2011 MERAGE SCHOOL
BUSINESS PLAN COMPETITION

PINNACLE ACUSHAPE™

BUSINESS PLAN

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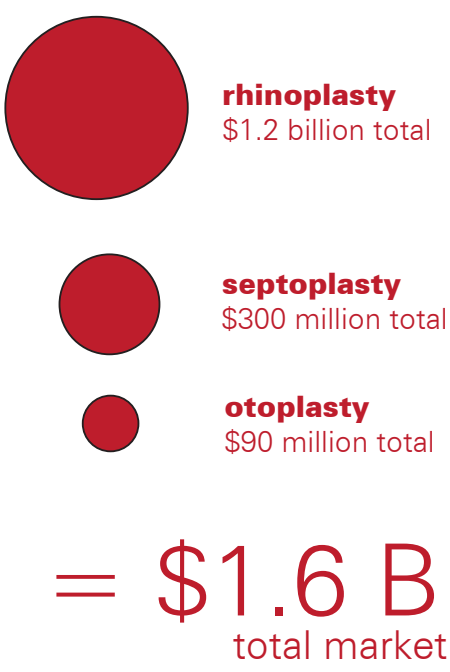
EXECUTIVE SUMMARY

Pinnacle Therapeutics is a privately held, development stage company located in Irvine, CA, focused on employing its patented technology to improve and correct functional and cosmetic malformations. Our AcuShape™ system is *real*. The technology promises to alter the traditional landscape of reconstructive surgery.

The Company has one issued U.S. patent no. 7,416,550 titled "Method and Apparatus for the Control and Monitoring of Shape Change in Tissue" and intends to further expand its intellectual property portfolio. AcuShape is currently undergoing preclinical evaluation. With the necessary capital in place, we believe the product can advance to the human clinical study phase in the next 12 to 18 months.

The Company is seeking U.S. Food and Drug Administration 510(k) approval for the clinical indication of "reshaping" the nose, ear, and nasal septum and in early 2012, the Company intends to file a pre-IDE (investigational device exemption) with the U.S. FDA for permission to run a multi-center clinical study in the U.S. For Europe, the company will be working to obtain a CE Mark on its product.

The market for AcuShape is highly addressable (see image, right). From an investor standpoint, the Company believes it offers an attractive opportunity. The business model is based on recurring revenue (e.g., razor/razor blade). The AcuShape power generator and first mold set are inexpensive to manufactureand therefore can be provide to physicians at nominal cost or free-of-charge. Revenue will be generated by having physicians purchase sets of disposable needle electrodes. It is anticipated that the gross margins on the sale of the disposable needle electrodes will **exceed 90 percent**.



COMPANY HISTORY

Pinnacle Therapeutics was founded in 2010 by renowned otolaryngologist and facial plastic surgeon Brian J.F. Wong, M.D., Ph.D. at the University of California, Irvine and Beckman Laser Institute and Clinic.

Dr. Wong's vision is to improve the lives of patients by harnessing the Company's novel technology for reshaping cartilage tissue for patients with functional and cosmetic malformations of the nose and ear. To date, research and product development has been funded by the Air Force Office of Scientific Research (FA9550–04–1–0101), Department of Defense Deployment Related Medical Research Program (DR090349), and the National Institutes of Health (DE019026, DC005572, DC00170, RR-01192) grants.

THE PRODUCT

ACUSHAPE VALUE PROPOSITION

AcuShape is a medical device for reshaping the cartilage of the nose, ear, and nasal septum. It promises minimal to no trauma as compared to conventional and invasive "cut-and-suture" surgery. Traditional surgery has inherent risk to the patient, remains highly invasive, and typically requires a long and painful recovery period (ranging from weeks to months). Additionally, unlike conventional surgical procedures, AcuShape allows for incremental corrections to better meet patient expectations over time.

Traditional surgery	**AcuShape**
Invasive	**Minimal to no trauma**
Long recovery	**30-minute recovery**
Expensive	**Cost-effective, with incremental corrections**
General anesthesia + risks	**No general anesthesia**
Bleeding, scarring	**Minimal blood loss & scarring**

Cosmetic surgery is largely a "cash business." Yet surgery is expensive and, therefore, often available to only certain segments of the population that can afford it.

