

Section I. Executive Summary

The rising prevalence of cataracts attributes to the significant market opportunity for cataracts treatment worldwide. The global market for cataracts is projected to affect approximately 50 million people by 2050, which is double the current number of cataracts patients.

Conventional treatments include surgery; however, many people do not get surgery because of the price concern and fear of the invasive method. Therefore eyedrops for treating cataracts have been developed recently in hope of providing a more accessible and inexpensive alternative.

Our products are two types of eyedrops, one for prevention and one for treatment of cataracts. The eyedrops contain chitosan nanoparticles that encapsulate the desired proteins that serve to prevent and treat cataracts, respectively. Chitosan nanoparticles are used for target delivery to the cornea and to ensure a more enduring treatment.

Our products stand out because we produce desired proteins through synthetic biology, which allows us to mass produce our desired product with *Escherichia coli* (*E.coli*). In other words, the low-cost of our production method allows us to provide products with a more affordable price.

Our vision is to provide an alternative to cataracts surgery: to prevent and treat cataracts using non-invasive methods at an affordable price.

Section II: Strategic Focus

A. Mission Statement:

Our goal is to prevent and treat cataracts through non-invasive means at an affordable price.

B. Core Competencies

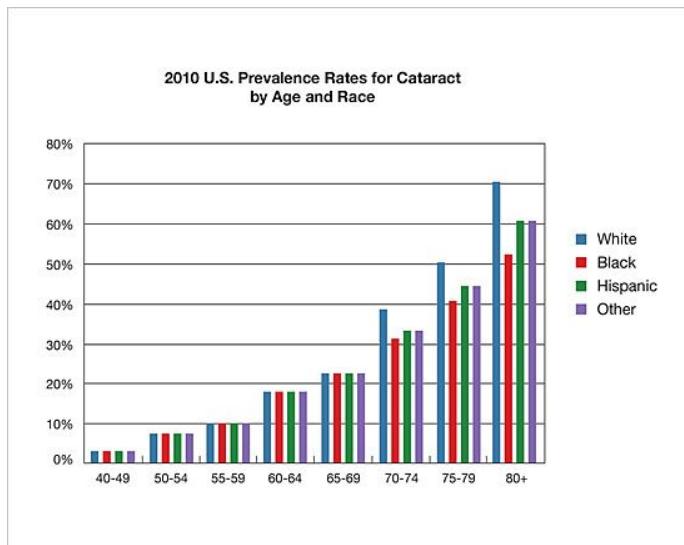
In comparison to our competitors, we have three distinctive advantages that make us stand a unique position in the market. Instead of adopting the conventional method of adding compounds that directly impact the formation of cataracts, we produce proteins that catalyzes the naturally existing pathways in our bodies that

functions to reverse the protein clumping that results in cataracts; in other words, our product alleviates the symptoms of cataracts through indirect influence, and thereby minimizing the side effects. Another innovation that we incorporated in our products is the use of nanoparticles to target delivery and sustain release. The chosen nanoparticle, chitosan nanoparticles, are lipidphilic and hydrophilic which are properties that allow the particles to pass through the cornea and sustain release the encapsulated proteins. Sustain release means the nanoparticles will slowly release the proteins over time, and thereby makes it a more enduring treatment. Lastly, the cheap method of mass producing desired proteins is one of our major advantages. Tweaking the genes in accordance to the desired protein expression in *E.coli* is a well-established means of producing recombinant proteins. *E.coli* serves as a perfect host because it requires a short culturing time, allows easy genetic manipulation, and most importantly costs very little to produce a lot.

