



# Market Analysis

Cornell iGEM  
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## Demographics and Segmentation

### In the United States

According to Progressive Publishing's 2015 statistics, there are 9,317,000 cows in the US and around 209 million of pounds milk was produced that year. At the average price of \$0.241 per pound of milk, all the milk produced amounts to \$50 billion dollars. On average, each cow in the US produced 22400 pounds of milk<sup>1</sup>.

Mastitis costs the dairy industry about \$1.7 to 2 billion annually, in other words 11% of the total US milk production. Most of the cost is from the lost profit due to the reduced milk production of when cows are affected with mastitis. Apart from the lost profit, costs also include labor, discarded milk, treatment, and veterinary services. Adding all these costs, a cow with mastitis could cost the dairy farmer anywhere ranging from \$117<sup>2</sup> to \$444<sup>3</sup>.

### Worldwide

Internationally, there are 264 million dairy cows and they produce about 600 millions tonnes (around 1.3 trillion pounds) of milk per year. United States is the biggest producer of milk and produces around 14.6% of the milk worldwide<sup>4</sup>. The cost of mastitis differs from country to country; it costs Dutch farmers €17 to €198 per average cow per year for example<sup>5</sup>.

### Summary

#### Table 1.

	# Cows	Lbs Milk Produced	Annual Loss to Mastitis	% of Total Milk Production Lost
US	9.3 million	2.1 billion	\$1.7-2 billion	11%

<sup>1</sup> U.S. Dairy Stats - Progressive Dairyman. Retrieved October 19, 2016, from <http://www.progressivedairy.com/site/stats/us-dairy-stats>

<sup>2</sup> Understanding the Basics of Mastitis. (2009, May 1). Retrieved October 19, 2016, from <http://animalwelfareapproved.org/2010/09/27/dairy-cattle-antibiotic-residue-review/>

<sup>3</sup> Rollin, E., Dhuyvetter, K. C., & Overton, M. W. (2015, December). The cost of clinical mastitis in the first 30 days of lactation: An economic modeling tool Retrieved October 19, 2016, from <http://www.sciencedirect.com/science/article/pii/S0167587715300490>

<sup>4</sup> Compassion in World Farming. (2007, January 7). Retrieved October 19, 2016, from <http://www.ciwf.org.uk/>

<sup>5</sup> Current status and future challenges in mastitis research. (2011, October 10). Retrieved October 19, 2016, from <http://www.milkproduction.com/Library/Scientific-articles/Animal-health/Current-status-and-future-challenges-in-mastitis-research/>

World	264 million	1.3 trillion	---	---
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\*total production loss takes into account lost profit from infected milk, treatment costs, and production lost due to infected cows being unusable

The dairy industry, both in the US and worldwide, is enormous. With an estimated domestic market size of \$50 billion and an estimated international market size of \$313 billion, there is no doubt that it is an industry of consequence. The US is the largest producers of milk in the world, accounting for 14.6% of the total production. In the US alone, bovine mastitis costs the industry an annual loss of up to \$2 billion dollars and roughly 11% of the total milk production. With a potential 305 day production loss (21,000 lbs of milk) and \$171-300 treatment fee per cow, the need for a more effective treatment is clear.

### **Current Mastitis Treatment**

Current mastitis treatment is very inefficient and is wasteful. Mastitis is detected from visible swelling and abnormal milk. To find the specific bacterial cause of the mastitis, a milk sample has to be sent to the lab for testing before treatment can begin. Sick cows are then separated from the rest of the cows for weeks. This separation of the cow is necessary but detrimental to the cow as it is stressful to the cow and affects the social structure. They then undergo antibiotic treatment. For a long period the cow can't be milked because the antibiotics are unsafe for human consumption. Often, antibiotic treatment is administered where there is not even any bacterial culture to kill. There are different types of bacteria that cause mastitis and often the wrong antibiotic is administered. This problem contributes to the low cure rate of 50-60%.

In addition to the inefficiencies of current mastitis treatment, it is also very expensive. A single case could cost up to \$444 (table below) per cow. Antibiotic treatment costs \$60 per case. Somatic cell counts are used for testing. Reducing mastitis saves significant amounts of money for farmers.

Our product is superior to the current solutions in that it does not involve antibiotics, it is more affordable in diagnosis, and that it is better for the cow. Unlike antibiotics which can be ineffective and carry the risk of resistance, bacteriocins are natural, safe for human consumption, and effective against specific strains of bacterial infection.

