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1 Executive Summary

1.1 Introduction

An estimated 28 million Americans and 250 million people worldwide suffer from hearing loss. This loss is devastating for the sufferers, isolating them from their friends, family, and daily acquaintances, as well as severely inhibiting their ability to fully function in society. To remedy this condition, people suffering from hearing loss often use hearing devices to augment their remaining hearing ability. Although these devices are not a perfect replacement for the sense of hearing, they enable the sufferer to once again function at a productive level and interact with family and friends. Unfortunately, hearing devices are not widely used among those suffering from some form of hearing loss. For decades hearing aids have reached only about 20% of those who could benefit from them in the United States, and the usage rate in the developing world is much lower still.

1.2 Industry

Currently, there are dozens of hearing aid manufacturers offering a breadth of products, but it is estimated that six major manufacturers account for 85% of worldwide sales. These incumbents are known as the “Big 6”, and their established positions in the market present a formidable obstacle to potential new entrants. Because many audiologists appreciate and value their current buying relationships with established manufacturers over smaller new manufacturers, success of new entrants into the market is rare. These relationships are fostered by reciprocity between audiologist and manufacturer, the convenience of consistency in such a relationship, and the trusted reputation of an established manufacturer as a maker of quality aids. Another challenge to new hearing device companies is the Federal Code of Regulations that includes FDA regulations relevant to the hearing aid industry. In order to ensure compliance with all legal provisions, a manufacturer must examine the statutes specific to the state(s) in which distribution occurs in addition to abiding by the broad yet inhibiting federal laws. Another characteristic of the industry is that good health practice requires a patient to undergo a medical evaluation by a licensed physician before purchasing a hearing aid. However, any fully informed adult over the age of 18 can sign a waiver declining medical evaluation.

1.3 Customer

The project has focused thus far on the population of the San Francisco Bay Area. By extrapolating from national statistics of hearing loss, the estimate of hearing impaired individuals in the Bay Area is 500,000. The Bay Area provides a diverse population with many different ages, races, and incomes to pilot the project. Within this group, a variety of hearing losses exist. Sensorineural hearing loss is one of the most common, resulting in the loss of the ability to discriminate consonants. High frequency hearing loss is also common, especially in the baby boomer population. Additionally, mild hearing loss results in a lack of amplification of sound, making hearing difficult in all situations. Unfortunately, many people suffering from these types of hearing loss go untreated. Hearing devices are used infrequently because of barriers that prevent sufferers of hearing loss from utilizing the technology available to treat their condition. These barriers include financial, informational, logistical, and psychological factors that inhibit or complicate an individual’s ability to purchase a hearing device. Financially, the purchase of a hearing device is quite difficult, with a midlevel-quality hearing aid costing about $1,000 per ear. Insurance does not cover this expense, and Medicaid reimburses such a low rate that patients are not able to obtain adequate technology. Also, patients often lack the information to help them recognize a loss of hearing or do not have information about how to remedy the condition.
Furthermore, the process of obtaining a hearing device is complicated, requiring multiple visits and inconvenient procedures. Finally, patients are often unwilling to recognize their hearing loss or are unable to adopt technology because of a stigma surrounding the use of a hearing device.

1.4 Product Innovations

To address these needs, the Social Entrepreneurship Startup (SES) team examined current technologies, ranging from established listening devices to innovative new technologies. After compiling these ideas, the team tested them with audiologists and consumers before selecting specific technologies that would best serve the millions in need of hearing devices. One particular device that combines high-quality technology and an affordable price is the Project Impact – Impact I, a behind-the-ear digitally programmable analog hearing aid for mild to moderate loss. It has a custom earmold and programming, making it equivalent to other devices currently offered in the market. The Pilot, a hearing aid made by the Danish company Microsound, is a less-custom hearing aid with a consumer electronic aesthetic (it comes in six different colors and resembles wireless earbuds). This hearing aid has rechargeable batteries and a bedside recharging cradle. It also avoids the more “medical” procedure of buying a hearing aid by using standard, non-custom silicone ear tips, which fit into most ears. The Pilot is also easily programmed, making the process easier for consumers and audiologists.

1.5 Process Innovations

To further lower the barriers to purchasing a hearing device and to bring hearing devices to the hundreds of millions of people in need of them, the SES team analyzed the current market, examined especially successful or novel concepts, and developed new methods for addressing the current market challenges. By minimizing inconvenience, streamlining the process, and increasing availability, our process innovations could dramatically improve the delivery of hearing devices. The combination of our superior products with efficient processes for diagnosis and fitting has the potential to greatly expand access to hearing devices at a reasonable cost.

1.5.1 Mobile Outreach Program and Community Clinic Program

The first distribution model is a two-part strategy based on mobile audiologists visiting patients in locations such as senior centers and community health clinics. These audiologists will work on a part-time basis, cycling between different locations. The first part of this strategy would involve a mobile team that would visit patients at senior centers, residential centers, and other convenient locations. This team would be equipped with an Otogram, a new technology that significantly streamlines the process of testing an individual’s hearing and producing an audiogram. The focus of the mobile team would be to do diagnostic testing of patients, followed by a short counseling session to discuss the patient’s treatment options. After receiving a treatment recommendation from the staff of the mobile unit, the patient would proceed to the second part of this strategy. This part would involve audiologists with visiting practices at existing community health clinics. At the clinic, the audiologist would complete the process the mobile team began and distribute products to the consumers. In both of these programs, we hope to be able to keep overhead costs to a minimum by using existing resources at the locations for appointment scheduling, billing, and patient logistics. Using existing facilities and resources, this distribution model would be a cost-effective organization dedicated to bringing hearing to people in need. Although both of these strategies, the mobile outreach program and the community clinics program, could function independently, they are more efficient and will be more effective in combination.
1.5.2 Buying Groups

A second distribution option is to utilize the buying groups that currently exist between private practice audiologists, dispensers, ENTs, and hearing aid manufacturers. Using this existing structure offers several advantages. First, private audiology practices are widely distributed. Having the same providers who take care of more affluent patients dispense hearing aids to low-income patients will lessen any perception of receiving a second-class product and fitting procedure. Second, the infrastructure in this channel is already established, simplifying the process of establishing and distributing to dispensers around the world. Finally, the sheer volume of devices that might be purchased by this channel coupled with a multi-tiered pricing model presents a potential revenue source that would make this venture self-sustaining and less dependent on philanthropy in the long-term. This option is a viable possibility, as executive management at several buying groups have indicated that they are receiving numerous requests from their members for a high-quality, low-cost devices for low-income patients. Our products could fill this need, with the key task being to find a win-win situation where buying groups would have incentive to carry this product and their members would have incentive serve low-income patients in addition to their current patient base. Overall, this distribution option offers the possibility of distributing low-cost products across the nation and the world, bringing these devices to the large percentage of people suffering from untreated hearing loss.