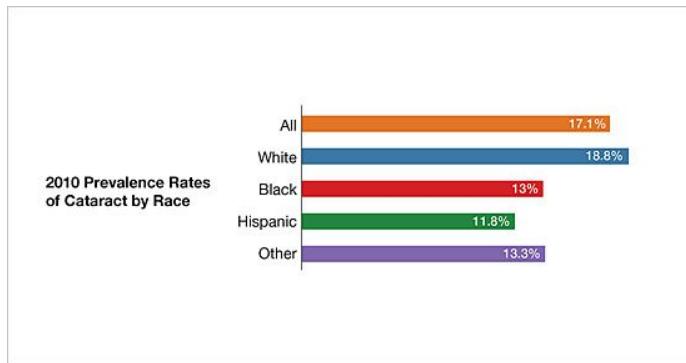
Section III: Situational Analysis

A. Market Research:

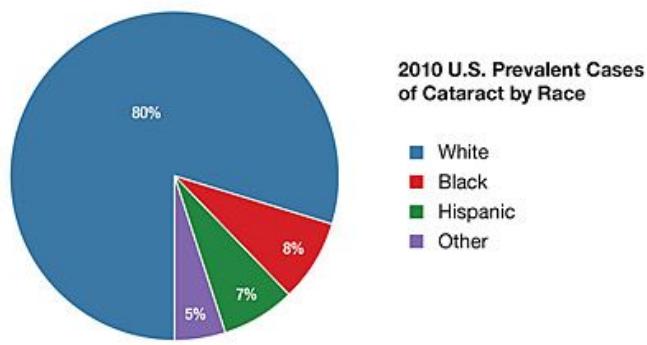
- a. Figure A. 2010 US Age-Specific Prevalence Rates for Cataract by Age, and Race/Ethnicity



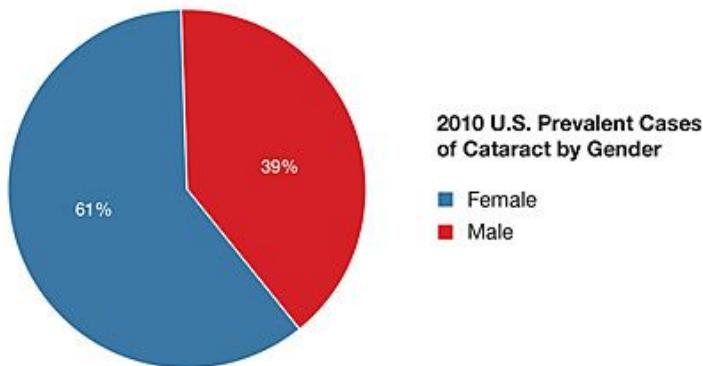
- b. Figure B. 2010 Prevalence Rates of Cataract by Race



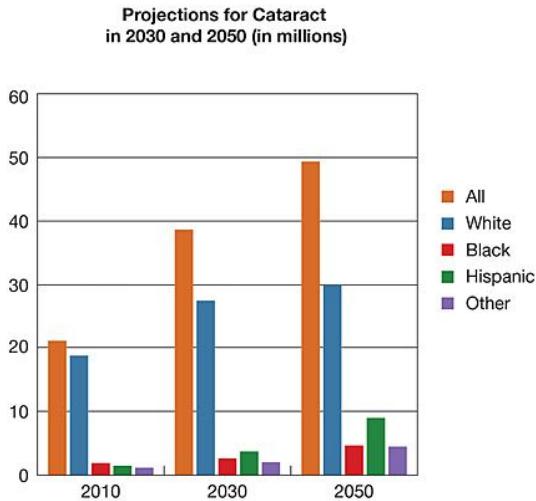
c. Figure C. 2010 US Prevalent cases of Cataract (in thousands) by Age, Race/ Ethnicity



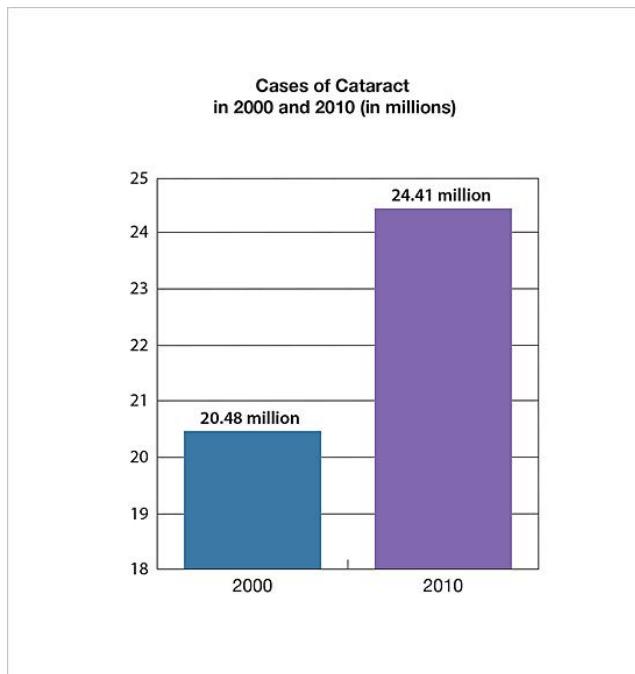
d. Figure D. 2010 US Prevalent Cases of Cataract (in thousands) by Age, Gender, and Race/Ethnicity