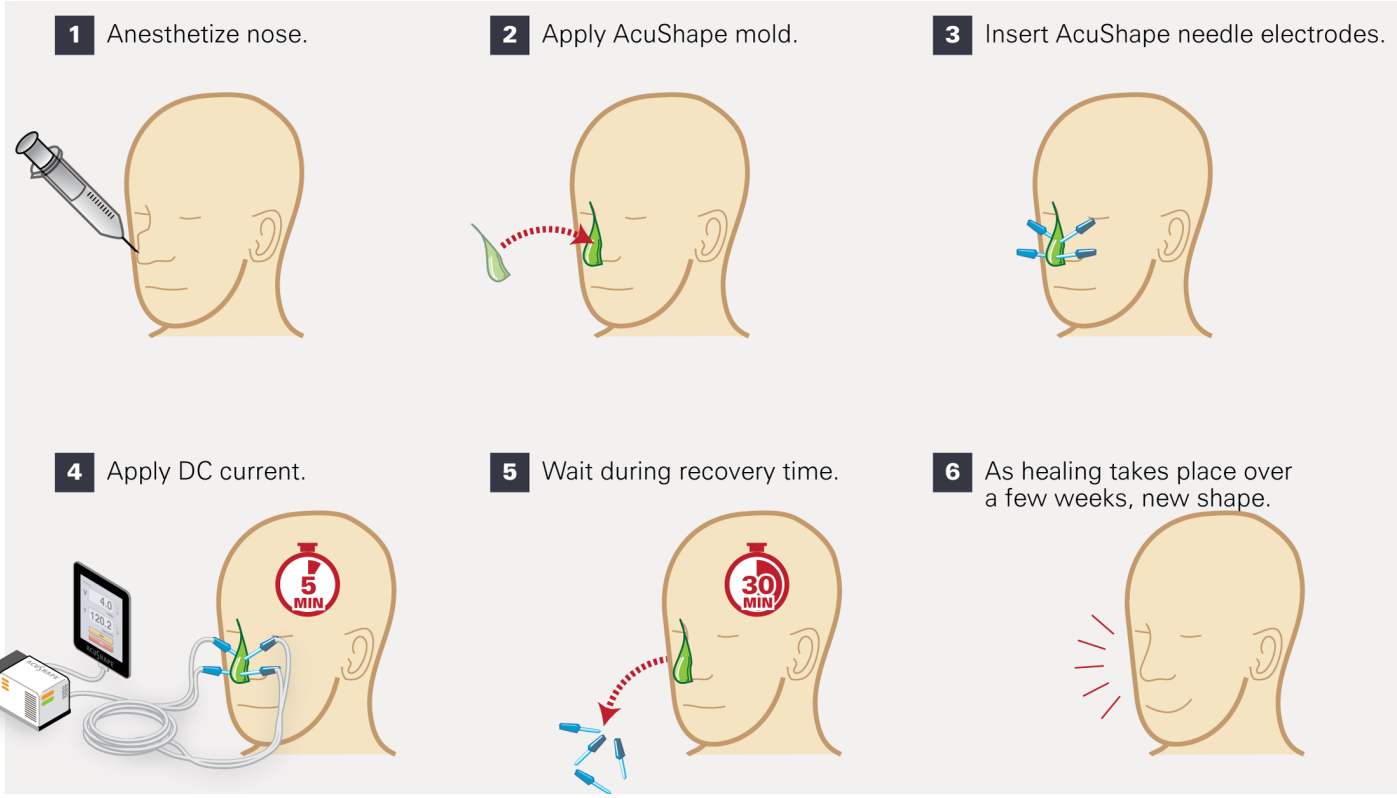
By providing a low cost, non-invasive approach with virtually no risk, minimal pain, and short recovery times, AcuShape offers an attractive alternative to patients and physicians alike.

