# bioaesthetics

## Off-the-Shelf Nipple-Areolar Complex Grafts

***The Next Step in Breast Reconstruction***

Founder/CEO: Nicholas Pashos
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Contact: info@bio-aesthetics.com

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## EXECUTIVE SUMMARY

**Company Information**
*Founder:* Nicholas Pashos
*Prodict:* Nipple—Areolar Complex Graft
*Contact:* info@bio-aesthetics.com; 603.714.8491
*Website:* www.Bio-Aesthetics.com
*Structure:* BioAesthetics has been incorporated as LLC in New Orleans, Louisiana

bioaesthetics
Off-the-Shelf Nipple-Areolar Complex Grafts
*The Next Step in Breast Reconstruction*

**The Product**
BioAesthetics offers the only tissue engineered Nipple—Areolar Complex (NAC) for patients with incomplete or removed NACs due to disease, surgery, or birth defects. BioAesthetics will provide an off-the-shelf-ready, human-derived NAC allograft to plastic and reconstructive surgeons. This product is currently in prototyping phase, transitioning from non-human primate tissues to human tissues.

To date, no tissue engineering strategies have been developed focused on NAC reconstruction. The application of decellularization to the whole, semi-glandular NAC can create a non-immunogenic NAC that retains the microarchitecture and gross structures of a native NAC. This tissue engineering approach to whole structure regeneration allows for the effective removal of cellular material, the retention of the extracellular matrix components and structure, as well as cell adhesion molecules. Once decellularized, the NAC should be able to be seeded with autologous cells to create an implant that is patient-specific (Figure 1). In addition, this technique generates a whole NAC graft that aesthetically, both visually and texturally, mimics the native nipple.

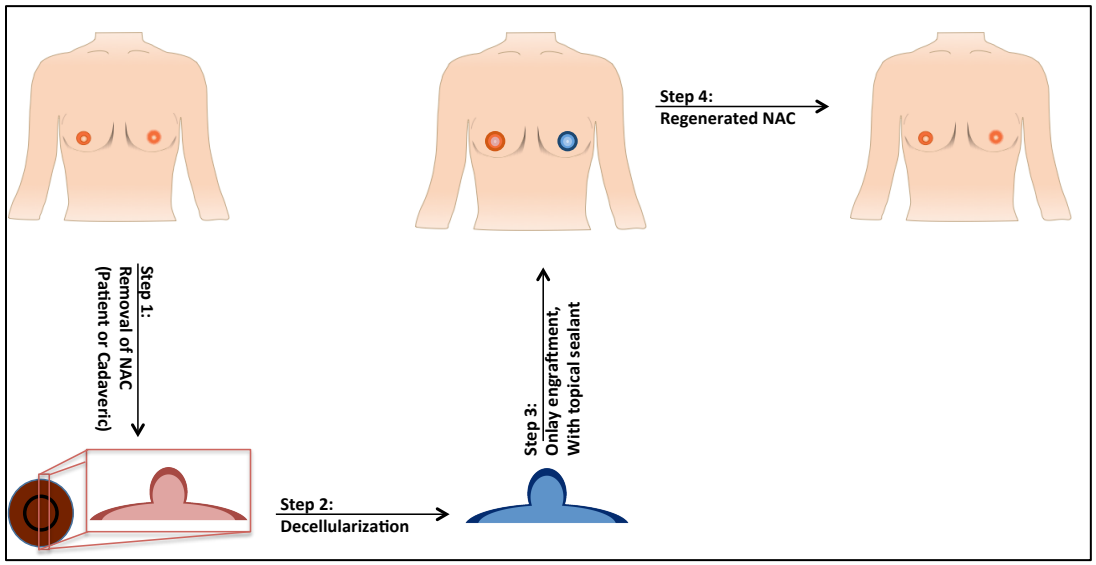


**Figure 1: Schematic of NAC Regeneration:**
Step 1) Removal of the NAC from either the patient, who will then receive her own regenerated NAC, or a donor NAC.
Step 2) Decellularization of NAC by BioAesthetics standard techniques.
Step 3) Acellular NAC graft is onlay engrafted onto the patient and a highly viscous topical surgical sealant is applied to act as a foreign body barrier, establishing a closed wound coverage.
Step 4) Over time, cell migration into the acellular scaffold results in a regenerated NAC.

**Intellectual Property**
- Patent Status: PCT patent application filed: October 2015
- Inventors: Nicholas Pashos and Bruce Bunnell.
- Representation: Hyman IP Law; San Francisco, CA

**Market Opportunity**
There exists a need for a reproducible and more naturally aesthetic architecture for nipple and areola reconstruction. There are more than 2.8 million breast cancer survivors in the United States, many of who have undergone reconstructive surgery. Approximately 36% of patients with early stage diagnoses and 60% of patients with late stage diagnoses undergo mastectomies. Moreover, immediate breast reconstruction following mastectomies has become more common, significantly increasing from 20.8% in 1998 to 37.8% in 2008. This increasing trend is not surprising as breast reconstruction likely provides psychological benefits for women who undergo mastectomies. There is evidence to suggest that nipple—areolar complex (NAC) reconstruction affects psychological wellbeing by increasing body image and self-

esteem, or decreasing the feeling of distress felt by female patients with mastectomies. Evidence also suggests that woman are more comfortable with getting a mastectomy if the nipple can be spared during the mastectomy procedure, or if nipple reconstruction is possible when a nipple-sparing mastectomy is not an option. Approximately 180,000 mastectomies are performed each year and because 63% of patients also have a breast reconstruction surgery, approximately 113,400 patients are potential customers. In addition, over 2.3 million breast cancer survivors may also be candidates for BioAesthetics product they either did not receive a breast reconstruction or because current solutions were inadequate at the time of their breast reconstruction.

**Competitive Landscape**

Current strategies for nipple and areola complex reconstruction are limited to surgical techniques that create a NAC structure from existing local tissue, secondary site grafting, 3D tattooing, or prosthetic rubber stick-on NAC. Generating a tissue-engineered, biocompatible NAC implant made of decellularized whole NAC for use in place of surgically created NAC structures is a promising approach to NAC reconstruction following mastectomies. Although the current standard of care is carried out through surgical technique with local or secondary grafts to create a NAC, there are major players in the acellular dermal matrix field, which is also used in breast reconstructive surgeries: LifeCell, Ethicon, Musculoskeletal Transplantation Foundation, and Synthes.

**Go To Market Strategy**

The current strategy and implementation plan consists of pursuing a Pre-Market Notification (PMN or 510k) through the FDA in order to gain access to the medical market, similar to all other commercially available acellular materials used in reconstructive surgeries. BioAesthetics' plan is to operate as a virtual manufacturing floor, outsourcing the isolation and packaging of the NAC to a nationally respected allograft organization such as the Musculoskeletal Transplantation Foundation (MTF). This product will be marketed to the customers, plastic and reconstructive surgeons, in order to penetrate the market. The plastic and reconstructive surgeons are expected to easily adopt this product because currently 56% of breast reconstructions utilize acellular material, which is similar to BioAesthetics' proposed NAC scaffold. BioAesthetics is currently participating in the NSF-ICORPS program, which is funding further market and customer validation.

