new moms with disposable income. They are likely career-oriented and want to breastfeed following their maternity leaves, and they are willing to pay a premium. These moms also might pump milk for donation or sale, or to have a little more control over their schedules.

Key Competitors

The vast majority of pumps are in the “horn style” (named because of their appearance). This basic design has been unchanged in the last 60 years.

Medela is the clear leader in the U.S. market in terms of brand awareness and market penetration. Anecdotal surveys at various national chain retailers like Target, BuyBuyBaby and Babies R Us demonstrate that Medela products (pumps and accessories) take up at least twice as much shelf space as all other pump/accessory manufacturers combined.

The following image accompanies the company’s Freestyle Breastpump¹⁰.



Spectra generally receives the most favorable reviews online. Other companies selling similar outdated pumps include Ameda, Evenflo, Lansinoh, Dr. Brown’s and Phillips AVENT.

Recently, some start-ups have injected a modicum of new thinking into the market. Freemie, for instance, is selling a hands-free version that allows women to “pump with your shirt on”¹¹, but given that the collection devices are bulky and remain on the breasts, the product is hardly discreet. Freemie

¹⁰ <http://www.medelabreastfeedingus.com/products/463/freestyle-breastpump>

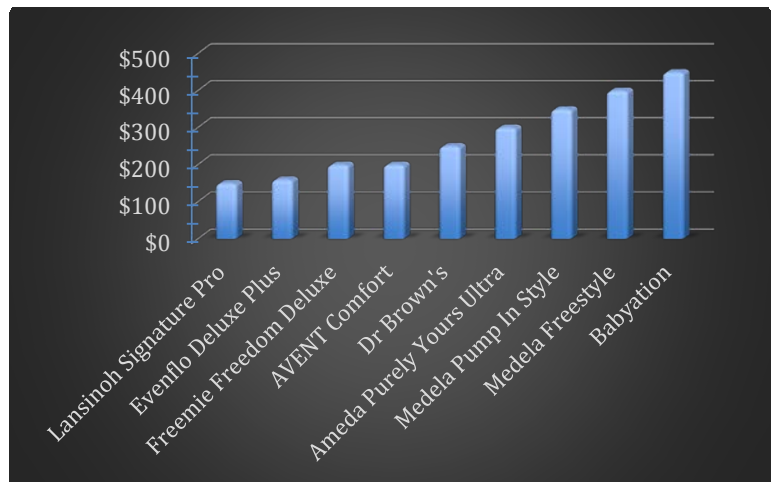
¹¹ <http://www.freemie.com/>

hasn't achieved national retail distribution yet, but sells its products through its website, Amazon.com, local retailers and durable medical equipment suppliers across the country.

Kohana first began product development in 2012 and still isn't selling its Gala pump. The company has secured funding and received some press for placing in various business competitions¹².

Moxxly and Naya Health are newer to the space. They are both startups that received funding and have some evolutionary ideas, but their pumps don't appear to be as revolutionary as Babyation's. Moxxly's pump still has collection devices attached to the breast. Lastly, the winners of the MIT Hackathon aren't listed because they haven't demonstrated commercialization intentions thus far.

Current high-end breast pumps retail for approximately \$400. Despite the initial lack of brand recognition, Babyation firmly believes that the product's expanded feature-set can command an increased price point of \$450. That price is also very much in line with the luxury baby market, where a stroller system cost can exceed \$1,000 and the price of a diaper pail is over \$300.



¹² <http://www.kohanainc.com/About-Us.html>

Marketing Plan

Moms know how to purchase breast pumps; they just need to be exposed to ours. Babyation's initial marketing strategy will focus on using word-of-mouth and social media to increase brand awareness.

The effort will consist of the following components:

- PR campaign targeted at the dozens of reporters that have written articles documenting the shortcomings of breast pumps.
- A robust social media effort.
- Courting "mommy bloggers." These women wield incredible influence over new/pregnant moms, who are desperate for information. Positive reviews from these bloggers will be crucial to our success, and as such, they will be provided free products to demo.
- Launching a crowdfunding campaign. This will have two benefits: receiving funding and as a marketing tool. Breastfeeding and pumping have been thrust into the social spotlight lately. Celebrities have posted many "brelfies" (breastfeeding selfies).
- Partnering with lactation consultants. We have identified some experts in the lactation space, and we will work with them to espouse the benefits of our products to their clients.
- Build a stable of Twitter followers and Facebook "likes" through posts about a variety of parenting issues and articles, especially breastfeeding and pumping.