1.6 Future Plans

Using these innovations, we will begin by distributing hearing devices to those in need in the San Francisco Bay Area, eventually expanding the scope to include areas throughout the United States and the world. While adaptations will be necessary, depending on the location, the fundamental innovations developed through this project will serve as the foundation for providing affordable hearing solutions worldwide.
2 The Industry

2.1 Current Industry Structure

Currently, there are dozens of hearing aid manufacturers offering a breadth of products but it is estimated that six major manufacturers account for 85% of worldwide sales. These incumbents are known as the "Big 6", and their established positions in the market present a formidable obstacle to potential new entrants. The six major manufacturers are: Siemens, GN Resound, Starkey, William Demant (Oticon), Phonak, and Widex.

Traditionally, strong ties have existed between manufacturers and hearing professionals. Manufacturers provide hearing professionals with value-added services to assist them in operating their practices, including loans as well as financial incentives in the form of rebates and discounts to encourage specific device recommendations to patients.

2.2 Current Industry Practices

Many audiologists appreciate and value their current buying relationships with established manufacturers over smaller new manufacturers. These relationships are fostered by reciprocity between audiologist and manufacturer, the convenience of consistency in such a relationship, and the trusted reputation of an established manufacturer as a maker of quality aids. These relationships are usually not established by a term-based contract but are instead sustained by the audiologist's preference towards a certain manufacturer's aids and the manufacturer's reciprocity by giving fitting equipment and marketing support for free or discounted prices back to the audiologist. Such existing relationships may discourage the audiologists from forming new relationships with other manufacturers.

Another barrier for audiologists in forming new buying relationships is that each manufacturer has its own software to program its hearing aids, so using another manufacturer's aids means having to learning a new software package and then keeping abreast of its updates and changes.

Lastly, and perhaps most importantly, a new manufacturer does not have the established reputation and track record that older and larger manufacturers enjoy, especially in areas such as product reliability and audiologist service and support.

Hearing aids are dispensed by audiologists, who have advanced degrees, or hearing aid dispensers, who have a minimum of a high school diploma. Federal law requires that adult patients receiving a hearing aid either first see an MD, to rule out a possible medical problem, or to sign a waiver.

Current high costs of hearing aids hinder low-income patients from obtaining them, especially since Medicare and most other insurance plans do not cover these devices. Medicaid offers very limited coverage.

2.3 Regulations

The Federal Code of Regulations includes the FDA regulations that are relevant to the hearing aid industry. These regulations are broad and general. In order to ensure compliance with all legal provisions, a manufacturer must examine the statutes specific to the state(s) in which distribution occurs.
The FDA defines a hearing aid as a “wearable sound-amplifying device that is intended to compensate for impaired hearing.” This includes the “aid-conduction hearing aid (Class I) and the bone-conduction hearing aid (Class II), but excludes the group hearing aid or group auditory trainer.”

Good health practice requires that a patient undergo a medical evaluation by a licensed physician before purchasing a hearing aid. This physician need not specialize in diseases of the ear. Any fully informed adult over the age of 18 can sign a waiver statement declining medical evaluation. After the patient receives a medical evaluation or signs the waiver, an audiologist or dispenser can perform a hearing aid evaluation as a basis for selecting and fitting a hearing aid to the patient’s individual needs.

The Code provides further details relating to the waiver process and labeling requirements. It does not, however, provide an explicit distinction between hearing aids and assistive listening devices (ALDs). According to the Enforcement Division within the FDA Office of Compliance, the FDA examines every aspect of a product, from its instruction manual to its design, to determine whether it conforms to existing regulatory standards. The distinction between hearing aids and ALDs is therefore quite vague.

The Federal Code also fails to specify what steps of the purchasing procedure must be conducted by an audiologist or dispenser. Individual state codes must be consulted for further clarification. For instance, the California State Code allows for the existence of “audiology aides,” who are allowed to “assist or facilitate while an audiologist is evaluating the hearing of individuals and/or is treating individuals with hearing disorders.”

Below is a list of related FDA regulations:

21CFR 801.420 – Hearing aid devices; professional and patient labeling
21CFR 801.421 – Hearing aid devices; conditions for sale
21CFR 874.9 – Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act
21CFR 874.3300 – Hearing Aid
3 The Customer

3.1 Market Size and Trends

The project has focused thus far on the population of the San Francisco Bay Area. The Bay Area consists of nine counties touching the San Francisco Bay, whose total population in the 2000 U.S. Census was 6,783,760. From national statistics on hearing loss, we estimate that the Bay Area has over 650,000 people with hearing loss and over 500,000 people with untreated hearing loss. The Bay Area has a diverse population with a broad spectrum of ages, races, and incomes to pilot the project. The medium household income of the region is $62,000, but 573,000 or 8.6% of the population is under the poverty line.

3.2 Customer Segments

3.2.1 Types of Hearing Loss

Hard of hearing people suffer from many different types of hearing loss. The common sensorineural hearing loss treatable with hearing devices is characterized by:

- Decreased audibility – softer phonemes, usually consonants, are unable to be heard.
- Decreased dynamic range – the distance between the threshold of audibility and the level of discomfort and is less than with normal hearing.
- Decreased frequency resolution – loss of ability to hear high frequency sounds.
- Decreased temporal resolution – intense sounds mask weaker sounds that precede or follow them.

High frequency loss affects many baby boomers. However, most people with hearing loss suffer from a loss of volume. They require amplification of sound in order to understand conversations. The degree of loss classified as: mild, moderate, severe, or profound.

3.2.2 National Statistics of Target Population

The goal of this project is to reach those with hearing loss who are not currently owners of hearing devices, especially low-income patients. Market research data show that there are a greater number of women that admit to their hearing loss than men. Most non-owners fall in the growing baby boomer age of 45-54. They mainly have a high school education or less and work full-time. This is contrary to the popular assumptions of those needing hearing aid as being relatively affluent seniors. There are more baby boomer and lower-income non-owners than affluent senior non-owners.