**Financial Plan and Business Model**

The NAC will be offered at $3,000, and with a market base of 113,400 reconstructions per year, BioAesthetics has a market potential of greater than $340 million per year, not including preexisting patients. **COGS:** Donor tissue procurement and processing cost approximately $35 per NAC scaffold, leaving a large margin of profit. This proposed product is expected to be reimbursed by the providers, under preexisting reimbursement code, with the same payment/reimbursement route as currently used for other acellular material in breast reconstruction. The goal of BioAesthetics is to obtain 510k clearance through the FDA and continue to collect letters of intent from key players, before exiting through the acquisition of BioAesthetics by a larger corporation such as LifeCell, Ethicon, Musculoskeletal Transplantation Foundation, or Synthes.

**Milestones:**

In order to achieve the FDA 510(k) clearance, BioAesthetics will need to complete small and large animal *in vivo* testing – biocompatibility and engraftment studies. These studies will be funded through private and government research grants that have been or are currently being applied for. An FDA 510(k) letter of intent is planned to be submitted mid 2016, and completion of animal studies is expected to be completed by the beginning of 2017, concluding the 510(k) application. FDA clearance is expected in the beginning of 2018. A small 150 patient, clinical evidence trial is expected to begin in 2018 and will last for approximately 2 years. This clinical evidence trial is for sales and marketing purposes to help gain the interest in the market. BioAesthetics forecasts achieving 4% market share in 2021.

**Management Team**

Currently, management reflects BioAesthetics' focuses on the product development. BioAesthetics would like to gain an experienced CEO as business focus shifts from University Lab Spin-Out to startup entering FDA 510(k) submission.

Founder/ CEO/Co-Inventor: *Nicholas Pashos*, Ph.D. Candidate, Tulane University; NSF Fellow; Biomedical Engineer
Director, Product Development: Samantha Kurtz, Ph.D. Candidate, Tulane University; NSF Fellow; Biomedical Engineer

Advisory Board:

| | | | |
|---|---|---|---|
| *Bruce Bunnell, Ph.D.*: Director, Center for Stem Cell Research and Regenerative Medicine; Tulane University; New Orleans, LA | *Abigail Chaffin, M.D:* Director, Tulane Outpatient Division of Plastic and Reconstructive Surgery; Tulane University New Orleans, LA | *Pleasant Hooper, M.D.:* Founder and President, TMS BioScience; New Orleans, LA | *Scott Sullivan, M.D.,* Co-owner/ Co-founder, Center for Restorative Breast Surgery, Plastic/General Surgeon; New Orleans, LA |

info@bio-aesthetics.com

## THE COMPANY

### Mission Statement and Role

BioAesthetics' is defining the standard of care for reconstructive breast surgery by offering the only off-the-ready acellular Nipple-areolar Complex (NAC) graft, for woman and men undergoing reconstructive procedures following mastectomy. BioAesthetics' mission: *To Develop Improved Breast Reconstruction Solutions for Women Following Mastectomies.*

### Ethics Statement

BioAesthetics is committed to acting in accordance with the fundamental principles of honesty, common sense, and fairness in all product development initiatives, business practices, and customer interactions. These practices will form the basis of all of our relationships with our customers, employees, competitors, suppliers, and partners. All services will be provided and maintained with the highest level of integrity and quality practices. All accounting practices will be maintained at the highest levels of ethical standards.

### History and Year Incorporated

Founded out of Tulane University, BioAesthetics was developed around nipple and areola tissue engineering research, conceptualized and carried out by Nicholas Pashos. Mr. Pashos, a doctoral candidate through the National Science Foundation (NSF) IGERT Bioinnovation program, developed this original idea after watching a documentary of sexual reassignment surgery, in which the description of mastectomies left a lot to be desired. As described by both the patient and doctor, the procedure is intimately tied to self-esteem and identity. Based on current surgical practices for reconstructive breast surgery, nipple and areola reconstruction after a total mastectomy often leaves patients disfigured. It was then that Nicholas recognized an area of unmet need, for a population of people who had already been robbed of so much of their selves, and set out to regrow nipple/areolas for breast cancer survivors and others whom had endured mastectomies.

BioAesthetics was incorporated in 2015 in preparation for applying for round one funding, through federal agencies in the form of translational research grants (SBIR, STTR).

### Legal Organization

BioAesthetics is incorporated as a Limited Liability Company (LLC) for the ease of operation in the first stages of company development. This particular designation will afford liability protection, as the company only being accountable for fraud, and will allow for postponed equitization until the company has reached appropriate maturity. Furthermore, the leniency under the tax filling process, namely shareholders that shareholders may file the business taxes on their own personal tax forms, avoids double taxation of money.

## THE PRODUCT DESCRIPTION

BioAesthetics offers a product and service combination, that results in a specialized organ transplantation product for nipple and areola regeneration.

*The Product:* *myNAC is an off-the-shelf ready acellular Nipple-areolar complex graft, for plastic and reconstructive surgeons to onlay graft onto the patients' reconstructed breast. myNAC is the only commercially available nipple and areola replacement to aid in the perfect breast reconstruction.*

Currently, the average cost of a nipple reconstruction is between $2100 and $3400,[1] with an added expenditure of the surgeon and operating room staff while the reconstruction is completed. Every minute under general anesthesia costs money, and highly trained employee resources. By outsourcing reconstruction of the nipple to an external vendor, namely BioAesthetics, hospitals can dramatically cut costs and provide improved, reporoducable outcomes. Therefore, an initial price point strategy will be to mimic the range of currently offered solutions, namely to be placed between $3000 and $4000 dollars, per *myNAC*.

## The Technology

The science behind *myNAC* is simple: combining a tissue engineering approach to breast reconstruction with an individual sample of skin, a nipple and areola acellular graft is turned into a fully regrown nipple and areola for the patient. This is personalized regenerative medicine at its finest. *myNAC* works by re-growing a patient's nipple, which had been lost to cancer removal, breast augmentation, nipple resection, birth defect, or other trauma. The result is a completely regrown nipple and areola made from the patient, for the patient. Unlike traditional transplants, the *myNAC* matches the biology of the patient—no immunosuppressive drugs required—allowing for improved standard of life and outcomes.

The application of decellularization to the whole, semi-glandular NAC can create a non-immunogenic NAC that retains the microarchitecture and gross structures of a native NAC. This tissue engineering approach to whole structure regeneration allows for the effective removal of cellular material, the retention of the extracellular matrix components and structure, as well as cell adhesion molecules. Once decellularized, the NAC should be able to be seeded with autologous cells to create an implant that is patient-specific (**Figure 1**). In addition, this technique generates a whole NAC graft that aesthetically, both visually and texturally, mimics the native nipple.