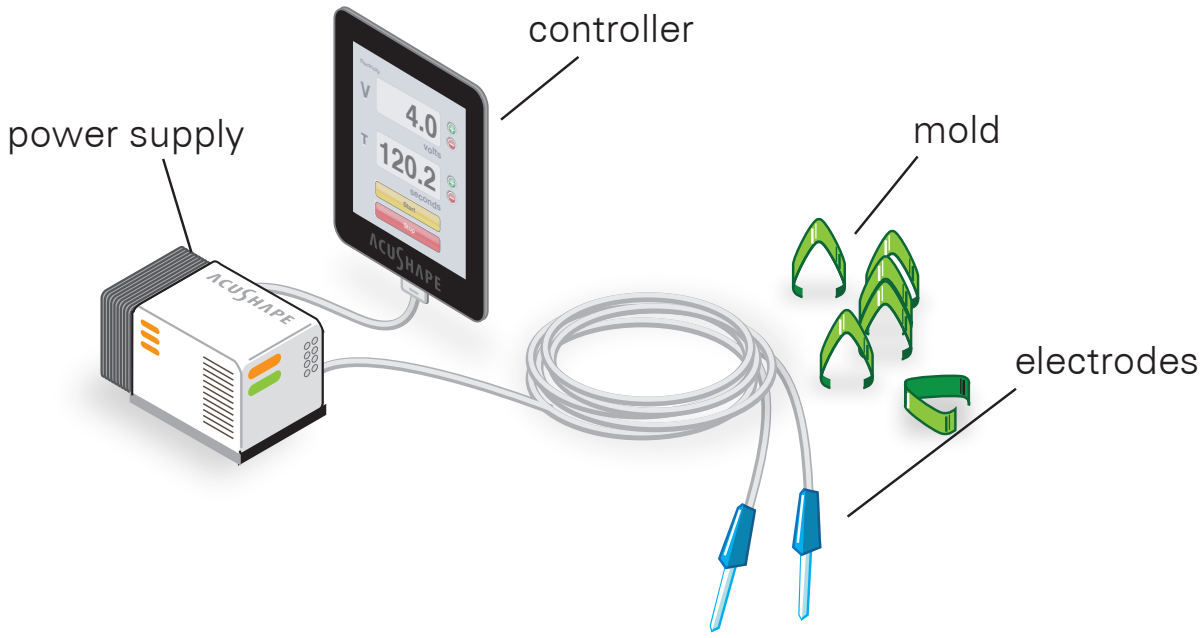
1. **AcuShape reduces the cost of procedures.**
2. **AcuShape can significantly reduce the recovery time for patients from weeks to hours.**
3. **AcuShape is safe and effective.**

RESHAPING THE TIP OF THE NOSE WITH ACUSHAPE

With AcuShape, the biomechanical properties of the ear or nose are altered at the site of treatment with the use of a mold and application of a DC electric current through strategically placed platinum needle electrodes, resulting in permanent shape retention.

The skin of the nose is first anesthetized, and a mold that produces a unique shape of the nose is used to apply gentle pressure to the tip of the patient's nose for a desired shape. Disposable AcuShape needle electrodes are then inserted through the skin into the nasal tip cartilage. DC current is delivered into the bent cartilage for approximately 5 minutes. The electrodes are then removed and the patient is observed in clinic for approximately 30 minutes while continuing to wear the splint. The patient continues to wear the splint for 1-2 weeks, after which the physician removes it and assesses the aesthetic result and mechanical stability at a follow-up visit. The surgeon may require the patient to keep the splint on a night after this 2-week period. A similar procedure may be performed for the ear using a customized ear mold.





THE ACUSHAPE SYSTEM

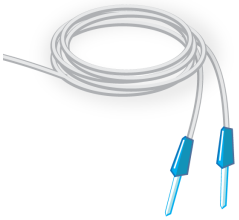
The device encompasses the following three main components:

Mold set

Each mold conforms the ear or nose into a desired shape. The molds are reusable and made in various sizes to accommodate a wide range of patients and adjusted by the physician. At this time we are focused on the rhinoplasty market and will therefore manufacture nose molds first, later expanding to ear molds.

Power supply and controller

The highly user-friendly AcuShape power supply unit is handheld with a programmable DC power supply (voltage and application time) via a touch-screen interface. It has an auto-off safety feature that immediately shuts off when any signs of electrical hazard are detected.

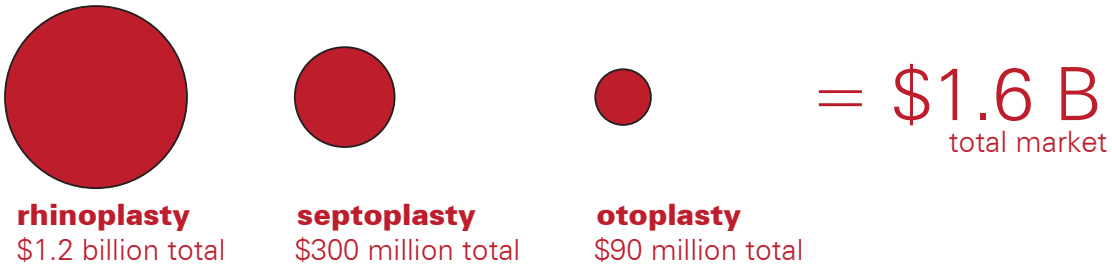


Platinum needle electrodes

Electrodes are ***disposable*** — designed for one-time use and then discarded after treatment. After therapy, the software logs the treatment settings and related data.