3.3 Customer Barriers

Potential hearing aid users face a multitude of individual barriers that hinder them from acquiring a well-fitted hearing aid. These barriers can be divided into four major categories: logistical, informational, psychological, and financial.

3.3.1 Logistical Barriers

Logistical barriers in the diagnostic and fitting process pose roadblocks to acquiring a hearing device. First, the diagnostic and fitting process is time consuming, typically requiring three or more visits to medical professionals. For low-income individuals who depend on public
transportation, the time required can be even more taxing. For immigrants or others who have a
weak command of English, the process can be particularly confusing.

### 3.3.2 Informational Barriers

Informational barriers include a lack of self-awareness about one’s hearing problems, as well as a
lack of knowledge about available solutions. Hard-of-hearing individuals have adapted to their
hearing loss over time and may not even recognize that they have a problem. Often, consumers
only purchase a hearing aid after repeated urging of a family member or friend, who helps them
to understand that their hearing loss is an impediment to their communications with those around
them.

Furthermore, once an individual recognizes that they have a problem, they often do not know
what to do next to enter into the process of acquiring a hearing aid. Having lived in the hearing
world their entire lives, they have never been required to seek assistance for this problem.
Incorrect perceptions about available technologies are present even among those with friends or
family members who use or have used a hearing aid. For example, individuals who were told in
the past that nothing could be done about their form of hearing loss may be unaware of newer
devices and treatments.

### 3.3.3 Psychological Barriers

Psychological barriers also prevent some from getting a hearing aid. Many people associate
hearing loss with age, and avoid seeking treatment for a hearing problem because they do not
want to admit they are old. In fact, over 60% of the population with hearing loss is under the age
of 54, and 28-32 million Americans, around 10% of the population, suffer from hearing loss.
Others are concerned about the visibility of their problem – they do not want to wear a hearing
aid, because they do not want other people to know that they have a disability. When talking to
people who have come to terms with their hearing loss, however, the opposite is true – these
individuals place great importance on the visibility of their device because it is an implicit cue for
others to face them and to speak clearly when having a conversation. As one woman we spoke
with explained, “I'd rather have them know I'm deaf than think that I am rude or stupid because I
didn’t respond to them!”

### 3.3.4 Financial Barriers

The cost of obtaining hearing aids poses a significant financial barrier. Ranging from $750-$3000
per ear, hearing aids are expensive, especially for low-income patients.

Unfortunately, it is difficult to find coverage for hearing aids and devices, due to the many specific
rules surrounding coverage. For example, Medicare will only pay for an audiological examination
if a doctor needs the test results for a medical diagnosis. The doctor must examine the patient
before an audiology referral is made, and testing done by an audiologist must have been ordered
by a physician in order to be reimbursable.

Medicaid follows similar regulations that require an initial referral by a physician. In this case,
Medicaid pays a limited amount for services to individuals with speech, hearing, and language
disorders, including diagnostic, screening, preventive, or corrective services under the direction of
or provided by licensed audiologists and speech pathologists. Coverage also includes payment
for necessary supplies and equipment. Medicaid recently started the Early and Periodic
Screening, Diagnostic, and Treatment (EPSDT) service. This is a preventive child health program
for those under the age of 21 that covers durable medical equipment such as hearing aids, as
well as services that take place in community-based services. Due to many stiff rules surrounding
Medicare and Medicaid coverage, it may be easier to reach large numbers of patients with low, affordable prices that may or may not be covered by Medicare and Medicaid.

Medi-Cal has also recently made budget cuts that raised the threshold of qualification, decreasing the number of people who can qualify for aid. Even for patients covered by Medicaid and Medi-Cal, audiologists are often unwilling to treat them, because they find the monetary compensation not enough to recover their own operating costs. Medi-Cal provides a low $150 reimbursement to audiologists for their services, making this more “community service” than a viable business option. As a result, there are an insufficient number of audiologists willing to these patients.

Finally, hearing aids are one the few medical devices that are typically not covered by insurers, due to their high costs. However, hearing health benefits are a current topic of investigation in the industry.
4 The Products

4.1 Current Competitor Products

4.1.1 Analog and Digital Hearing Aids

Analog hearing aids use analog circuitry to convert signals from the microphone of the aid into signals for the earphone of the aid. Better analog aids use automatic gain control to amplify quiet sounds as well as suppress loud sounds. Analog aids are typically the least expensive aids on the market.

Digital hearing aids convert signals from the microphone into bits of data for processing by a digital signal processor to produce signals for the earphone of the aid. These aids have substantially more adjustability and more expensive than analog models.

4.1.2 Styles of Hearing Aids

Hearing aids differ not only in their circuitry but also their styles or form factors, which have different properties in terms of durability, comfort, size, and the range of hearing loss that they can treat.

Behind-the-ear (BTE) aids are comprised of two parts: the earmold, which sits inside the ear, and the aid, which rests behind the ear. A plastic tube connects the two. The BTE is the most common model of hearing aid. Since the electronics rest behind the ear, problems due to ear wax and moisture are reduced, making these aids more durable. Their larger bodies allow for easier battery changing and manipulation of the controls by users with limited manual dexterity. BTE aids are suitable for mild to most forms of severe hearing loss.

The in-the-ear (ITE), in-the-canal (ITC), and completely-in-the-canal (CIC) aids have all working parts within the earmold, which is a shell that allows the entire aid to fit inside the ear. These types require more frequent repair. They are often not suitable for severe hearing loss and are intended for mild to moderate hearing loss. The small size of these aids can require more manual dexterity. Ear wax and moisture can also pose problems, because the whole aid is inside the ear.

Body-worn hearing aids operate through a unit that the user can clip to clothes or carry in a pocket. These are not to be confused with Assisted Listening Devices, because body worn aids are still considered FDA-regulated hearing aids. The speaker and mold connect to the aid itself by a cord. A very durable aid, the body-worn style can work with all types of hearing loss. It is often used in cases of extreme loss, when the power requirements exceed the capability of a regular aid. It also offers a clear signal with low distortion for strong word recognition.
Bone conduction hearing aids transmit sound through the skull by way of vibrations. They are usually worn on a headband or eyeglasses.