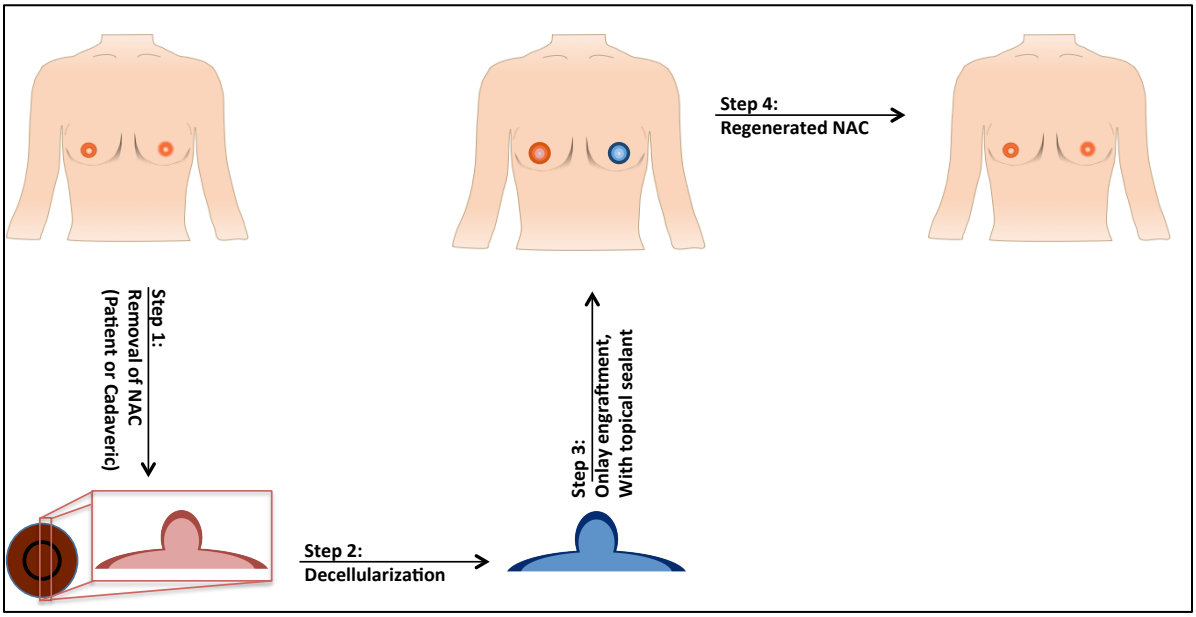


**Figure 1: Schematic of NAC Regeneration:**
Step 1) Removal of the NAC from either the patient, who will then receive her own regenerated NAC, or a cadaveric NAC. Step 2) Decellularization of NAC by BioAesthetics standard techniques. Step 3) Acellular NAC graft is onlay engrafted onto the patient and a highly viscous topical surgical sealant is applied to act as a foreign body barrier, establishing a closed wound coverage. Step 4) Over time, cell migration into the acellular scaffold results in a regenerated NAC.

[1] Chen, Wei F., David Barounis, and Ramasamy Kalimuthu. "A novel cost-saving approach to the use of

### Value Proposition

BioAesthetics Value proposition is that we offer an off-the-shelf acellular graft for the regeneration of NACs

- Unique NAC characteristics: the unique characteristics that differentiate the NAC from other skin tissues, the shape and feel, are maintained.
- Structural integrity: the structural integrity of the NAC is maintenanced during the processing of the NAC tissue. Allowing for a permanent solution to NAC reconstruction, through regeneration.
- Mitigate revision surgeries: current methods of reconstruction require a healthy blood supply, which can cause problems, when adequate blood supply isn't available.
- Time efficient for surgeons: The current methods require the surgeon to create nipple-like structures, which is very time intensive. By offering an off-the-shelf ready graft, we bypass the need to surgically create one.
  - Not disruptive to current workflow
- Regeneration, not reconstruction

### Current Analogues and Distinguishing Features

Currently, there is no company that offers to regrow nipple and areola for a patient. There are however: surgeries, where normal skin is crafted into a nipple and areola shape on the patient's chest; prosthetics, allow for a rubber nipple and areola with an adhesive back to stick to the patient's breast; tattooing, as an alternative to surgery and prosthetics, where a nipple and areola are tattooed onto the patient's breast in a 3D fashion.

BioAesthetics' product, *myNAC,* is different from the currently offered alternatives because it is the only solution the is a regenerative solution, not just a reconstruction. This product has the structural small details of a nipple down to the molecular level, because it is ultimately a real nipple.

## Target Market

### Market Description

BioAesthetics' primary target market is men and women in the U.S. who require breast reconstruction after a mastectomy. Mastectomy is a surgery to remove all or part of a breast as a way to treat or prevent breast cancer. Women are most likely to be diagnosed with breast cancer between the ages of 30 and 70, and men are most likely to be diagnosed between the ages of 60 and 70. The cause of breast cancer is unknown but there are several factors that increase the risk of breast cancer in women (in men, the only known risk factor is older age). The following demographic and psychographic factors are known risk factors for breast cancer in women:[2]

- **Age:** The risk of breast cancer increases with age. Most breast cancers occur in women aged 50 or older.
- **Income:** A higher socioeconomic status increases the risk of breast cancer.
- **Family size:** Never being pregnant or having fewer children increases the risk of breast cancer.
- **Ethnicity:** According to the National Cancer Institute, white, non-Hispanic women have the highest overall incidence rate for breast cancer among U.S. racial/ethnic groups.
- **Education level:** Higher education increases the risk of breast cancer.
- **Lifestyle/behavioral:** A high-fat diet, physical inactivity, consumption of more than one alcoholic drink per day, and the use of oral contraceptives all increase the risk of breast cancer.

[2] http://www.mdanderson.org/patient-and-cancer-information/cancer-information/cancer-topics/prevention-and-screening/cancer-risk-factors/index.html

### Market Size and Trends

The market for nipple and areola reconstruction is large and growing. There are approximately 180,000 mastectomies each year in the United States, with 65% of all mastectomies undergoing breast reconstruction. Lending to a US market potential of >113,400 patients each year.

Among men, the incidence of breast cancer is very low, about 0.6% of the 240,000 cases of breast cancer diagnosed each year in the U.S.[3] However, among men diagnosed with breast cancer, mastectomy surgery is the most common treatment. Men who have breast cancer undergo mastectomy surgery 87% of the time, in comparison to only 38% for women. Because men have less volume of breast tissue to replace, breast reconstruction is not commonly used in men who have a mastectomy, but nipple and areola reconstruction is suitable for men and will noticeably improve appearance.

### Identified Companies for Acquisition

BioAesthetics' exit strategy is to be acquired by a larger pharmaceutical company. There have been four large pharmaceutical and medical device companies, which have been identified, with known interest in regenerative medicine products. GlaxoSmithKline, a global health company, currently working on ear regeneration; Eli Lilly and Company, a global leader in the health industry, has one fifth of their company focused on bio-medicines; Davol Inc, a subsidiary of BARD, is the manufacturer of ALLOMAX, which is a widely breast reconstruction biomaterial; and Johnson & Johnson was also identified as an ideal due to it's Janssen Labs, Janssen and Regenerative Alliance, all focused on up and coming biotechnology and regenerative medicine initiatives.