e. Figure E. Projections for Cataract (2010-2030-2050)



f. Figure F. Changes of Cases between 2000 and 2010



B. Customer Analysis

a. Customer demographics

The age group of our target customers will be people in their 40s and 50s & above for prevention and treatment respectively. According to statistics from National Eye Institute there are more women than men in the US that

have cataracts, and therefore we will be expecting more female customers than male.

b. Key customers

Our key customers will lay in the age group of 40-80 with lower-middle income and upper-middle income. In order to appeal to our targets we will be employing two methods to monitor customer complaints. We will be providing not only social media platforms such as twitter, facebook to resolve customer complaints, but since our targeted customers are older in age we will also have a customer support phone number to help resolve their problems or questions. Customer complaints aside we will be sending monthly emails as well as hard copy booklets to update them the newest products and company news, furthermore we will establish a membership system to both benefit and develop loyal customers.

c. Customer management

In addition to monitoring customer complaints, we will build individual profiles for each customer in order to investigate their age, gender, income, occupation, frequency of purchasing and preferred products. By analyzing the information gathered from the profiles we can then adjust our product's price and our CRM (Customer Relationship Management) plan.

We will also increase personalized services so that we can have better knowledge about our customer's needs, and this is important to build a good relationship with our customers. Personalized services will be based on the profiles we've created for them, and we'll also be categorizing our customers so that we can employ different methods to appeal to them accordingly.

C. Environmental / Industrial Analysis

The population of people with cataracts in the US rose by 20%, from 20.5 million to 24.4 million from 2000 to 2010. In the US, there are 9000 ophthalmologists who perform cataract surgery regularly, in fact 3.6 million in the US and 20 million worldwide cataract surgeries have been performed in 2015. Since our objective is to sell our eyedrops at a much inexpensive price, patients are anticipated to be more inclined to purchase our products rather than receiving surgery, and therefore the number of cataract cases should decrease after we emerge in the market.

D. Regulatory

a. Quality control:

Sources of variation

Materials	<ul style="list-style-type: none">• Variations among suppliers of same substances• Variations among batches from same suppliers• Variations within a batch
Machines	<ul style="list-style-type: none">• Variation of equipment of same process• Difference in adjustments of equipment• Aging of machines and improper care
Methods	<ul style="list-style-type: none">• Wrong procedure• Inadequate procedure• Negligence in procedure by chance
Workers	<ul style="list-style-type: none">• Improper working conditions

	<ul style="list-style-type: none"> • Inadequate training and understanding • Lack of interest and emotional upheavals • Dishonesty, fatigue and carelessness
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b. Control of product

Material Control	<ul style="list-style-type: none"> • Check if materials are in proper containers • Check labels • Check expiry dates • Make sure materials are stored in a proper way (alphabetical order, properties)
Control of Records	<ul style="list-style-type: none"> • Master Formula Record <ul style="list-style-type: none"> ◦ Must be prepared for each product ◦ The language must be clear and straightforward so it won't be misinterpreted. ◦ Should include: <ul style="list-style-type: none"> ■ Name of the product, dosage form and strength ■ Complete list of ingredients including excipients

	<ul style="list-style-type: none"> ■ Manufacturing and control instructions, specifications and precautions ● Batch Production Record <ul style="list-style-type: none"> ○ Must include (in addition to the Master Formula Record) <ul style="list-style-type: none"> ■ Batch number ■ Code number ■ Manufacturing date ■ Expiry date
IPQC (In Progress Quality Control)	<ul style="list-style-type: none"> ● Drug contents determination ● Assay of active ingredients ● pH ● Weight per mL ● Particle size ● Sterility ●

c. Facilities Control

Personnel Control	<ul style="list-style-type: none"> ● Proper selection and training in all departments i.e. production, packaging, labeling, etc, ● Should be properly educated supervisors working above workers
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	<ul style="list-style-type: none"> Supervisors should be always available to help workers when they encounter problems
Equipment and Building	<ul style="list-style-type: none"> Equipments should be constructed in a proper size and proper way so that a complete batch can be processed all at once Surface of equipments should be non-reactive, non-absorptive, and non-additive Equipments should be constructed and fitted in such way that makes it easy to be replaced, washed and operated.