THE MARKET FOR ACUSHAPE

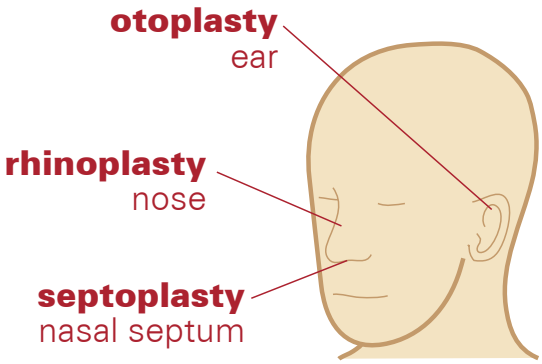
We have identified three potential *immediate* markets for AcuShape: otoplasty, rhinoplasty, and septoplasty.



1) Rhinoplasty

Rhinoplasty is the surgical alteration of the shape of the nose (colloquially known as a "nose job"), often by manipulating cartilage. It is a common aesthetic procedure performed by plastic surgeons, and is one the most popular cosmetic procedures performed.

The current market and future growth potential for AcuShape within rhinoplasty is expected to be significant.



- The ASPS reports nearly 280,000 rhinoplasties were performed in 2008, representing a **$1B market.**
- Regionally, the average established plastic surgeon in Newport Beach, CA performs at least 5 rhinoplasties in any given month.
- The growth rate of qualified surgeons has not kept pace with the demand for rhinoplasty.
- Currently, patients have no alternative to invasive, potentially dangerous, and lengthy rhinoplasty procedures — up to 2-6 hours — for reshaping the nose.
- **AcuShape reduces the cost and time of a rhinoplasty procedure with comparable outcomes to traditional surgery.** We expect surgeons will appreciate the speed of the procedure and potential profit margins.
- **AcuShape is significantly less invasive than traditional rhinoplasty and can cut the recovery period by more than half with less pain.**

2) Otoplasty

Otoplasty is the surgical reshaping of ear cartilage. It is indicated for correcting many deformities, including macrotia (large, attention-drawing ears), commonly called protuberant ears.

- The American Society of Plastic Surgeons estimates that over 27,000 procedures were performed in the U.S. in 2009 alone.
- At around $3,400 per procedure, this represents an annual market of more than **$90M**.

We expect the adoption rate of AcuShape for use in otoplasty to be *extremely* high:

- Today, patients *do not have safe alternatives for ear reshaping* other than traditional surgery, which carries along with it surgical risks.
- **AcuShape can significantly reduce the recovery time for patients.** Whereas traditional post-surgery recovery periods vary, they are often long and intensive, almost up to 3 months. In contrast, recovery time following AcuShape treatment is estimated to be 30 minutes. Compare to traditional surgery, which lasts hours, even days.
- **AcuShape will offer a safe, effective, and reduced cost (by more than $1,000) per treatment.**
- **The growth potential within the otoplasty market is very promising.** The American Academy of Facial Plastic and Reconstructive Surgery estimates increased demand for procedures.

3) Septoplasty

Septoplasty is the surgical correction of a deviated cartilage of the nasal septum. There are multiple indications for this procedure, but it is most commonly performed to help patients breathe better. For instance, the cartilage of the nasal septum, even if normal, may be naturally deviated to one or both sides, obstructing breathing through either or both sides of the nose.

We are optimistic about the current market and growth potential for AcuShape used for septoplasty.

- Over 2 million Americans suffer from a deviated nasal septum, according to 2004 Census data.
- More than 300,000 patients undergo septoplasty per year. The annual market is estimated to be **$300M**. ***AcuShape promises to reduce the cost and recovery burden of septoplasty patients.***
- Currently surgical treatment is the only option for patients. The cost per procedure is $3,000 to $4,000 and is rarely fully covered by insurance.
- Recovery from traditional septoplasty takes 7-10 days with the patient having to endure extremely uncomfortable gauze packing.
- AcuShape promises to drastically reduce recovery time with comparable outcomes.