## COMPETITIVE ANALYSIS

### Description of Competition

Breast reconstruction greatly increases quality of life for breast cancer survivors, and more women who undergo mastectomies are choosing breast reconstruction. According to a recent study, reconstruction use increased from 46% in 1998 to 63% in 2007.[4] The increased demand for breast reconstruction is driving the need for nipple and areola reconstruction. To address this need, several techniques are currently being used to re-create the nipple. The current options for nipple and areola reconstruction are as follows:

- **Areola tattooing** – Some patients choose tattooing without surgical reconstruction. Because of its simplicity, this is a widespread method of areola reconstruction. Tattooing allows for a good color match with the contralateral side, but tattooing alone does not produce a natural appearance. Tattoos are strictly an optical effect and lack projection and texture. Additionally, tattoos fade or discolor over time and may require touch-ups.
- **Skin graft** – This approach entails transfer of tissue from another part of the body such as the inner thigh, labia, or areola of the other breast. Potential disadvantages of this approach include creation of scars where tissue was removed and risk of incomplete survival of the skin graft.
- **Local flap technique** – This technique uses tissue from the surrounding breast skin to recreate a projecting nipple. Examples of commonly used local flaps include skate flap, modified skate flap, double opposing tab flap, star flap, and cervical visor (CV) flap. Complications of the local flap technique include substantial loss of nipple projection, partial or total loss of the nipple, and discoloration.

[3] http://consumer.healthday.com/cancer-information-5/breast-cancer-news-94/most-men-with-breast-cancer-undergo-mastectomy-study-says-682164.html
[4] http://jco.ascopubs.org/content/early/2014/02/18/JCO.2013.52.2284.abstract

- **Nipple prosthesis** – Nipple-areola prostheses are a potential solution for patients who wish to forego additional surgery. Nipple prosthesis is an inexpensive alternative to surgical nipple reconstruction, and custom made versions reproduce the natural nipple's texture and color. However, secure adherence is an issue with nipple prostheses. Additionally, the aesthetic result of nipple prostheses is significantly inferior to the results achieved with surgical reconstruction.
- **Nipple-sparing mastectomy (NSM)** – NSM is a breast reconstruction technique that allows for preservation of the native nipple and areola. This technique allows for the best aesthetic outcome. NSM also obviates the need for a second reconstructive surgery. However, NSM is a technically challenging procedure. Additional limitations of NSM include strict selection criteria, higher risk of cancer recurrence, and necrosis of the nipple.

### Competitive Positions

There are numerous techniques for nipple and areola reconstruction. However, no single technique is perfect. In choosing which option to pursue, breast cancer patients must weigh several factors. The most important factor is oncologic safety. The best option for nipple and areola reconstruction is one that minimizes the risk of recurrent breast cancer. Another very important factor is aesthetic results. An aesthetically pleasing reconstruction can provide breast cancer patients with considerable psychological and social benefits such as increased self-esteem and self-body image. The ultimate aesthetic outcome for nipple and areola reconstruction is a new nipple that matches the position, size, texture, color, and projection of the natural one.[5] The level of surgical complications is also an important consideration in nipple and areola reconstruction. Ideally, nipple and areola reconstruction should be immediate and occur at the same time as a mastectomy. Nipple and areola reconstruction should not be a protracted process requiring multiple surgeries. Furthermore, nipple and areola reconstruction should minimize complications, particularly nipple necrosis.

### Advantages Over Competition

Although there are several options for nipple and areola reconstruction, no single method currently available provides an optimal solution that satisfies the most important requirements which include oncologic safety, a natural and aesthetic appearance, and surgical efficacy. Unlike the current options for nipple and areola reconstruction, BioAesthetics' proposed solution to use tissue engineering techniques and autologous stem cells to regenerate a nipple and areola will meet all the requirements of safety, aesthetics, and surgical efficiency. Because BioAesthetics will use regenerative medicine to regrow a new nipple and areola, there is no risk that the new nipple and areola will contain residual cancerous breast tissue. Furthermore, because this method requires a sample of native tissue, it is guaranteed to match the characteristics of the native nipple and areola. And finally, this method allows for immediate reconstruction of the nipple and areola following a mastectomy.

### Barriers to Entry

BioAesthetics largest barrier to entry is obtaining FDA 510(k) clearance through the FDA. As with any medical device, FDA regulation is the hurdle to market entry. BioAesthetics has a clear path through the FDA by the 510(k), following the same route to market as many other acellular dermal products used in currently used breast reconstruction, such as: AlloDerm, Acelity; AlloMax,Davol; and many other human-derived acellular grafts.

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5 http://www.cancer.org/cancer/breastcancer/moreinformation/breastreconstructionaftermastectomy/breast-reconstruction-after-mastectomy-nipple-and-areola-recon

## MARKETING

BioAesthetics marketing primary concentration is in a business-to-investor strategy, with additional focus on creating a brand surrounding the *myNAC* product. Ultimately, the intended exit necessitates concentrating on investors or companies who may acquire BioAesthetics during mid-stage FDA regulatory approval. As a biotech start-up, BioAesthetics does not hold the core competencies or financial backing to sustain the lengthy and expensive clinical trials during late premarket investigation. Initially, a website has been designed to help inform investors, regenerative medicine firms and the breast cancer community of the benefits of BioAesthetics, specifically with regards *myNAC*. **Figure 2** below depicts the general schematic of the website design, which incorporates interactive data regarding the company and the technology.

The website is also designed to guide media reactions and provide up to date information on the products development and accreditations. While the technology behind *myNAC* may be several years from reaching end users, educating the public to the eventual availability of this product will position BioAesthetics in a more comprehensive light to future investors or buyers.