E. S.W.O.T Analysis

a) Our Products

Strengths	Weaknesses
<ul style="list-style-type: none"> <i>Low cost thus inexpensive prices</i> <i>Covers both prevention and treatment, thus a wider customer audience</i> <i>Also Includes eye drops suitable for pets</i> 	<ul style="list-style-type: none"> <i>Many competitors</i> <i>Anticipated anxiousness from people about trying new pharmaceutical products</i>

b) Competitors

Competitor	Value to customers	Strengths/Opportunities	Weaknesses/Threats
Ocluvet	<p>Their products specifically targets cataracts in animals, and is available online; its specificity and convenience appeals to those who seek for treatment for pets and online services.</p>	<ul style="list-style-type: none"> • Treats cataracts in several animal species • Has a lot of good reviews from its customers on Amazon 	<p>Market is too narrow, because they only treat animals.</p>
Virbac	<p>It is a prestigious pharmaceutical group that has been working on the field of various treatments for animals, and thus its reputation generates customers' trust in their products.</p>	<ul style="list-style-type: none"> • It is a long established company which is the 8th largest veterinarian pharmaceutical group. The company has had 736 million euros in 2013, and its huge funds allow the company to do constant research and revisions to 	<p>Only targets animals, and therefore is more limited.</p>

		<p>improve their products.</p> <ul style="list-style-type: none"> Has various products including dental health, dermatology, endocrinology, euthanasia, urology, antibiotics and antiparasitic products 	
Can-C	<ul style="list-style-type: none"> Can-C is available on various platforms such as Amazon, phone ordering, and it also provides phone service that is available. Furthermore it is convenient for its customers, 	<p>Strengths</p> <ul style="list-style-type: none"> Provides beneficial results to various eye diseases, not only cataracts Also treats canines & pets Human trials ⇒ effective <p>Opportunities</p> <ul style="list-style-type: none"> Can expand to different animals Can-C plus (+ 	<ul style="list-style-type: none"> Doctors & optometrists tend to not recommend their eyedrops because performing surgery is more profitable for them (kickbacks for

	<p>because it has efficient management and widely spread locations which allows all orders to be shipped within 24 hours</p>	<p>future advancements)</p>	<p>referring to surgeons)</p> <ul style="list-style-type: none"> • NAC lacks FDA approval as a cataract cure (listed as “inactive ingredient” & eyedrops promoted to “soothe tired eyes”)
Clarastill	<p>The Company Bruchettini was founded in 1910 and is famous for its high quality pharmaceutical products. Thus its reputation makes its products more trustworthy.</p>	<ul style="list-style-type: none"> • Sells various products (not only cataract eye drops) • Their cataract eye drops (clarastill) uses anti-oxidative and anti-free radicals in order to reduce the possibility of causing mechanical stress, solar radiation, smoke, 	

		<p>powder, air conditioning and computer radiation.</p>	
Similasan Cataract Care Eye Drops	<ul style="list-style-type: none"> • Uses organic ingredients rather than chemicals, and therefore appeals to environment-conscious customers 	<p>Strengths</p> <ul style="list-style-type: none"> • No harsh chemicals • No known side effects or drug interactions <p>Opportunities</p> <ul style="list-style-type: none"> • Natural ingredients + gluten & dairy free - able to target a wider audience (lactose-intolerant, vegans etc.) 	<p>Weaknesses</p> <ul style="list-style-type: none"> • Temporarily relieves symptoms • Requires regular eye exams • “Not a replacement for regular medical care” (may potentially require additional medical care in the future)

Section IV: Market-Product Focus

1. Anticipated Demand:

- a. Customers that have already developed cataracts are anticipated to purchase a new bottle every month.