4.2 Potential Hearing Devices for Affordable Program

4.2.1 Project Impact—Impact 1

Impact I is a BTE, digitally programmable analog, two-channel, two-memory hearing aid for mild to moderate hearing loss. It uses a custom earmold. The current programming software has been reported by testers to be non-intuitive and hard to use. It has a long battery life (up to 800 hours) and can be used with non-rechargeable or rechargeable batteries using a solar battery charger. A directional microphone is available as an option. A possible wholesale price is $100 with a one-year warranty in which the defective or damaged hearing aid would be replaced immediately with no wait for repairs.

4.2.2 Microsound—Pilot

The Pilot, a hearing aid made by the Danish company Microsound, is a less-custom hearing aid with a consumer electronic aesthetic: it comes in six different colors and resembles wireless earbuds. It has rechargeable batteries, and with a bedside recharging cradle in which the aids can be placed in at night, it has a usage pattern that resembles that of a cell phone. It also avoids the more “medical” procedure of taking an earmold and having a custom fabrication by using standard, non-custom silicone ear tips which fit into most ears. These ear tips are easily cleaned, but need to be replaced every month (a pair of replacement tips cost about a dollar). For users who prefer or require a custom earmold, the Pilot can take custom molds. It is programmed using relatively easy-to-use software. It can accommodate one or two programmable presets.

4.2.3 Assistive Listening Devices (ALDs)

Current ALDs for hearing loss are generally bulkier than and technologically inferior to hearing aids. They have not been marketed nearly as extensively as hearing aids have been, despite being less expensive and more convenient to purchase than hearing aids, and despite their suitability to treat a wide range of hearing impairments. The SES project is exploring the development of a new ALD with circuitry comparable to that of the best hearing aids, but without sacrificing price or convenience. Through our user research, we have gained an understanding of consumer preferences relating to product characteristics and features.
5 Distribution Strategy: Integrated Mobile Outreach Program and Community Clinic Program

5.1 Overview

This distribution model is a two-part strategy based on mobile audiologists visiting patients in locations such as senior centers and community health clinics. These audiologists will work on a part-time basis, cycling between different locations.

The first part of this strategy consists of a mobile team staffed by one audiologist and one aide that would visit patients at senior centers, residential centers, and other convenient locations. This team would have newly developed equipment for automated audiometry such as the Otogram. The focus of the mobile team would be to do diagnostic testing of patients, followed by a short counseling session to explain the test results and to discuss the patient's options. Patients with possible medical problems would be referred to a physician. Low-income patients without medical problems who are candidates for and who wish to receive a hearing device would have two possible solutions: 1) a hearing aid, in which case the patient would be referred to a participating community health clinic; 2) an assistive listening device (ALD), which could be fitted and sold on the spot.

The second part of this strategy consists of audiologists establishing visiting practices at existing community health clinics that serve low-income neighborhoods. Audiologists would visit the clinics with a frequency depending upon demand, ranging from perhaps one day per month to one day per week. The audiologist would see patients referred by the mobile team as well referrals from the clinic itself. The audiologist would be fully equipped with an Otogram and the necessary equipment to fit and program hearing aids. Existing staff and other resources at the clinic would be used to assist the audiologist throughout the day.

In both of these programs, we hope to be able to keep overhead costs to a minimum by using existing resources at the locations for appointment scheduling, billing, and patient logistics. The locations could charge patients an additional fee to cover their costs in these areas. Equipment costs could also be partly subsidized by the network of clinics and health centers or by grant money and transported from location to location by the audiologist.

Both of these strategies could work independently, as will be discussed in the next section. However, they are more efficient and will be more effective in combination. A scale-up strategy would involve starting with fewer days of operation at community clinics and then increasing the number of days as the mobile team reaches more patients and demand for the clinics' services grows. This plan would also start in only one part of the Bay Area before expanding to others.

To summarize, the mobile audiologists will provide affordable hearing devices and services for the following reasons:

- The Otogram allows for fast and accurate automated hearing tests without expensive soundproof booths, requiring only a quiet room.
- Overhead costs will be kept to a minimum by using existing resources at the locations.
- This model allows a simple way to scale-up according to demand. The programs are financially self-sustaining, and the number of locations and the frequency of visits can be easily adjusted to meet demand.

5.2 Participant Experiences
5.2.1 Mobile Outreach Program

- Mobile team visits senior centers, nursing homes, and other convenient locations.
- Information sessions precede the mobile team visit.
- For those interested in getting a hearing test, appointments are scheduled after the information session by the staff at the location.
- When the mobile team arrives and sets up the equipment at the community center, the community center staff already has the patients scheduled throughout the day and helps direct patients into the right rooms as they arrive.
- Patients will first go through a screening process involving a simple pure-tone test. This streamlines the process by eliminating those patients who do not have hearing loss.
- Next the patient is directed to a quiet room where and aide sets them up to be tested by the Otogram, and automated audiometer that uses a touch screen.
- The test takes about 20-25 minutes and does not require anyone except for the patient to be present.
- If the patient has any questions or they have completed the test, they can call in an aide by using a pager that was given to them. The aide is trained in answering questions about the Otogram and brings the patients to the audiologist when they are done.
- Counseling with an audiologist to explain the test results and to discuss the patient’s options. Possible outcomes include:
  - The patient is referred to a physician to be examined for possible medical problems.
  - The patient looks at demos of assistive listening devices (ALDs) and hearing aids provided by the mobile team.
  - The patient buys an ALD after simple and quick programming.
  - The patient receives a referral to a participating community health clinic that fits low-income patients with hearing aids.
- The screening and diagnostic fee of $21 is paid directly to the community center, and a lump sum is paid to the audiologist and aide for their day of work.

5.2.2 Community Clinic Program

- Patients schedule an appointment with the community clinic’s administrative staff for a day when the audiologist is visiting.
- If the patient has not gone through the diagnostic process, the appropriate testing will be done with an Otogram on the day of the appointment.
- When the referred patient arrives, the audiologist helps them make the choice between a Project Impact hearing aid and the Microsound hearing aid.
- If the patient chooses the Project Impact hearing aid, an instant earmold is taken by an audiologist so that the patient only needs one visit to get the hearing aid.
- The patient then goes through programming, fitting, and counseling with the audiologist in their first visit to the community clinic.
- The visiting audiologist brings their own programming equipment.
- The audiologist counsels the patient to manage their expectations as well as to teach them how to properly use the hearing aid.
- Cost for hearing aid and service will be bundled to ensure that the patient receives appropriate follow-up, but the patient will be told exactly what fraction of the cost goes to the hearing aid and what is the service fee. Any additional follow-up visits will incur an additional charge.