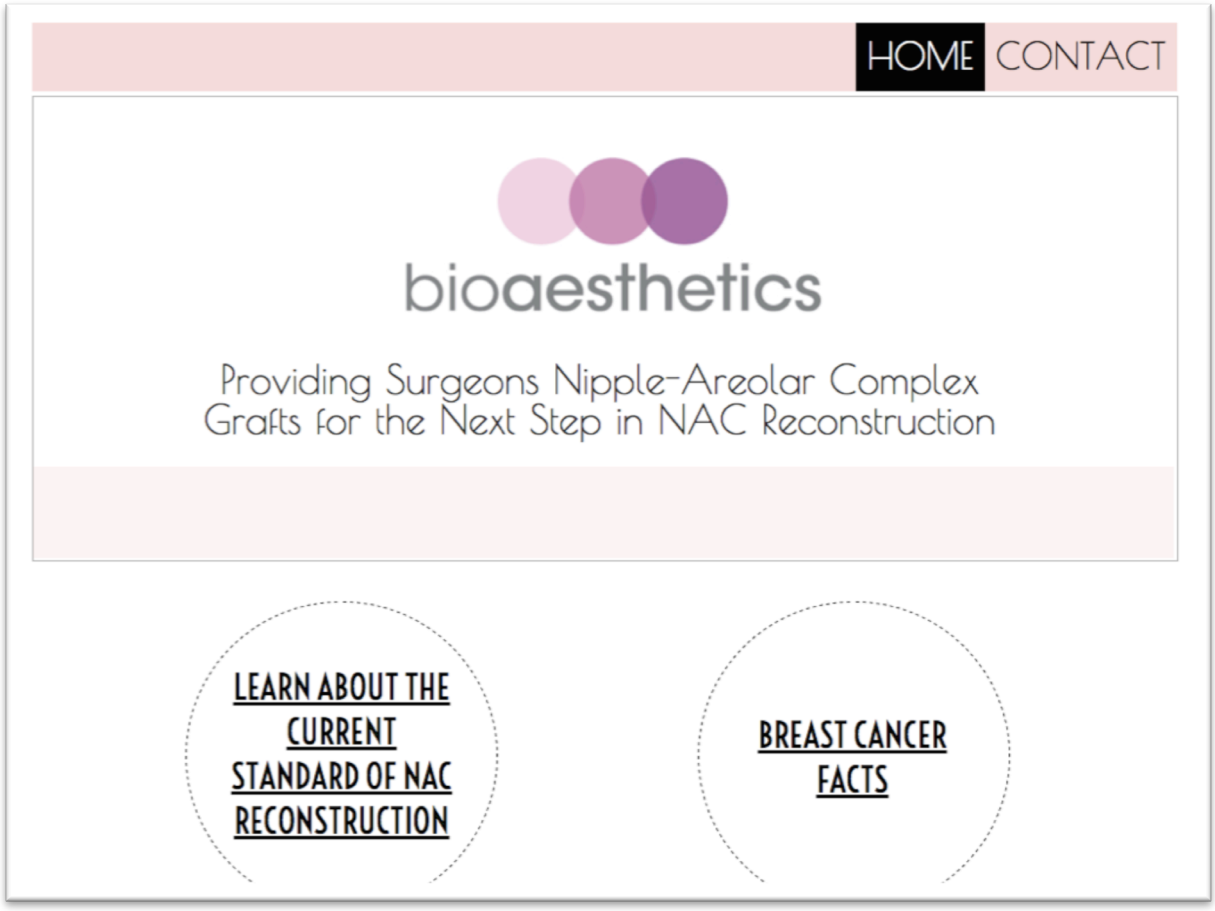


**Figure 2. Screenshot of BioAesthetics' Webpage**

### Company and Product Logos

A secondary component of the marketing strategy is to create a brand around the *myNAC* and BioAesthetics. In this way, the reputation and message of the company can be directed as desired: namely, positioning as an innovator in the regenerative medicine arena, and a champion of breast cancer survivors. The company logo can be seen in **Figure 3** below.


**Figure 3. BioAesthetics Logo**

While both men and women undergo mastectomies, the market for reconstructive nipple tissue is primarily composed of women, and the respective logos emulate this statistic. The modern and sleek design speaks to the cutting edge nature of regenerative medicine, and focuses on the aesthetic benefit provided by BioAesthetics. Furthermore, the company logo for BioAesthetics is pink-purple color of three circles and the company name in grey, bolded. The three circles symbolize the, resilience of cancer survivors and their transition to complete reconstruction. The grey-bolded company name, reflects the bold strength of the survivors

### Publications and Professional Society Presentations

A key aspect to scientific research is reputation and credibility before the scientific and medical communities adopt a new method or product. To obtain credibility in the scientific community articles must be published in respected scientific journals, which are peer reviewed for experimental completeness. BioAesthetics 's spans multiple disciplines in science, and key interdisciplinary journals identified are: Journal of Plastic, Reconstructive & Aesthetic Surgery; Journal of Plastic and Reconstructive Surgery; Nature Biotechnology; New England Journal of Medicine; Tissue Engineering Part A. This scientific and medical community credibility is essential to BioAesthetics 's success and integration with the medical community; therefore, it is part of the marketing strategy to aim to publish research findings and progress in these journals.

Currently, our first publication in under consideration in: Journal of Plastic and Reconstructive Surgery. Our second paper, currently in progress, will be submitted to Tissue Engineering Part A; with plans to submit the pre-clinical large animal trials to Nature Biotechnology.

### Community Awareness and Outreach

There are a number of opportunities of community outreach targeted at educating the breast cancer survivor community of the availability of reconstructive nipple options. The campaign for breast cancer awareness is among the best for any medical issue, as everyone has a loved one or acquaintance whose life has been changed through a diagnosis. Consequently, the community has a substantial following and a great deal of visibility—for example, the campaign to wear pink during the month of October to commemorate Breast Cancer Awareness Month.

One means of positioning BioAesthetics as a member of this community is to form an alliance with the American Cancer Society (ACS), specifically targeting sponsorship in Relay for Life events. All major metropolitan areas have local ACS offices which host annual—quarterly—or even monthly Relay for Life walks. In addition to being a fundraising opportunity, these events hold a great deal of significance for survivors and various participants who have been touched by a cancer diagnosis. Furthermore, sponsoring efforts will focus in specific cities, namely San Francisco, San Diego, Boston, New York and Washington D.C. where venture capital firms have more of a presence and word-of-mouth marketing will have a greater impact towards the ultimate goal.

## RISK ASSESSMENT: CRITICAL SUCCESS FACTORS

The biotech industry is the epitome of risky business; while the necessary investment (both financial and temporal) is high, the rewards can be tremendous if the technology is properly managed. In order to mitigate the risk, a proper understanding of the landscape can provide a worthwhile tool for positioning a product towards optimal profitability.

### FDA Regulation

Ultimately, the feasibility and profitability of BioAesthetics relies on successfully navigating the regulatory requirements of the Food and Drug Administration (FDA), both in the pre-market and post-market environment. All current acellular dermal products that are used for breast reconstruction have entered the market through 510(k) clearance.

### Intellectual Property Strategy

Representation: Hyman IP Law; San Francisco, CA

In order to sustain a competitive market position, appropriate and comprehensive intellectual property surrounding *myNAC* technology must be ensured. Ultimately, the value of the company is dependent on the intellectual property standing upon maturity of the technology.
BioAesthetics' has had two provisional patents have been converted to a PCT international patent application as of October 2015.

- PCT patent application: "Surgical grafts for replacing the nipple and areola or damaged epidermis"
  - Filed: 31 October 2015
  - PCT: PCT/US2015/058527
- Provisional patent applications: "A biocompatible device for nipple and areola replacement."
  - 62/212,846 and 62/073,719

Continuous development and security of intellectual property is the primary strategy for BioAesthetics growth and increased value. During the course of research and development, any supplementary derivative products and methods which arise will be pursued for patent claims. In this way, the company not only provides a wide scope of protection surrounding *myNAC* technology, but additionally acquires additional assets towards the eventual exit.

### Market Adoption Risk: Reimbursement

56% of all prosthetic breast reconstruction currently uses acellular dermal tissue; so the plastic and reconstructive surgeons are very familiar and acellular dermal products. The procedural codes, will

remain the same for NAC reconstruction, which is seen as essential for breast reconstruction purposes. Additionally, like most other acellular dermal product, a HCPCS will need to be obtain (**Figure 6**).

According to the Centers for Medicare and Medicaid Services (CMS):

*Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective non-cosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason*[6].