COMPETITORS

Traditional surgery is the current standard of care.

There are currently no known direct competitors in the U.S.

OPERATIONS PLAN

INTELLECTUAL PROPERTY

Since 2008, AcuShape has been protected under issued U.S. patent no. 7,416,550, titled "Method and Apparatus for the Control and Monitoring of Shape Change in Tissue."

PRECLINICAL TESTING

AcuShape is currently in preclinical evaluation employing a live rabbit model. Additional preclinical experiments for larger animals are envisioned as the next phase in the preclinical testing plan.

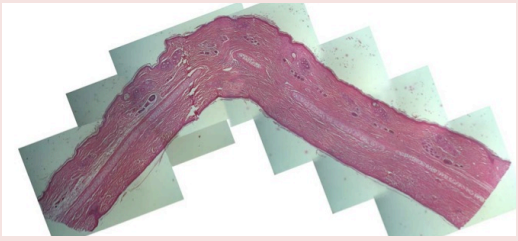
PRODUCT DEVELOPMENT

We are currently in live rabbit studies (see images, right).

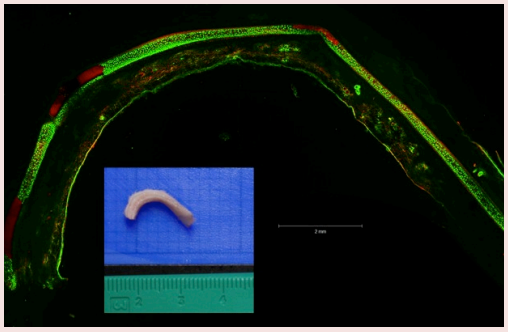
- We are optimizing clinical efficacy and safety voltage and time parameters.
- We are evaluating tissue survival, histology, and biomechanical property changes
- A study of 16 ears has been completed. The results are in the process of being submitted for publication.

Our next step is to move towards human clinical trials. To get to this next milestone:

- We will complete the live rabbit studies within 2011.
- We will validate our portable AcuShape device. Previous studies were performed using a device with a bulky



Cartilage sample treated by histologic techniques. General tissue architecture is intact, with the area of the bend showing biomechanical changes.



Cartilage sample treated by AcuShape viewed under fluorescent microscope.

- Green color indicates most cells are alive after treatment with AcuShape.
- Red color indicates area of needle electrode insertion.

The right ear was treated by AcuShape and left bent for a month. The left ear was bent for a month without AcuShape.

power supply and standard bench testing equipment that can easily be reduced in size.

- We will aim towards achieving optical anatomical design of ear and nose molds.

REGULATORY STRATEGY

Pinnacle is focused on getting AcuShape to the market in the shortest possible time frame.

- The Company believes that the U.S. market offers the largest opportunity in terms of adoption and potential revenue; however, the pathway to market approval is sometimes longer in the U.S. than in Europe.

- Therefore, the Company will pursue regulatory approval in both Europe and U.S. In Europe, the company will be working to obtain a CE Mark. In the U.S., the Company believes that its product will be designed as a Class II device, and qualify for FDA 510(k) status - however, we assume that a human clinical study to prove safety will be required.

SALES & MARKETING STRATEGY

AcuShape has a highly addressable market insomuch as there are tens of thousands of cosmetic surgeries being performed in the U.S. annually. Given the fact that any licensed physician in the U.S. can practice cosmetic medicine, this provides the Company with an opportunity to approach various groups of physicians.

AcuShape will be marketed to physicians through a recurring revenue model (e.g., razor / razor blade industry). Specifically, we will attract surgeons by supplying the AcuShape power generator and first mold set free-of-charge, while our initial revenue will be derived from the recurring cost of surgeons purchasing disposable needle electrodes.

Initially, we plan to focus our marketing efforts to the following groups of physicians:

- Otolaryngologists / Head and Neck Surgeons (ENT)

- Plastic Surgeons

- Dermatologists

We identified key opinion leaders (KOLs) from the fields of otolaryngology and facial plastic surgery and have enrolled these KOLs to work with the Company and join the Company's Medical Advisory Board. We plan to leverage these relationships and reach out to their network of colleagues to foster widespread adoption of AcuShape.

From a tactical standpoint, we plan to hold information sessions at surgeons' clinics on-site and at various national, regional, and local otolaryngology, dermatology, and plastic surgery conferences. Like dermatologists, other physicians will rely on the credibility of otolaryngology and plastic surgery experts.