5.3 Economics of Business

5.3.1 Mobile Outreach Program
### Assumptions

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<td>A24</td>
<td>% of patients who do nothing</td>
<td>15%</td>
</tr>
<tr>
<td>Derived</td>
<td>Number of ALDs sold per day</td>
<td>0.40</td>
</tr>
<tr>
<td>A25</td>
<td>Wholesale cost for each ALD</td>
<td>$25.00</td>
</tr>
<tr>
<td>A26</td>
<td>Retail cost for each ALD</td>
<td>$50.00</td>
</tr>
</tbody>
</table>

### Unit of Analysis = Equipment Costs

<table>
<thead>
<tr>
<th>Equipment Item</th>
<th>Cost</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A22</td>
<td>Cost of screening equipment</td>
<td>$26,500</td>
</tr>
<tr>
<td>A23</td>
<td>Otogram (1)</td>
<td>$1,200</td>
</tr>
<tr>
<td>A24</td>
<td>Computer and printer</td>
<td></td>
</tr>
<tr>
<td>Derived</td>
<td>Total screening equipment costs</td>
<td>$27,700</td>
</tr>
</tbody>
</table>
5.3.1.1 Fixed and Variable Costs

- Fixed Costs: Equipment (Otogram, computer, printer)
- Variable Costs: Audiologist and aide (paid daily), fuel, mileage, ALDs, and insurance
- Costs assumed covered by others: Admin for billing

5.3.1.2 Revenues

The revenue sources for this model come from fees collected in the mobile team: a screening fee of $21 charged to each patient and the sale of ALDs to an estimated 5% of clients. The $21 fee is the wage-based cost of diagnosis and counseling provided by the audiologist and aide. Other potential sources of revenue not included in the calculations could come from Medicare and Medi-Cal reimbursement for the audiogram ($47), tympanometry ($19) and ear wash ($44). However, in order to bill these costs, Medicare and Medical both require a physician's referral.

5.3.1.3 Requirements for Breakeven

Under the assumption that 5% of patients purchase ALDs and no reimbursement is received from Medicare or Medi-Cal, break even for the Mobile Team would result if each patient paid a $21 fee for diagnostic (audiogram) and counseling services received.

5.3.2 Community Clinic Program
### Assumptions

| A1 | Number of audiologists | 1 |
| A2 | Audiologist diagnostic time per patient (hours) | 0.00 |
| A3 | Audiologist post-diagnostic counselling time per patient (hours) | 0.25 |
| A4 | Audiologist fitting time per patient (hours) | 0.25 |
| A5 | Audiologist post-fitting counselling time per patient (hours) | 0.50 |
| A6 | Audiologist follow-up visit time per patient (hours) | 0.50 |
| A7 | Operating hours per day | 8.00 |
| A8 | Total available audiologist hours | 8.00 |
| A9 | Number of patients on initial visit - diagnostic and counselling only | 3.00 |
| A10 | Number of patients on initial visit - diagnostic, counselling, and fitting | 3.00 |
| A11 | Number of patients doing follow-up visit | 4.00 |

| A12 | Percent of fitting patients who purchase hearing aid | 75% |
| A13 | Annual audiologist salary (including benefits) | $80,000 |
| A14 | Number of working days in a year | 250 |
| A15 | Hearing aid cost (wholesale) per patient (1 hearing aid) | $50.00 |
| A16 | Administrative overhead charged by clinic per patient | $10.00 |

| A17 | Total cost per patient on initial visit - diagnostic and counselling only* | $20.00 |
| A18 | Total cost per patient on initial visit - diagnostic, counselling, and fitting* | $50.00 |
| A19 | Total cost per patient on initial visit - fitting and counselling only (no diagnostic)* | $40.00 |
| A20 | Total cost per patient doing follow-up visit | $30.00 |

Note: Community clinic staff would do patient scheduling, set-up, and billing, as well as preparing and administering the Otogram diagnostic. The clinic would charge an admin fee to patients for these services, as well as recoup Medical reimbursements for the Otogram as applicable.

* Excludes cost of hearing aid
<table>
<thead>
<tr>
<th>Financials</th>
<th>Daily</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td></td>
</tr>
<tr>
<td>Hearing aid purchases</td>
<td>$200.00</td>
</tr>
<tr>
<td>Audiologist fees</td>
<td>$320.00</td>
</tr>
<tr>
<td>Clinic administration fees</td>
<td>$130.00</td>
</tr>
<tr>
<td><strong>Total Revenue</strong></td>
<td>$650.00</td>
</tr>
<tr>
<td><strong>Expenses</strong></td>
<td></td>
</tr>
<tr>
<td>Hearing aid cost of goods sold</td>
<td>$200.00</td>
</tr>
<tr>
<td>Audiologist salary</td>
<td>$320.00</td>
</tr>
<tr>
<td>Administrative overhead</td>
<td>$130.00</td>
</tr>
<tr>
<td><strong>Total Expenses</strong></td>
<td>$650.00</td>
</tr>
</tbody>
</table>

5.3.2.1 Fixed and Variable Costs

- Fixed Costs: Fitting equipment (computer, etc.)
- Variable Costs: Audiologist (paid daily)
- Costs assumed covered by others: Otograms (by clinics or grant); clinic staff for scheduling, patient logistics, and billing

5.3.2.2 Revenues

Community clinics would charge patients a visit fee (for the audiologist’s time), the cost of the hearing aid (if purchased), and a small fee to cover the clinic’s costs.

5.3.2.3 Requirements for Breakeven

The community clinic program has low fixed costs and is staffed to meet demand at a break-even level.

5.4 Marketing Plan

The mobile solution is designed to serve underserved, low-income populations with hearing tests, information, services, and affordable hearing devices. By coming to patients, the mobile team lowers the barriers to hearing testing, diagnosis, counseling, and treatment. If necessary, the mobile team may also provide screening and diagnostic services to higher-income retirement homes and to corporations for their employees.