This places the *myNAC* technology within the scope of reimbursable medical care. Furthermore, the reconstruction of nipple tissue by BioAesthetics equates to a better patient outcome with fewer expenditure on behalf of the reimbursement agency: essentially, because the product is being generated out-of-house, it saved the surgeon time and resources from harvesting skin and fashioning a nipple-like appendage for each patient. As the time spent in surgery decreases, ultimately the cost to the insurance provider decreases as well. In lieu of this, it is highly probable that technology adoption of *myNAC* will be welcomed by all participating parties; however careful attention must be paid to this arena.

## MANAGEMENT TEAM AND KEY PERSONNEL

### Standing CEO and Future CTO: Nicholas Pashos

The Chief Executive Officer is Mr. Nicholas Pashos. Nicholas Pashos is the originator of this business idea and its core technology. He first began developing implantable biocompatible medical devices in early 2007, during which time has worked on spinal cord injury repair device with directed neurite growth; bioengineered whole lung transplantation alternative; bioengineered muscle. Additionally, he has years of experience in reliability and test engineering at BAE SYSTEMS, a leader in government defense; he understands the importance of logistics, security and reliability of products and services that he plans to translate to patient- specific biocompatible implantable medical devices. Mr. Pashos earned his BS in Biomedical Engineering from Drexel University School of Biomedical Engineering, Science and Health Systems; and is currently a PhD Candidate in BioInnovation as a National Science Foundation (NSF), Integrated Graduate Education Research Trainee (IGERT) Fellow, at Tulane University.

### Director, Product Development and Quality Assurance: Samantha Kurtz

Ms. Samantha Kurtz. Samantha has a passion for breast cancer research. She began researching breast cancer vaccines using autologous cells as a source of immune antigen recognition. Samantha also has experience in optimizing drug delivery for various routes including oral, intranasal, transdermal and transpapillary drug delivery. She recognizes the importance and desireability of patient-specific treatments not only for the purposes of preventing rejection, but also as a more patient centered focus for treatments and breast reconstruction. Ms. Kurtz earned her BS in Biology and MS in Biomedical Engineering from the University of Arkansas. She is currently pursuing her PhD in BioInnovation from Tulane University as a NSF IGERT Fellow.

[6] National Coverage Determination (NCD) for Breast Reconstruction Following Mastectomy, title 140, section 2.

### Additional Hires

- **Chief-Executive Officer (CEO)**: An experienced CEO with a proven track record of getting biologically–derived medical devices through the FDA 510(k) process is key in order to push this device to market.
- **Accountant/ Payroll administrator:** Accounting and payroll duties will first be managed by the CEO with pro-bono assistance from private contractor, a relative of the CEO who has offered their assistance. When the company begins to higher additional employee and contractor, the payroll administrative duties will be outsource to PayRollRx.com[7], an online payroll administration company, located in Metairie, Louisiana.
- **Contract Research organization (CRO):** The FDA consultant will be brought on during the preclinical trials to ensure that the appropriate safety profiles and efficacy analysis are being performed to best position the company for clinical trials. Although the company's goal is for an exit post preclinical and prior to clinical trials, the FDA consultant would allow for a clean exit, as all preclinical data will be properly in order for a clean acquisition by a larger pharmaceutical company.
- **Sales and Marketing Strategist Consultant:** The marketing strategist will be consultant for the best way to reach the large pharmaceutical companies and community awareness.

Each key personnel outlined in this section are committing themselves and their experience to BioAesthetics, and as such they are entitled to 5% of the company and its holding. This percentage will not diminish with investor holdings.

### Executive Committee

- **Dr. Abigail Chaffin, M.D.:** Dr. Chaffin is an experienced plastic surgeon located in New Orleans, focusing on breast reconstruction surgery. She is the Program Director for the Tulane Plastic Surgery Residency Program, as well as the Director of the Tulane Outpatient Burn Clinic. Dr. Chaffin has conducted research into the behavior of stem cells in the breast tissue microenvironment, and is therefore the ideal expert and critical advisor on *myNAC* research efforts. Furthermore, as a renowned plastic surgeon, Dr. Chaffin can provide guidance regarding future market positioning and provide insight into what reconstructive surgeons would adopt as a new standard of care.

- **Bruce Bunnell, Ph.D.:** Dr. Bunnell is a distinguished researcher and professor in the field of Pharmacology and Tissue Engineering. He is the acting director of the Tulane Center for Stem Cell Research and Regenerative Medicine, as well as the Chairman for the Division of Gene Therapy at the Tulane National Primate Research Center. With over 100 publications to his name, he will act as the key scientific advisor for research efforts completed in BioAesthetics . Initial work on the development of *myNAC* was completed under the tutelage of Dr. Bunnell, giving him an in-depth understanding of the development of the technology.

- **Pleasant Hooper, Ph.D.**: Dr. Hooper has several years of experience in primary healthcare in a rural setting from his practice of Emergency Medicine across the state of Mississippi. He received advanced training in science at LSU and was recruited to implement clinical mass spectrometry screening for metabolic disease in children born across Louisiana. Under his direction, the Louisiana Office of Public Health Biochemical Genetics Laboratory, began expanded newborn screening in 2004 with over 100,000 tests performed. Several affected children were discovered

[7] http://www.payrollrx.com

by the tandem mass spectrometry method and treatment could begin prior to any symptoms of illness occurred. This successful program was interrupted by the damage of Hurricane Katrina to the New Orleans facility. Dr. Hooper became interested in the method of monitoring transplant patient anti-rejection (immunosuppressant) medications by mass spectrometry being pioneered in Europe. At the encouragement of his partners and collaborators, he undertook the effort to establish a mass spectrometry transplant monitoring laboratory in New Orleans. In collaboration with Tulane Transplant Program, a study was performed to demonstrate the effectiveness of mass spectrometry for monitoring immunosuppressants and to show the equivalence of obtaining blood from finger-stick (capillary) vs. traditional venous samples in testing. Dr. Hooper then developed HomeTrak™, a system for patients to obtain blood samples at-home and have their immunosuppressant drug levels and essential medical tests performed accurately and conveniently. Since establishing, TMS BioScience, Dr. Hooper's lab has performed hundreds of monitoring tests on patients - both for client hospitals and in the regional community by use of HomeTrak™.

- **Scott K. Sullivan, MD, FACS**: Dr. Sullivan is board certified as both a Plastic and General Surgeon, is the co-founder of the Center for Restorative Breast Surgery (CRBS), and the St. Charles Surgical Hospital – the only hospital in the world dedicated to breast reconstruction for women facing breast cancer, where he is pioneering landmark breast reconstruction techniques. Dr. Sullivan is a leader in the area of breast reconstructive surgery at a national and international level. Dr. Sullivan has performed over three thousand breast reconstruction surgeries since the inception of the CRBS in 2003. Within the field of microsurgery he has made some major practical surgical advances, seen nowhere else in the world. His particular area of focus is breast reconstruction utilizing the body's own tissue. These state-of-the-art techniques, referred to as Perforator Flaps, now represent the leading choice in breast reconstruction. Dr. Sullivan, in collaboration with Frank J. DellaCroce, MD, FACS, has pioneered several of these revolutionary breast reconstructive techniques, including Bilateral Simultaneous GAP and Hip flap Reconstruction, Stacked Flap (Stacked DIEP, Stacked Hip flaps), Extended DIEP Flaps, Single Stage Composite Breast Reconstruction (Single Stage DIEP flap with Implant), Body Lift Flap, and Endoscopic Assisted DIEP Flap breast Reconstruction. These techniques were developed for the patient that is thin and those unfortunate patients that have had prior reconstructive failures. Because of their expertise in the field of reconstructive microsurgery, their practice is the referring destination for very complex reconstructive challenges. The American Cancer Society has named Dr. Sullivan a Spirit Award Honoree for going above and beyond in the fight against cancer. Best Doctors, Inc. recently named Dr. Sullivan, one of the "Best Doctors in America."