Once the product has received FDA 510k clearance, a more traditional marketing/PR campaign can begin, in addition to:

- Partnering with lactation consultants regarding product recommendations.
- Selling through durable medical suppliers and attaining coverage by insurance companies.
- Attending trade shows like the ABC Kids Expo.

Distribution

The distribution strategy will consist of two separate phases. In the first phase, starting in 2016 upon receipt of the FDA's 510k clearance, the product will be sold directly through Babyation.com and other online channels (Amazon.com, etc.). Distribution will be sought at boutiques and medical supply stores, as well as national retail chains, once volume becomes sufficient and production economies of scale are realized. Babyation will also work with insurance companies and durable medical equipment suppliers to ensure the device is covered by Affordable Care Act subsidies.

Once sales exceed 10,000 units per year (projected to occur in 2018), Babyation envisions implementing a series of design changes in order to transition the production methodology from a manual process to a more automated approach. This is projected to decrease the per-unit assembly cost. Additionally, the increase in batch size will significantly decrease the component costs.

Management Team and Board of Advisors

Babyation was founded by Jared Miller and Samantha Rudolph, a husband-and-wife team based in Connecticut. Jared is primarily responsible for product invention and oversight, as well as sourcing and technology. Samantha's area of responsibility includes all business aspects.

Jared (CTO) is an expert in the implementation of emerging technologies. With a background in system integration, IT engineering, and software development, his skillset encompasses all phases of high-tech project execution, from proposal development through conceptual and detailed design, to project management and execution. He has also been responsible for implementing quality systems and change-management practices at multiple organizations. Jared is adept at building anything electronic or involving computers. He has developed the circuitry, microcontroller firmware and related software behind Babyation's pump. Jared received his Bachelor of Science in Engineering with a concentration in Computer and Telecommunications Engineering from the University of Pennsylvania. He has owned his own software and technology consulting firm since 2007.

Samantha (CEO) excels at designing innovative strategies for startups, nascent businesses and cutting-edge product launches. Sam spent nine years as a serial entrepreneur within ESPN, where she founded the pre-game area of ESPN's Stats & Analysis team, the group responsible for live scores and stats across platforms. She produced ESPN's creative staging for three days of live television from the floor of the Consumer Electronics Show, focusing on the company's big picture and brand. Sam graduated with a Bachelor of Science in Economics from The Wharton School at the University of Pennsylvania, where she received dual concentrations in Operations and Information Management (Decision Processes) and Management (Strategic Focus). She specializes in project management and budgetary oversight, as well as strategic/creative thinking. Since 2013, Sam has operated a consulting company that advises startups, private equity firms and management consulting companies.

Jared and Sam are in the process of identifying members of an advisory board. Those members will have expertise in the following areas:

- FDA 510k clearance process for Class II medical devices
- The insurance industry and getting devices covered
- Lactation
- Retail
- Manufacturing

Overall Timeline

As with many new ventures, Babyation's timeline is greatly impacted by funding milestones. An additional factor in the timing is the FDA's regulatory process. Should Babyation receive FDA clearance and the necessary funding, the product is projected to be available for sale by early-to-mid 2016.

Priorities for the remainder of 2015 include (in no particular order):

- Installing a board of advisors
- Continued consumer outreach and crowdfunding campaign
- Prototype finalization and independent lab testing
- FDA 510k clearance
- Procure requisite funding for start-up costs

Key milestones in 2016 include qualifying for insurance coverage, online sales and distribution at boutiques. A product redesign will highlight 2017, followed by national retail distribution in 2018.

Critical Risks and Barriers to Entry

While a tremendous opportunity exists in the market and the need is strong, potential pitfalls remain. The biggest initial hurdle is completing the FDA clearance process. Once approved, it will still be difficult to compete with industry giants entrenched in the market. Those companies are better funded, boast name recognition/brand loyalty, and have cost benefits intrinsic to mass-production.

However, those exact qualities that make the established companies fierce competitors also represent their weaknesses. Babyation can be more nimble and innovative. Through a robust grass-roots and social marketing campaign, Babyation can generate buzz that doesn't exist for competitors. Positive reviews from early adopters and appropriate endorsements will enable Babyation to establish a foothold in the market.

Another potential issue includes other start-ups beating Babyation to market. Given the amount of coverage breast pumps have received over the past year, it is clear that competing companies are working to develop breast pumps that address some of the deficiencies of currently-existing products. There is a chance that a start-up further along in development can get to market sooner, potentially eroding Babyation's market share.