We aim to have our medical advisory leaders share their expertise in AcuShape at medical conferences, symposia, and meetings.

At each information session, we aim to emphasize AcuShape's key characteristics:

- Lower cost to patients and reduced time per procedure for physicians.
- No risks of surgery and anesthesia for patients.
- The technology was "**developed by surgeons for surgeons.**"

DISTRIBUTION STRATEGY

AcuShape will be distributed by both direct sales to end users as well as through qualified distributors in the U.S. and outside the U.S.

PRICING STRATEGY

It is expected that AcuShape will have a low cost of production. Specifically:

- The GUI-based power generator is estimated to have a material cost of $100 per unit.
- Packs of 10 disposable platinum needle electrodes have an approximate manufacturing cost of $20.
- The mold has an estimated manufacturing cost of $250 for the first set and template creation and $50 per set thereafter.

The Company will derive a revenue stream from surgeons through a "razor / razor blade" recurring revenue model:

- The GUI-based power generator and first mold set will be provided either free or at a nominal price to physician customers.
- A set of disposable needle electrodes sufficient for one procedure will be sold for $1,000.

Table 1 – Pinnacle Revenue Stream

Item	Manufacturing Cost	Expected Sale Price	Gross Margin
Power Generator	$100	$0	-$100
Molds (1 set of 5)	$250 (initial tooling cost) + $50 per set	$500	>$250
Disposable Needle Electrodes (pack of 10; one procedure)	$20	$1,000	$980

Table 2 – Cost to Physicians

Item	Cost to Physician (per procedure)	Cost to Patient (per procedure)	Profit for Physician (per procedure)
AcuShape package (one procedure)	$1000	$2500	$1500

Table 3 – Cost Savings for Patient

Average Patient Cost - Rhinoplasty	Patient Cost - AcuShape	Patients Savings (per procedure)	Cost Savings
$5000+	$2500	$2500	50%

AcuShape's value to surgeons is significant. AcuShape allows surgeons to charge at a high margin ($5,000+ for surgery vs. $2,500 for AcuShape) while performing the procedure much quicker (2+ hours for surgery vs. 15 minutes for AcuShape; not factoring in recovery time).

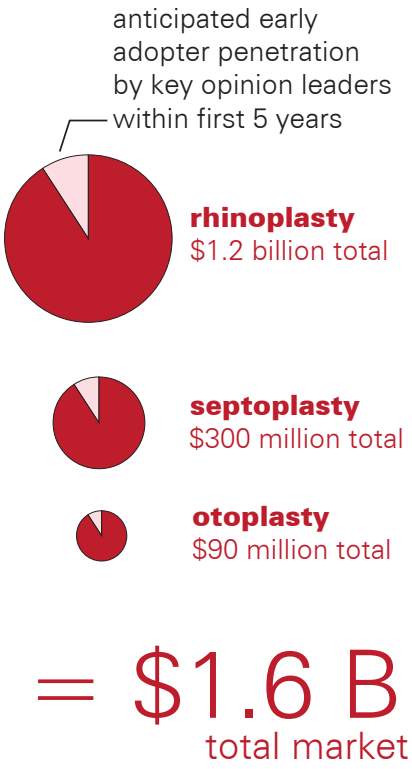
FINANCIAL PLAN

Sales Forecast

AcuShape aims to penetrate the rhinoplasty, septoplasty, and otoplasty markets. These markets have a combined value of $1.6B per year (rhinoplasty $1.2B, septoplasty $300M, otoplasty $90M). We believe that AcuShape has the potential to capture 5 to 10% of each of these markets within 5 years after product launch. This roughly translates to a potential revenue of $80M to $160M per year.

As adoption continues and procedure volume increases, AcuShape is expected to yield **pharmaceutical-like (>90%) margins** through this recurring revenue model.

The vast majority of these procedures are elective and cash-based. As such, there will be little or no need for surgeons to seek insurance reimbursements for AcuShape.



Capital Requirements

The Company is seeking **$500,000** in seed funding to recruit and hire qualified personnel, complete preclinical testing, and produce devices suitable for human clinical testing.

PERSONNEL

MANAGEMENT TEAM

Steven Chan is currently a graduate student at the UC Irvine School of Medicine and Merage School of Business who will be pursuing a career in psychiatry. He has experience in online marketing and medical device business development.