## OPERATIONS

### Location

New Orleans is a unique city known as a home to music, food and culture; the saying *laissez les bons temps rouler* (let the good times roll) extends beyond Mardi Gras and permeates into everyday life. What most people overlook in this statement is the profound opportunity New Orleans holds for establishing a biotech company, namely BioAesthetics. The city is home to several universities in addition to multiple hospitals, presenting a local atmosphere which would provide mutual benefits for both the biotech industry and the academic and medical entities alike.

Additionally, New Orleans is anxious to enter the biotech arena, and has been investing in projects such as the Bioinnovation Center and the Biosciences Center in order to bring a new industry to the city. This push towards research and science centers is a progressive move for a city so entrenched

in its history, and in order for this movement to succeed, businesses must follow suit. Fortunately, the New Orleans convention center—one of the largest convention centers in the US—is home to large research, biotech, business and science conventions on a monthly basis. Convention goers not only prime the hospitality industry in New Orleans, but the influx of educated individuals and field leaders brings traffic of intellectuals to the city, who in turn can improve the health service and research sectors. The unique nature of the city provides a draw for young, eager professionals, who continually influx into the city looking to establish new opportunities. Capitalizing on these unique attributes, BioAesthetics will establish operations in New Orleans until such a time where it is no longer feasible to remain in the city.

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- **Facility:** BioAesthetics will initially be located in the New Orleans BioInnovation Center (NOBIC), baring the successful acquisition of funding. NOBIC is located in New Orleans, Louisiana, and offers, flexible leasing terms of state-of-the-art biotech facilities for start-up companies. Being tenant of NOBIC allows for access to its shared administrative office equipment, an in-house Commercialization team to offering help to the NOBIC tenants, and includes all of the major cell culture and cellular analysis equipment that is necessary to continue business until the closure of the exit strategy[8].
- **Tax Incentives for BioAesthetics:** New Orleans is an ideal location to for a new regenerative medicine research and development start-up company, as it offers substantial tax incentives for both the company and investor of the company. The Phase Zero Program[9] also provides financial support for the initiation and application of Small business Innovation Research (SBIR) and Small business Technology Transfer (STTR) grants.
- **HUBZone-Like Advantages:** The Historically Underutilized Business Zone (HUBZone) system is a means of classifying regions in the U.S. on the basis of the local environment surrounding small business development. Counties are ranked on various criteria; those that are deemed disadvantaged gain access to preferential procurement of Federal funding sources. In competing for SBIR and STTR funding, grant applications coming from Louisiana receives preference over applications coming from California or Massachusetts, based solely on the historically smaller volume of grant submission from that region.

### Production Strategy

The production of BioAesthetics *myNAC* is completely outsourced to preexisting tissue bank/tissue processing facilities. These facilities, such as Musculoskeletal Transplantation Foundation (MTF), one the of largest tissue bank and allograft supplies in the United States, commonly partners with cooperate entities to allow them to plug into MTF's existing processes to process and package their human derived products.

## FINANCIAL STATEMENTS

For the initial stages of research and development, operations and company formation, BioAesthetics will seek funding through grant source: namely the Small Business Innovation Research Grant (SBIR) or Small Business Technology Transfer Grant (STTR). The majority of funds will be applied towards general business establishment costs, research materials costs and legal council surrounding patent protection. Ideally, the leanest company model will be employed, with minimalization of redundencies and unecessary costs.

[8] http://www.neworleansbio.com/facilities/core-facilities/
[9] http://tbdc.latech.edu/resources/incentives/

## Key Milestones and Development Benchmarks

BioAesthetics will be The FDA will be approached in mid 2016 as a 510(k) submission. During this 18 month process*, in vivo and in vitro* safety and efficacy trials will be completed, in order to obtain FDA clearance by 208 (**Figure 4**). Immediately after obtaining the 510(k) clearance a clinical evidence trial to obtain patient satisfaction will be conducted. In order to obtain 1 year follow –up one 150 patients over 48 centers in the United States, this is estimated to last approximately 2.25 years (**Figure 4**).

Round A funding of $3.3 million dollars will allow for 24 months of operations; recruitment of a full-time CEO who have experience with human-derived medical devices, appropriate for 510(k) submission; and hire a sales and marketing time, to allow for early adopters as soon as the device is FDA cleared (**Figure 5**). Round B funding of $5.5 million will allow for a large ramp up of sales and marketing team and to allow for the completion of the clinical evidence trial **(Figure 5**), with a planned exit between the obtaining Healthcare Common Procedure Coding System (HCPCS) reimbursement code and acquiring 3.9% of the market share (**Figure 6**).

BioAesthetics' **Break-even Point**, is in the first quarter of 202, with 3,000 *myNAC* units sold at $3,000 per, allowing for the recuperation of the $9 million investment (combined Round A and Round B) funds. This break-even point is also the point at which this BioAesthetics becomes a sustainable business with steady revenue stream. With the **Costs of Goods Sold** (**COGS),** including donor tissue procurement and processing, estimated at $35 per NAC scaffold unit, allows for a healthy margin of profit. This proposed product is expected to be reimbursed by the providers, with the same payment/reimbursement route as currently used for other acellular material in breast reconstruction.