A final problem is the moderate cost barrier to entry into the market. There are cash flow concerns inherent to the need to fund the company through the duration of the FDA regulatory process and initial sales growth period.

Potential for Future Expansion and Additional Revenue Streams

While the breast pump market is huge, the baby ecosystem is astronomical. According to Statista, "the baby care market was worth 44.7 billion U.S. dollars in 2011 and is expected to increase total sales to 66.8 billion U.S. dollars by 2017¹³." If Babyation can establish itself as a brand parents know and trust, the potential for future expansion is much larger than the significant breast pump market.

The most obvious area of product extension would include pump accessories, including additional tubing, proprietary soap and replacement nipple shields. Medela currently sells a significant amount of accessories, and there is tremendous profit to be made if Babyation can emulate that model.

Babyation also has plans to expand into hospital-grade pumps. These pumps boast a much higher price point (in the thousands) and are available for rental.

¹³ <http://www.statista.com/statistics/250853/global-baby-care-market-size/>
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Beyond breast pump accessories and hospital-grade pumps, an opportunity exists to expand into categories such as baby care products, toys and even furniture. We also see the potential for co-branding and strategic alliances with other players in the market in order to expand our presence.

Financials and Sales Projections

Babyation as a company was formed in 2015 Q1 after a stealth year of R&D. All expenses have been self-funded through savings; no debt has been incurred and no equity has been distributed.

Development has occurred out of a home office thus far, precluding the need for commercial rental or utility costs.

Babyation's financials reflect projections for breast pump sales only; sales for the accessories market or additional potential revenue streams are not included in this document.

Based on timelines and sales projections, Babyation anticipates breaking even in 2018. This is principally due to the anticipated Phase 2 redesign for manufacturability that will occur during 2017.

Uses of Start-Up Funds

Below is a summary of estimated start-up costs; they don't include any compensation for Sam and Jared. They are only approximations and may vary; hence a 10% contingency was included to account for unexpected occurrences. Babyation anticipates that all startup expenses will be incurred in 2015, however no revenue is anticipated until 2016 due to the timeline for FDA clearance.

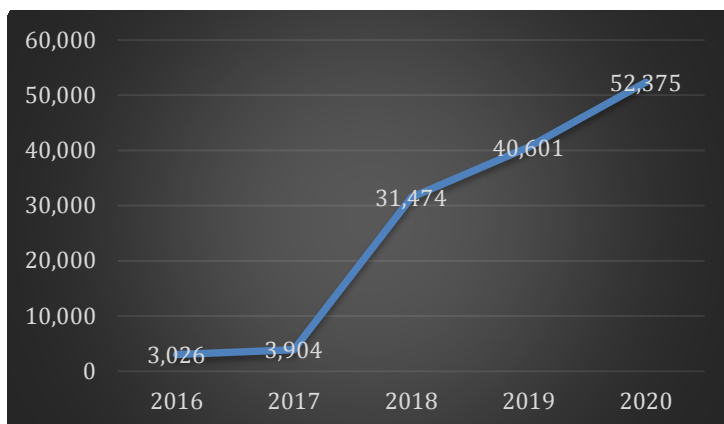
General and Administrative	\$ 42,000
Initial Research and Development	\$ 14,500
Design Refinement	\$ 92,000
Sales and Marketing	\$ 16,500
FDA Clearance	\$ 206,155
Initial Production	\$ 51,000
10% Contingency	\$ 42,216
Total Start Up Costs	\$ 464,371

Sources of Start-Up Funds

To date, Babyation has relied on self/family funding, business plan competitions, grants and a planned crowdfunding campaign on Indiegogo.

Sales Projections

The annual sales projections include very modest sales estimates. Projections are based off an assumption of one tenth of one percent initial market penetration. Steady growth is assumed from there, with a one-time moderate jump as Babyation expands into national retail in 2018.



Profitability by Sales Outlet

This chart highlights Babyation's expected profit by distribution outlet. As Babyation expands into national retail, the profit margins will shrink, but they will be more than compensated for by significant sales volume increases.