Table 2.<sup>6</sup>Breakdown of estimated cost per case of clinical mastitis in the first 30 days of lactation.<sup>a</sup>

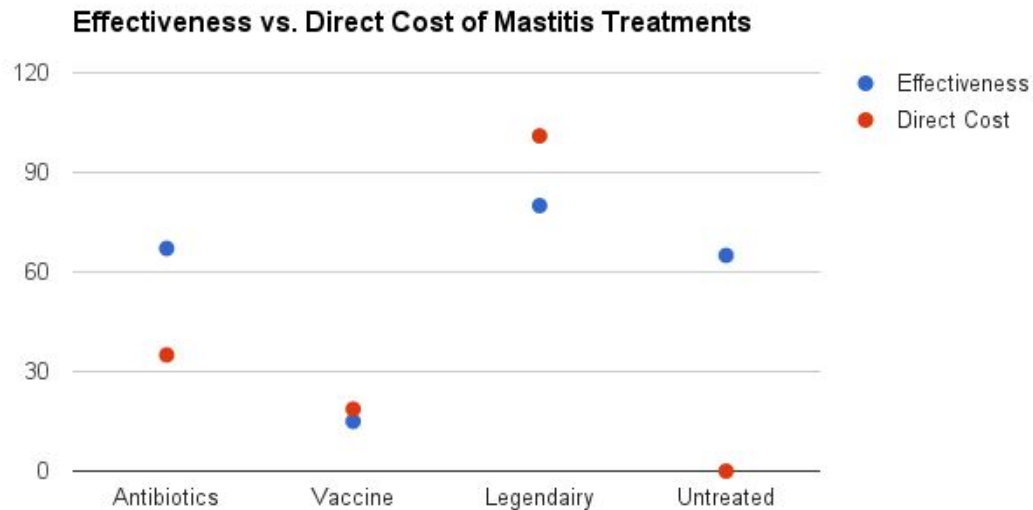
		Lact = 1		Lact > 1		Overall		
		Cost incident case	per	Cost incident case	per	Cost incident case	per	% of total cost
<b>Direct costs</b>	Diagnostics	\$9		\$11		\$10		2.3
	Therapeutics	\$30		\$40		\$36		8.1
	Non-saleable milk	\$18		\$30		\$25		5.7
	Veterinary service	\$4		\$4		\$4		0.9
	Labor	\$19		\$22		\$21		4.7
	Death loss	\$19		\$40		\$32		7.2
	Direct cost/case	\$100		\$146		\$128		28.9
<b>Indirect costs</b>	Future milk production loss	\$149		\$111		\$125		28.2
	Premature culling loss	\$176		\$185		\$182		40.9
	Future repro. loss	\$9		\$9		\$9		2.0
	Indirect cost per case	\$333		\$305		\$316		71.1
<b>Average cost per case</b>						\$444		

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<sup>6</sup> Rollin, E., Dhuyvetter, K. C., & Overton, M. W. (2015, December). The cost of clinical mastitis in the first 30 days of lactation: An economic modeling tool

Results are rounded to the nearest whole US dollar.

Graph 1.<sup>7</sup>



The graph above outlines the effectiveness versus direct cost of the mastitis for different types of treatments. It is important to notice that direct cost does not include cost that profit that is lost due to the sick cow. The indirect costs increases according to the time that cows are sick. Although the cure rates of cows that are untreated and cows that are treated with antibiotics are similar<sup>8</sup>, cows that are treated cure faster than the ones that are untreated and as a result, the indirect cost for treated cows is significantly lower than the ones that are untreated. It is also important to note that when antibiotics are used, cows can develop antibiotic resistance and the treatment becomes ineffective. On

<sup>7</sup> Wilson, D. J., Gonzalez, R. N., Case, K. L., Garrison, L. L., & Groöhn, Y. T. (1999). Comparison of Seven Antibiotic Treatments with No Treatment for Bacteriological Efficacy Against Bovine Mastitis Pathogens. *Journal of Dairy Science*, 82(8), 1664-1670. doi:10.3168/jds.s0022-0302(99)75395-6

Ruegg, P. (2005). Evaluating the Effectiveness of Mastitis Vaccines. *Resources Milk Money*. Retrieved October 19, 2016, from <http://milkquality.wisc.edu/wp-content/uploads/2011/09/evaluating-the-effectiveness-of-mastitis-vaccines.pdf>

Lysigin | PBS Animal Health. (n.d.). Retrieved October 19, 2016, from <http://www.pbsanimalhealth.com/details/Lysigin/20-135553.html>

<sup>8</sup> Nemeč, A. (n.d.). Cow Talk with an Expert: Mastitis Treatments | Dairy Science. Retrieved October 19, 2016, from <http://dysci.wisc.edu/2014/08/29/cow-talk-with-an-expert-mastitis-treatments/>

the hand, cows will not develop resistance to natural proteins so our bacteriocin treatment is more effective.

## **Barriers to Entry**

### Ethics

In order to take into consideration of ethics of the project, we must take into consideration the harm bacteriocins can cause to animals and humans involved in the production and consumption of the dairy industry. Researchers have found bacteriocins to be a lot less harmful than antibiotics in human consumption. There are no known side effects from the consumption of bacteriocins<sup>9</sup>. As for the cows that are being treated with bacteriocins, there has been shown irritation of the mammary glands when injected with larger amounts bacteriocins. However, it is important to note that the mammary glands also become irritated by normal injections (7). Due to the irritation of the glands, the milk from these cows that were treated with bacteriocins had clots and flakes. Those symptoms were persisted for 24 hours<sup>10</sup>.