5.4.1 Pricing

- For clients who have received a referral from their physician and are eligible for Medicare or Medi-Cal, the cost of the audiogram will be billed to the appropriate program.
- Clients not covered by Medicare or Medi-Cal or who have not gotten a physician referral will be charged a diagnostic fee of $21 that includes the audiometric test (Otogram) and diagnostic evaluation.
- The cost of the hearing aid will start at $50, and the audiology service fees will be added depending upon the amount of time the audiologist spends with the patient.
- Follow-ups are paid for separately and are not included in the service fees.
5.4.2 Promotion

- Marketing of the two programs depends heavily on promotion provided by the organizations that the mobile team visits. The community partners can provide information about the visits through signage, pamphlets, their newsletters, and other existing means of communicating with their members.
- Each screening and diagnostic visit will be preceded by an information session at the location to explain the program and to sign up and schedule patients.
- The community partners’ existing multilingual staff will be available for outreach.
- Information pamphlets and handouts will be available in the appropriate languages for the diverse communities served.
- Media advertisement for the programs will take place through community newspapers and public service announcements on both radio and local television outlets. These ads will describe the programs and provide locations and dates for upcoming visits. All ads will also provide a phone number for further information.
- The local Lions Club can also help promote the programs.

5.4.3 Positioning

- The program will sell three types of hearing devices: a high-quality, low-cost, custom, behind-the-ear hearing aid; a more stylish, one-size-fits-most, in-the-ear hearing aid; and a high-quality, low-cost assistive listening device.

5.5 Operations Plan

5.5.1 Entry and growth strategy

Entrance into the market would begin first through partnering with community health clinics. Our services would be provided to community clinics in one county, most likely in the South Bay, starting at one clinic once a month with one audiologist. After a couple of months as the program becomes known in the community, it would increase the frequency of visits to match demand. At the next level, the model would be implemented in San Francisco as well as the East Bay. Initially, all diagnostic and fitting work would be done at the center.

As relationships with referring physicians and visiting audiologists solidify, we would introduce the mobile outreach program on a county-by-county basis. We list below the organizations, which we have identified as potential partners for the mobile outreach program and the community clinic program.

In the South Bay, we have identified Community Health Partnership, the Gardner Family Health Network, the Indian Health Center, San Mateo County Department of Health Services, Santa Clara County Municipal Health Services, Coastside Opportunity Center, and Daly City Community Service Center as potential partners.

Within San Francisco, we have made strong contacts with the San Francisco Community Clinic Consortium, the Hearing Society for the Bay Area, San Francisco State University, and the San Francisco Hearing and Speech Center.

In Alameda County (East Bay) the Community Health Care Network, a network of seven community health centers within the county, as well as the county’s Department of Adult and Aging Services would be ideal initial partners.

The mobile outreach program would begin operations in the same county where we begin our clinic partnerships. Over time, as the process is fine-tuned and our relationships and reputation
have grown, we would expand our outreach to other counties within the Bay Area in order to reach a larger portion of low-income and hard-to-reach clients.

5.5.2 Facility and Equipment Needs

The mobile outreach program and the community clinic program would require a portable automated audiometry machine, such as the Otogram, and a backup. It would also require a computer printer to provide results and recommendations. The audiologists visiting the community clinics would each bring a laptop with fitting software and equipment as well as the hearing aids and instant molds. The programs would use existing space, infrastructure, and administrative staff of the partnering organizations.

5.5.3 Staff Needs

The mobile outreach program requires one audiologist assisted by one aide, both working part time. The aide will help administer the Otogram, while the audiologist will do an initial ear screen, provide post-diagnostic counseling, and remove earwax as needed.

The staff visiting clinics and health centers would include one audiologist, working part time. The community clinic would provide their administrative staff and a volunteer or current staff member to assist with the Otogram.

5.5.4 Regulatory and Legal Issues

Medicare and Medi-Cal can only provide reimbursement for the diagnostic testing (audiogram) with a physician’s referral. The community clinic must follow ASHA and Hearing Aid Board requirements for their staffing model. Audiology aides must be registered with the Hearing Aid Board. Supervision of audiology aides requires one audiologist for every three aides. Licensing laws require full-time “in the line of sight” supervision of aides. The community health clinics must also have liability and malpractice insurance.

5.6 Key Assumptions, Critical Risks, and Potential Problems

Many assumptions still remain for this promising model. The most crucial of these assumptions deal with the proposed partnerships with Bay Area clinics and health centers. This scenario assumes that clinics have space available for the audiologist, the administrative resources to coordinate appointments, and the financial resources for the necessary equipment. However, we have received substantial promising feedback in this area, with clinics and consortiums indicating their willingness to participate.

Furthermore, for the community health clinic program, it is unclear as to whether there are sufficient audiologists willing to work part-time or volunteer their services. Again, feedback has been positive, but a mutually beneficial arrangement will be important to attracting participating audiologists.

Finally, a key component of this model is its self-sustaining aspect. Therefore, some of the financial figures in the economic models are conservative assumptions and are listed as such. For example, the percentage of people that would purchase an assisted listening device could vary by location.

5.7 Future Development
While still in the early stages, the proposed programs have been very well received by the audiology community and potential community partners. The team has performed substantial research, and a valuable next step would be a small-scale pilot to test the model. A pilot would reveal faulty assumptions and allow them to be rectified.
6 Distribution Strategy: Differences for Stand-Alone Components

6.1 Mobile Outreach Program

As a stand-alone operation, the mobile outreach program would follow a strategy similar to the proposed integrated solution. The mobile team would counsel the patients about their hearing loss, the options available to them including the suitability of assistive listening devices or hearing aids, and make referrals to local community health clinics and audiologists. Patients would be given the Otogram results to take to a clinic or an audiologist of the patient’s choice for follow-up.