Profit and Loss Projection

	(\$ In Thousands)						2015	2016	2017	2018	2019	2020
Revenue												
Pumps Sold Through Babyation.com	\$	-	\$	341	\$	351	\$	694	\$	895	\$	462
Pumps Sold Through Other Online Channels	\$	-	\$	564	\$	583	\$	1,174	\$	1,514	\$	1,563
Pumps Sold Through Boutiques	\$	-	\$	189	\$	391	\$	1,180	\$	1,320	\$	1,571
Pumps Sold Through National Chains	\$	-	\$	-	\$	-	\$	4,957	\$	6,577	\$	9,192
Total Revenue	\$	-	\$	1,094	\$	1,325	\$	8,005	\$	10,307	\$	12,788
Direct Expenses												
Pumps Sold Through Babyation.com	\$	-	\$	148	\$	152	\$	224	\$	288	\$	149
Pumps Sold Through Other Online Channels	\$	-	\$	304	\$	314	\$	447	\$	577	\$	595
Pumps Sold Through Boutiques	\$	-	\$	152	\$	314	\$	670	\$	749	\$	892
Pumps Sold Through National Chains	\$	-	\$	-	\$	-	\$	3,129	\$	4,151	\$	5,801
Total Direct Expenses	\$	-	\$	604	\$	780	\$	4,469	\$	5,765	\$	7,437
Gross Profit	\$	-	\$	490	\$	544	\$	3,536	\$	4,541	\$	5,351
<i>Gross Profit Margin</i>				45%		41%		44%		44%		42%
Operating Expenses												
General and Administrative												
Management Salaries	\$	-	\$	200	\$	200	\$	300	\$	300	\$	300
Customer Support Costs	\$	-	\$	35	\$	70	\$	175	\$	280	\$	280
Corporate Travel	\$	-	\$	46	\$	91	\$	109	\$	131	\$	158
Office Lease + Utilities	\$	-	\$	50	\$	60	\$	100	\$	120	\$	144
Office Supplies	\$	-	\$	8	\$	10	\$	19	\$	23	\$	28
Insurance - Liability, Key Person, etc.	\$	-	\$	15	\$	20	\$	40	\$	45	\$	50
Legal / Tax / Accounting	\$	-	\$	75	\$	90	\$	180	\$	216	\$	259
Total G&A Expenses	\$	-	\$	429	\$	541	\$	924	\$	1,115	\$	1,218
<i>% of Revenue</i>				39%		41%		12%		11%		10%
Sales and Marketing												
Marketing / Promotion / PR	\$	-	\$	225	\$	275	\$	300	\$	360	\$	432
Sales / Business Development Support	\$	-	\$	200	\$	250	\$	150	\$	150	\$	150
Marketing / PR Support	\$	-	\$	50	\$	60	\$	120	\$	144	\$	173
Total S&M Expenses	\$	-	\$	475	\$	585	\$	570	\$	654	\$	755
<i>% of Revenue</i>				43%		44%		7%		6%		6%
Information Technology												
Hardware, Software	\$	-	\$	2	\$	3	\$	4	\$	6	\$	7
Telecommunications	\$	-	\$	2	\$	3	\$	3	\$	4	\$	4
Hosted Environment	\$	-	\$	9	\$	12	\$	20	\$	22	\$	24
IT Support	\$	-	\$	-	\$	-	\$	100	\$	100	\$	100
Total IT Expenses	\$	-	\$	13	\$	17	\$	27	\$	31	\$	35
<i>% of Revenue</i>				1%		1%		0%		0%		0%
R&D												
Engineering Support	\$	-	\$	100	\$	200	\$	200	\$	200	\$	200
Research and Development	\$	-	\$	20	\$	150	\$	75	\$	75	\$	75
Total R&D Expenses	\$	-	\$	120	\$	350	\$	275	\$	275	\$	275
<i>% of Revenue</i>				11%		26%		3%		3%		2%
Start-Up Costs	\$	464	\$	-	\$	-	\$	-	\$	-	\$	-
Total Operating Expenses	\$	464	\$	1,037	\$	1,493	\$	1,796	\$	2,075	\$	2,283
Operating Income (EBIT)	\$	(464)	\$	(546)	\$	(949)	\$	1,740	\$	2,466	\$	3,068
<i>% of Revenue</i>				-50%		-72%		22%		24%		24%

Financials don't include depreciation or amortization. Support costs shown are inclusive of benefits, as necessary. There is a planned product redesign in 2017 to coincide with expected national retail distribution in 2018. That redesign will allow for improved economies of scale and increased production batch sizes. Those R&D costs are reflected in 2017, along with additional marketing, sales and business development costs necessary to enter the national retail market. Once the product is distributed nationally, Babyation will break even and begin demonstrating robust yearly profits.

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