### Safety for Consumption

Our product would have to undergo guidelines set by the Food and Drugs Administration to be able considered safe for consumption. There will be the need of conducting a study where cows are treated with bacteriocins and the quality of their milk will need to be analyzed. Tests will have to be made to analyze the content of bacteriocins in the milk. The content of nutrients of the will need to be compared to the milk from cows that are not treated with bacteriocins to see if there are any nutrient difference. It is important to note that there are already several bacteriocins that are present in food that have been approved by the FDA to preserve the food, which means the public has been consuming bacteriocins in their daily lives<sup>11</sup>.

### Public Doubts about Genetically Modified Organisms

Frequently, the public attach a bad connotation to Genetically Modified Organisms (GMOs), but they are often poorly informed on the principles and safety

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<sup>9</sup> Cleveland, J., Montville, T. J., Nes, I. F., & Chikindas, M. L. (2001, December 4). *Bacteriocins: Safe, natural antimicrobials for food preservation*. Retrieved October 19, 2016, from <http://www.sciencedirect.com/science/article/pii/S0168160501005608>

<sup>10</sup> Wu, J., Hu, S., & Cao, L. (2007). Therapeutic Effect of Nisin Z on Subclinical Mastitis in Lactating Cows . *Antimicrobial Agents and Chemotherapy*, 51(9), 3131–3135. <http://doi.org/10.1128/AAC.00629-07>

<sup>11</sup> Cleveland, J., Montville, T. J., Nes, I. F., & Chikindas, M. L. (2001, December 4). *Bacteriocins: Safe, natural antimicrobials for food preservation*. Retrieved October 19, 2016, from <http://www.sciencedirect.com/science/article/pii/S0168160501005608>

protocols of genetic modification. In order to positively market our drug, we need to educate the public about GMOs and start conversations with people about the benefits and the harms of GMOs. Many advances in science have used GMOs such as insulin production for patients with diabetes. We need to show that our drug's benefits outweigh the harms it could potentially cause.

## Regulation

### Food Safety

Bovine mastitis is a health concern when it comes to food safety. When a cow contracts mastitis, its milk contains a higher somatic cell count, and other properties of the milk vary from normal as well. When antibiotic treatments are effectively used to treat mastitis, milk from the ill cow is still not marketable until drug residues have left the cow's system. However there is still a risk of antibiotics getting into the milk. Organic farms do not use antibiotics and therefore must use different methods to treat mastitis, though antibiotics is one of the most standard treatments. Many of the bacteria that cause bovine intramammary infections like mastitis are also the causative agents of human diseases such as Escherichia coli and Staphylococcus aureus. Most of the time, pasteurization of milk kills the common mastitis-causing bacteria but it usually does not destroy the negative effects of toxins that mastitis pathogens yield. Controlling mastitis, and other diseases like it, is very important to ensuring that dairy products are safe for consumption.

Table 3.<sup>12</sup>

Constituent	Normal Milk	Mastitis milk with high SCC
Fat	3.5	3.2
Lactose	4.9	4.4
Total Protein	3.61	3.56
Total Casein	2.8	2.3
Whey Protein	0.8	1.3 ↑
Serum Protein	0.02	0.07 ↑
Lactoferrin	0.02	0.1 ↑
Immunoglobulin	0.1	0.60 ↑
Sodium	0.057	0.105 ↑
Chloride	0.091	0.147 ↑

### Animal Treatment

<sup>12</sup> Hamadani, H., Khan, A. A., Bandy, M. T., Ashraf, I., Handoo, N., Bashir, A., & Hamadani, A. (2014, February 22). Bovine Mastitis - A Disease for Serious Concern for Dairy Farmers. Retrieved October 19, 2016, from <http://en.engormix.com/MA-dairy-cattle/health/articles/bovine-mastitis-disease-serious-t3079/165-p0.htm>

Since mastitis is a disease that affects the cow's udder, it can be painful to the cow, and severe mastitis is a large problem. Sanitary conditions and milking procedures are important to decrease the risk of intermammary infection. Antibiotics are often used to treat the cow, but organic farms cannot use that method. Mastitis can sometimes get better on its own. When a cow does have mastitis, farmers often use teat dips to maintain the sanitation of the cow's udders, along with intramammary infusions.

### Device Regulation

Our device would be an attachment for existing Automatic Milking Installations (AMIs). The FDA has strict regulations on the usage of AMIs that our product would need to adhere to. The shell will not need to go through much regulation because it is not in direct contact with the cow, but is a replacement part for the milking machine.

### GMO Regulation

Our product is not a GMO, but a product of GMOs. Considering that our proteins exist in nature and we are just using synthetic biology to produce it in a way that it can actually be used in application, we will not have to through the extensive regulation process for GMO food. We are also using the bacteria in a contained environment and not releasing it. As far as genetic engineering goes, our product is structured as to avoid most regulations. However we do need to go through the approval process for an animal drug. The FDA requires NADA (New Animal Drug Application) approval, which we are planning to apply for.