6.2 Community Clinic Program

The community clinic program will be a full-service solution: it will provide screening, diagnosis, and treatment. Without pre-screening and diagnosis, patients will have to spend more time at the clinic for these services. Audiologist time per patient will not increase, since testing by the Otogram is automated, so the cost for obtaining a hearing aid will not increase. A stand-alone clinic program would require more marketing, since it would not have the benefit of referrals from the mobile outreach program.
7 Distribution Strategy: Volume-Purchasing Groups

7.1 Overview

Private practice audiologists, dispensers, and ENTs organize themselves into buying groups, primarily to negotiate volume discounts with manufacturers. In addition, some buying groups offer practice management support to its members. Prominent large groups include:

- EPIC – approximately 375 physicians and over 600 audiologists
- HearPO – approximately 1,400 audiology practices
- HearUSA – over 1,500 independent and company-owned audiology centers

Smaller volume-purchasing groups also exist, but these groups mainly advertise directly to consumers through the Internet and contract with private practice hearing professionals to fit the products that patients buy directly through the Web sites. These include:

- HearingPlanet.com
- Ahearingaid.com

There are several reasons to consider volume-purchasing groups as a distribution channel to reach the low-income, hearing-impaired population. First, private audiology practices are widely distributed. Second, the infrastructure in this channel is already established, simplifying the process of establishing and distributing to dispensers around the world. Finally, the sheer volume of devices that might be purchased by this channel coupled with a multi-tiered pricing model presents a potential revenue source that would make this venture self-sustaining and less dependent on philanthropy in the long-term.

The main question, however, is whether buying groups and their members would actually want to distribute a product for low-income patients. Executive management at several buying groups indicated that they are receiving numerous requests from their members for a high-quality, low-cost product for low-income patients. Several manufacturers have shown interest in exploring offering a product for this niche as well. Given this, the key is to find a win-win situation where buying groups would have incentive to carry this product and their members would have incentive to fit some low-income patients in addition to their current patient base. Even if an individual audiologist saw 1-2 incremental patients per week for such a product, and even if just a fraction of the total membership of the buying group participated, the volume of hearing aids that would be distributed through this channel is considerable.

7.2 Participant Experiences

Although the process of purchasing a hearing device through the traditional audiologist and buying group networks will depend on the type of product desired, the basic steps for such a process are as follows. These steps present an overview of the process, ignoring factors such as customer emotions and logistical difficulties that may influence it.

- Product advertised through buying group (on Web site or through network)
  - Solution for low-income patients
- Low-income patient hears of product/receives referral from MD or other individual/group
- Patient applies to Lions for certification of low-income status
  - Used to receive discounted price if audiologist deems hearing device necessary
- Patient seeks out audiologist carrying product
- Audiologist tests hearing and performs an audiogram
- Audiologist recommends particular low-cost product based on patient’s voiced preference, or knowledge of the patient’s economic situation
If audiologist carries supply of product, the patient may receive it on the first visit (most applicable to Microsound product and assistive listening devices, but also possible for the Lions product with instant mold)

- If necessary (for Lions product), audiologist takes impression of patient's ear and obtains product through buying group
  - If not in stock, audiologist orders Lions aid through buying group
  - If not instant mold, audiologist sends out mold

- Audiologist programs product
- Patient tries product and receives instruction on use and maintenance
- Patient begins use of aid
- Patient returns to audiologist when experiencing problems
  - Maximum of two follow-up visits covered by initial cost

### 7.3 Economics of Business

#### 7.3.1 Microsound Pilot Distribution

<table>
<thead>
<tr>
<th>Financials</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
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<td>Total Revenue</td>
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<tr>
<td>Cost</td>
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<tr>
<td>Total Costs</td>
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<td>Net Income</td>
<td>$11,500</td>
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<table>
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<tr>
<td>Total Revenue</td>
<td>$7,500,000</td>
</tr>
<tr>
<td>Cost</td>
<td></td>
</tr>
<tr>
<td>Total Costs</td>
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<tr>
<td>Net Income</td>
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<table>
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<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>$6,750,000</td>
</tr>
<tr>
<td>Total Revenue</td>
<td>$6,750,000</td>
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<tr>
<td>Cost</td>
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<td>Total Costs</td>
<td>$5,725,000</td>
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<tr>
<td>Net Income</td>
<td>$1,025,000</td>
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</table>
Audiologists or other hearing professional:
- Fixed costs – none incremental
- Variable costs – additional professional time to fit incremental patients
- Revenues – $90 fee for 45-minute fitting, $25 markup on buying group price for a total retail price of $225

Buying group:
- Fixed costs – incremental advertising costs of $100,000
- Revenues – $20 markup per aid on $180 wholesale price from Lions
- Membership – assume 1,500 members in group and 25% willing to carry product

Lions:
- Fixed costs – incremental advertising costs of $100,000
- Variable costs – $150 manufacturer’s price per aid
- Revenues – $30 markup per aid on $150 manufacturer’s price to Lions

### 7.3.2 Lions Product Distribution

<table>
<thead>
<tr>
<th>Unit of Analysis = Audiologist/HA Dispenser</th>
<th>Financials</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of new patients for Lions product per year</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Fee for fitting process (3 total 45-minute visits)</td>
<td>$300.00</td>
<td>Total Revenue</td>
</tr>
<tr>
<td>Total equipment costs</td>
<td>-</td>
<td>Cost</td>
</tr>
<tr>
<td>Lions product retail cost</td>
<td>$150.00</td>
<td>Cost of goods sold</td>
</tr>
<tr>
<td>Lions product buying group discounted price</td>
<td>$120.00</td>
<td>Total Costs</td>
</tr>
<tr>
<td>Markup</td>
<td>$30.00</td>
<td>Markup margin</td>
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<tr>
<td>Net Income</td>
<td>$33,000</td>
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<table>
<thead>
<tr>
<th>Unit of Analysis = Buying Group</th>
<th>Financials</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lions product wholesale price</td>
<td>$100.00</td>
<td>Revenue</td>
</tr>
<tr>
<td>Lions product buying group discounted price</td>
<td>$120.00</td>
<td>Lions product purchases</td>
</tr>
<tr>
<td>Markup</td>
<td>$20.00</td>
<td>Total Revenue</td>
</tr>
<tr>
<td>Markup margin</td>
<td>20%</td>
<td>Total Costs</td>
</tr>
<tr>
<td>Net Income</td>
<td>$650,000</td>
<td></td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Unit of Analysis = Lions</th>
<th>Financials</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lions product manufacturing cost including shipping</td>
<td>$50.00</td>
<td>Revenue</td>
</tr>
<tr>
<td>Lions product wholesale price</td>
<td>$100.00</td>
<td>Lions product purchases</td>
</tr>
<tr>
<td>Markup</td>
<td>$50.00</td>
<td>Total Revenue</td>
</tr>
<tr>
<td>Markup margin</td>
<td>100%</td>
<td>Total Costs</td>
</tr>
<tr>
<td>Net Income</td>
<td>$1,775,000</td>
<td></td>
</tr>
</tbody>
</table>
Audiologists or other hearing professional:
- Fixed costs – none incremental
- Variable costs – additional professional time to fit incremental patients
- Revenues – $300 fee for three 45-minute visits in fitting process, $30 markup on buying group price for a total retail price of $150