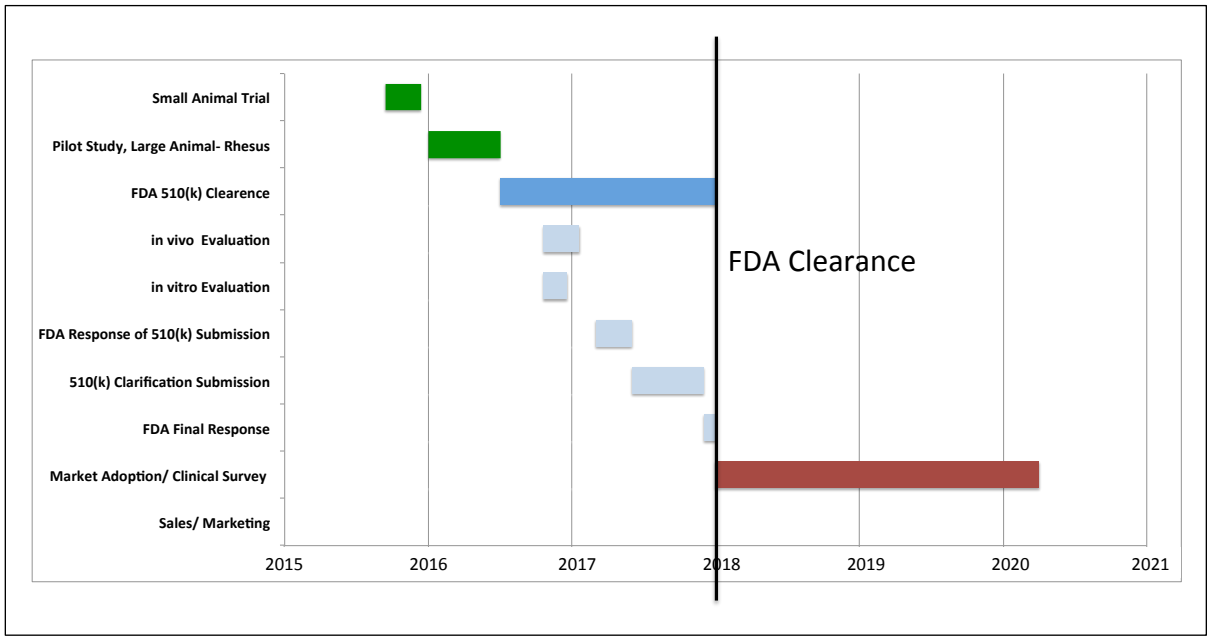


**Figure 4: Milestones of FDA Clearence**

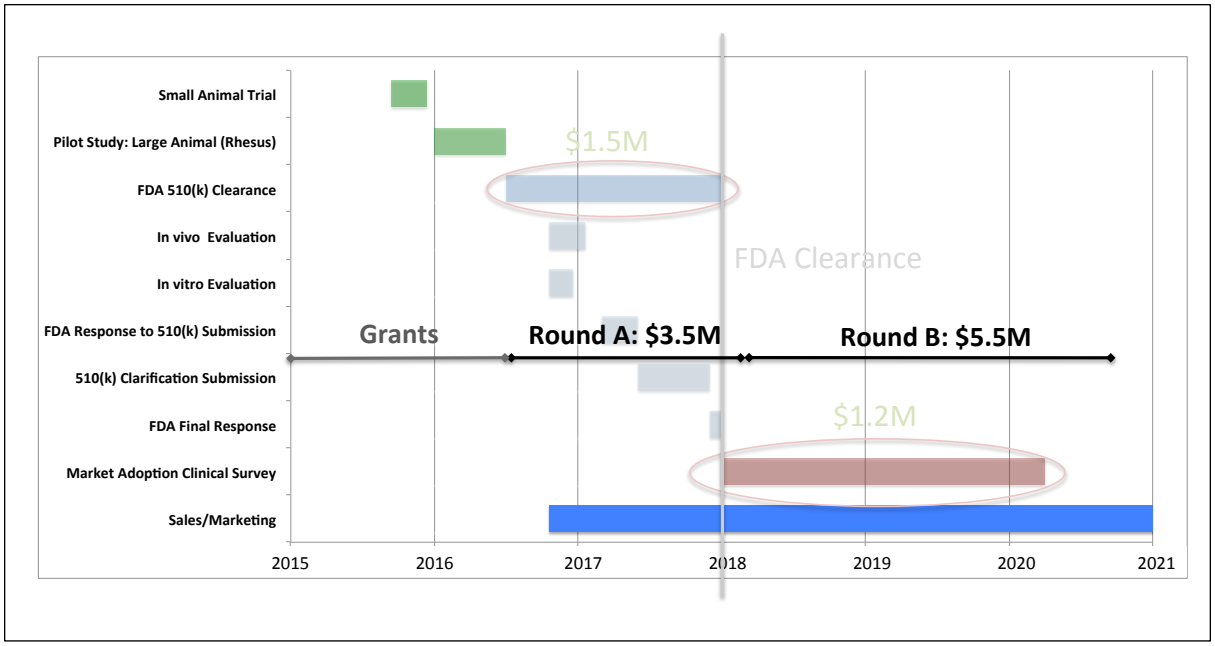


**Figure 5: Round A and Round B Funding**

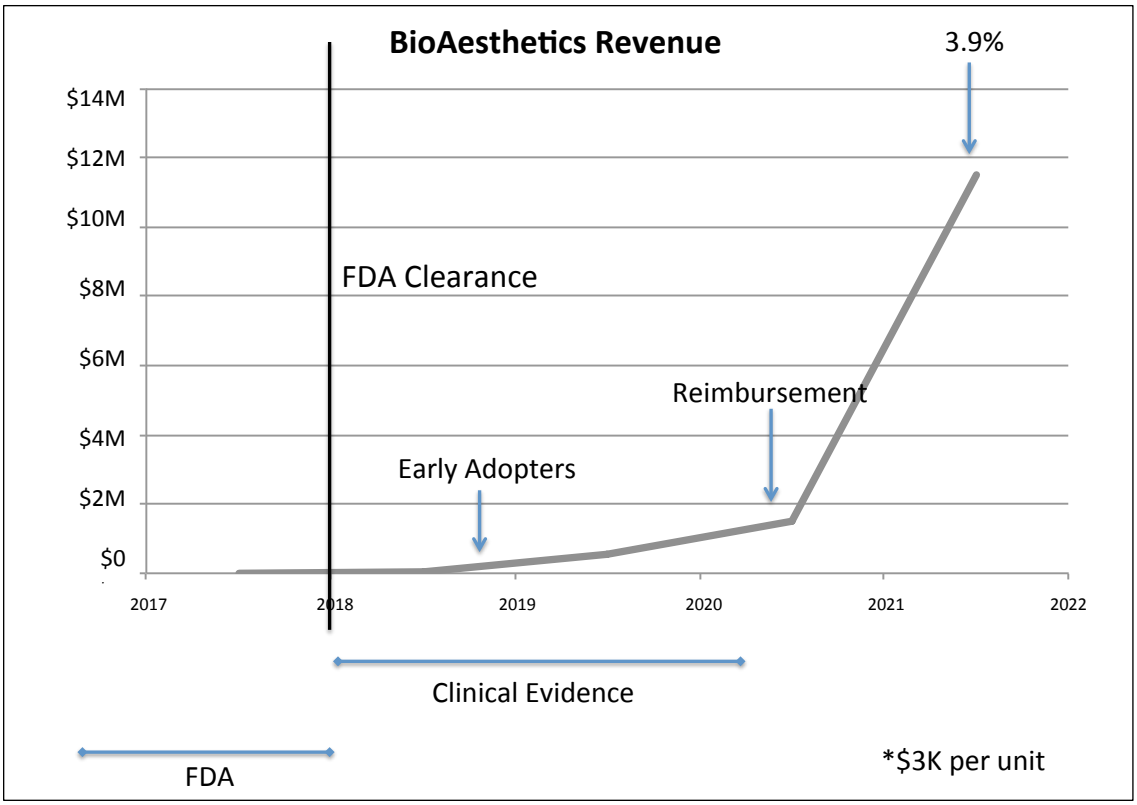


**Figure 6: Early Adopters, HCPCS Reimbursements and 3.9% Market Adoption**