Mohammed Elayan is a former market researcher with experience in the consumer products industry with The Nielsen Company and The Kellogg Company. He is currently a second-year law student at UCI and will pursue a career working with emerging and high-growth companies.

Allen Foulad is currently a medical student at the UC Irvine School of Medicine and will enter a head and neck surgical residency this fall. He serves as a clinical consultant who will identify and address the needs of potential consumers.

Lawrence Kim is currently a graduate student at the UC Irvine School of Medicine and Merage School of Business who will be pursuing a career in internal medicine. His interests include biotechnology and entrepreneurship.

Cyrus Manuel is a junior project scientist at the Beckman Laser Institute and Clinic at UCI who will be pursuing a career in head and neck surgery. He is currently heading live animal studies to further establish the clinical efficacy and safety of AcuShape.

Khoa Tu is currently a graduate student at the UC Irvine School of Medicine and Merage School of Business who will be pursuing a career in emergency medicine. He has experience conducting clinical research on medical devices.

Ed Wu is currently a graduate student at the UC Irvine School of Medicine and Merage School of Business who will be pursuing a career in head and neck surgery. He has conducted extensive basic science research on cartilage reshaping under the direction of Dr. Brian Wong.

SCIENTIFIC AND MEDICAL ADVISORS

Brian J.F. Wong, MD, PhD is Vice Chair and Professor of Otolaryngology, Facial Plastic Surgery, and Biomedical Engineering at UC Irvine with his lab at the Beckman Laser Institute in Irvine. Dr. Wong received his degrees from the University of Southern California (BSBME), Johns Hopkins (MD), and the University of Amsterdam (PhD), along with an additional year at Oxford University (Wolfson College) as a Rotary Foundation Scholar. His residency and facial plastic and reconstructive surgery fellowship were completed at UC Irvine, where he has remained on faculty. He has published over 75 peer–reviewed publications, is on the editorial board of *Lasers in Surgery and Medicine* and *Lasers in Medical Science*, and performs editorial review for ten other journals. He is currently the principal investigator on three NIH grants, in addition to substantial support from other extramural agencies including the Department of Defense, State of California, and the Air Force. Dr. Wong's basic research is in thermoviscoelasticity and shape change in cartilage tissue, wound healing, and applications of optical coherence tomography in surgery. Dr. Wong has received a Mentored Clinical Scientist Award from NIH (1998), the Young Investigator Award from the American Society for Laser Medicine and Surgery (2001), the Sir Harold Delf Gillies Award from the American and Academy of Facial Plastic and Reconstructive Surgery (1998), and the Clinical Innovator Award from the Flight Attendant Medical Research Institute (2003). He has served on numerous study sections for the National Institutes of health. He is the former President of Sigma Xi at UC Irvine.

The Company is in the process of recruiting additional scientific and medical advisors.

BOARD OF DIRECTORS

Brian J.F. Wong, MD, PhD — *see bio above*

Raymond W. Cohen is is currently the Chief Executive of Minnow Medical, Inc. a development stage company focused on a device treatment for hypertension and various peripheral vascular diseases. He also serves as an advisor to Fjord Ventures, LLC., a life-science incubator located in Laguna Hills, CA and is a member of the Board of Directors of several public and private medical technology firms. Previously, Mr. Cohen was the Chairman and Chief Executive Officer of Nasdaq listed Cardiac Science, Inc. In 2004, Cardiac Science was ranked as the 4th fastest growing technology company in North America on *Deloitte and*

Touche's Fast 500 listing. In 2008, Mr. Cohen was named by AeA as the *Private Company Life Science CEO of the Year*. Mr. Cohen was named *Entrepreneur of the Year* in 2002 by the Orange County Business Journal and was a finalist for *Ernst & Young's Entrepreneur of the Year* in the medical company category in 2004. Mr. Cohen is a member of a number of local Southern California organizations, notably the Forum of Corporate Directors, Advisory Council Member Keck Graduate Institue, BioScience MBA program and OCTANe where he is a member of the Biomedical Leadership Council. Mr. Cohen is an Accredited Public Company Director and holds a B.S. in Business Management from the State University of New York at Binghamton.

The Company is in the process of recruiting additional board members.

SUMMARY

AcuShape™ is a nonsurgical, cost-effective, and safe electroforming technology that is leading the paradigm shift from open surgery to noninvasive and atraumatic modalities. In short, AcuShape is the future of aesthetic medicine.