- b. Customers that are purchasing the eye-drops for treatment are anticipated to purchase a new bottle every 2 months.

2. Sales and Marketing Objectives

a. Build brand awareness

- i. Referral Programs: give \$10 dollars for every friend one refers.
- ii. Collaboration with apps: include information on our products with health-related apps in both IOS and Android stores.
- iii. Social Media Contests: run contests on social media in which contestants submit photos or videos, and other contestants vote a winner, who receives a year of free prevention or treatment eyedrops by their choice.
- iv. Podcasts: Start podcasts where we interview experts in the field of cataracts.
- v. Influencer Marketing: Find influencers in the industry, and rather than competing with them, we will start partnerships with them and utilize their influence to promote our brand.

b. Enhance customer relationships

- i. Investigate in the customer's positions and the worth of our product to them
- ii. Analyze the source of customer's enthusiasm in buying a certain product
- iii. Understand what is the problem customers seek to solve by buying your product
- iv. Investigate how much value they attach to in buying your product

Section V: Marketing Program-Pricing Strategy

We will be giving discounts to customers who purchase our products consistently. For those who order 3 months of number of bottles needed, there will be a 5% off discount, and for those who order 6 months of number of bottles of our eyedrops,

there will be a 15% off discount, and for those who order a year of number of bottles, there will be a 30% off discount.

Section VI: Marketing Program-Promotional Strategy

Planned promotion /advertising type	Expected business improvement	Cost (\$)	Target date
<i>Google AdWords (pops up at the very top when you search on google)</i>	Our products will get more exposure and since our ad would pop up only when people search keywords such as, "cataracts", our ad would be able to be more focused on our target market.	[\$150 and above]-not required to pay if there are no visitors/clicks; we pay for each click we get	One Year
<i>social media (instagram, facebook, twitter)</i>	We can not only use social media as a means to resolve customer complaints, but also use it as a means of promotions. We can take photos of our production process so that people can have a better understanding of our company. We can also use social media to raise awareness of cataracts, and if successful a wider audience	[\$0]	[Permanent]

	would be willing to investigate in not only our treatment products, but also our prevention products.		
giveaway	We can have people go on the streets and hand out booklets giving them information on cataracts in general and our products in specific.	[\$6000NT]-f or 6000 booklets	[1 Month]-see if people are interested first and then decide if we keep this method
Collaborations with eye doctors	We can pay optometrist in exchange for their recommendation of our products when patients with cataracts consult with them.	[\$]100,000NT	1 year

Section VII: Cost of Eye Drops Raw Materials

The total material cost of a 3 month supply is \$7.88. 1 bottle contains 200 drops and can be used for both eyes for 3 months. 1 bottle contains 4.2 mg of proteins encapsulated in nanoparticles. Accounting for the protein encapsulation efficiency (72%) of our nanoparticles, we determined that we need to grow 160 mL of liquid culture in order to produce each bottle. Below is the material costs for making 1 bottle of our Counteracts eye drop.

Material	Unit	Price (\$NT)	Amount needed	Cost (\$NT)	Cost (USD)
LB (LBL407)	1000 g	2700	4 g	15.56	0.50
Ampicillin Sigma Aldrich	5 g	3300	.00016 g	1.52	0.05
Histag Column	1 column purifies 200 mg protein	1581	5.761 mg	62.66	1.99
Xtractor buffer	500 mL	8280	6.4 ml	105.98	3.37
Wash buffer	500 ml	5041	2 mL	20.17	0.64
Elution buffer	250 ml	4931	2 mL	39.45	1.26
Sodium Tripolyphosphate	500 g	350	20 mg	0.01	0.00
Chitosan	250 g	6420	60 mg	1.54	0.05
Acetic Acid	500 mL	300	200 uL	0.12	0.00
Sodium Hydroxide	500 g	600	0.4 g	0.48	0.02
Total				247.48	7.88

Citations:

- <http://www.who.int/blindness/causes/priority/en/index1.html>
- <http://www.allaboutvision.com/conditions/cataracts.htm>
- <http://www.allaboutvision.com/conditions/iols.htm>
- <https://nei.nih.gov/eyedata/cataract#5>
- http://www.strategyr.com/MarketResearch/Intraocular_Lenses_IOL_Market_Trends.asp