Buying group:
- Fixed costs – incremental advertising costs of $100,000
- Revenues – $20 markup per aid on $100 wholesale price from Lions
- Membership – assume 1,500 members in group and 25% willing to carry product

Lions:
- Fixed costs – incremental advertising costs of $100,000
- Variable costs – $50 manufacturing cost per aid
- Revenues – $50 markup per aid on $50 manufacturing cost

### 7.3.3 Assistive Listening Device (ALD) Distribution

<table>
<thead>
<tr>
<th>Unit of Analysis = Audiologist/HAs/Dispenser</th>
<th>Financials</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of new patients for ALD per year</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Number of new patients for ALD per week</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Fee for 45 minutes fitting process</td>
<td>$90.00</td>
<td>$24,000</td>
</tr>
<tr>
<td>Fixed equipment costs</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>ALD retail cost</td>
<td>$150.00</td>
<td>$12,000</td>
</tr>
<tr>
<td>ALD buying group discounted price</td>
<td>$120.00</td>
<td>$12,000</td>
</tr>
<tr>
<td>Markup</td>
<td>$30.00</td>
<td></td>
</tr>
<tr>
<td>Markup margin</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>ALD equipment cost</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>ALD purchases</td>
<td>$15,000</td>
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<tr>
<td>ALD wholesale cost</td>
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<tr>
<td>Markup margin</td>
<td>20%</td>
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</tr>
<tr>
<td>ALD total revenue</td>
<td>$24,000</td>
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</table>

<table>
<thead>
<tr>
<th>Unit of Analysis = Buying Group</th>
<th>Financials</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALD wholesale cost</td>
<td>$120.00</td>
<td>$4,500,000</td>
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<tr>
<td>Markup</td>
<td>25%</td>
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<tr>
<td>ALD total revenue</td>
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<tr>
<td>Advertising cost</td>
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<td></td>
</tr>
<tr>
<td>Total volume purchased for one buying group</td>
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<td>Net Income</td>
<td>$650,000</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Unit of Analysis = Lions</th>
<th>Financials</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALD cost from contract manufacturer, including shipping</td>
<td>$50.00</td>
<td></td>
</tr>
<tr>
<td>ALD wholesale cost</td>
<td>$150.00</td>
<td>$3,750,000</td>
</tr>
<tr>
<td>Markup</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>ALD total revenue</td>
<td>$3,750,000</td>
<td></td>
</tr>
<tr>
<td>Advertising cost</td>
<td>$100,000</td>
<td></td>
</tr>
<tr>
<td>Total costs</td>
<td>$1,975,000</td>
<td></td>
</tr>
<tr>
<td>Net Income</td>
<td>$1,775,000</td>
<td></td>
</tr>
</tbody>
</table>
Audiologists or other hearing professional:
- Fixed costs – none incremental
- Variable costs – additional professional time to fit incremental patients
- Revenues – $90 fee for 45-minute fitting, $30 markup on buying group price for a total retail price of $150

Buying group:
- Fixed costs – incremental advertising costs of $100,000
- Revenues – $20 markup per aid on $100 wholesale cost from Lions
- Membership – assume 1,500 members in group and 25% willing to carry product

Lions:
- Fixed costs – incremental advertising costs of $100,000
- Variable costs – $50 manufacturing cost per ALD
- Revenues – $50 markup per ALD on $50 manufacturing cost

7.4 Marketing Plan

7.4.1 To Patients
- TV ads: public service advertisements, Ad Council
- Advertisements in physicians’ offices: posters, brochures
- Referrals from channels without a solution for low-income patients

7.4.2 To Audiologists
- Product promotions: free trial devices, fitting materials
- Advertisements via buying groups (included in existing ads)
- Stressing solution for low-income individuals who can not afford other devices

7.5 Operations Plan

The decision to pursue volume-purchasing groups as a distribution channel will depend upon the Lions overall strategy, especially how the Lions wishes to position itself relative to existing manufacturers. The next step in establishing this distribution channel would be to explore partnerships with one or two of the large buying groups who have expressed interest in offering a product for low-income patients.

This distribution channel could provide benefits to all parties involved, facilitating entry and growth in the market. For low-income patients, all of the product options provide an affordable hearing solution. For audiologists, the products are easy to fit and provide addition income from patients who cannot afford existing products. For buying groups, affordable hearing devices are a means of increasing the customer base by expanding to previously unreachable customers. Finally, for Microsound, this program can increase the exposure to the Pilot to audiologists in the United States and could lead to its use with higher-income patients, thereby increasing revenues and production rates. This distribution strategy has the potential for being a win-win for all of the participants involved.
7.6 Key Assumptions, Critical Risks, and Potential Problems

The success of this distribution strategy will require testing several key assumptions:

- Availability of product that can easily be fitted – in the case of the Microsound Pilot and the ALD with no follow up visits – so that private practice providers can indeed make a reasonable profit, assuming that audiologists would feel adequately compensated with $90 per hour for their time
- Product will be advertised adequately and awareness will be high
- Product will be appropriately positioned to avoid potential conflict with other manufacturers’ offerings

7.7 Key Partnerships

Throughout the course of the project, key partnerships have been established or suggested that would serve to facilitate this distribution channel through buying groups:

- Distribution through buying groups: executives at EPIC and HearPO are excited and willing to explore distributing a high-quality, low-cost product
- Referrals through other buying groups, such as Hearing Planet, that have expressed willingness to refer low-income potential customers to groups with suitable products

7.8 Future Development

To begin using this method of distribution low-cost product, several key steps need to be taken in the next few months:

- Narrow down specifications for, and if necessary create, specific products
- Negotiate with manufacturers
- Present products to buying groups and allow them to evaluate it internally and possibly externally through a few member audiologists
- Decide whether multi-tiered pricing based upon the customer’s income could be implemented and would be preferable to a standard price
8  Key Advisors

Rhonda McClinton-Brown, Executive Director, Community Health Partnership

Rhonda McClinton-Brown leads a coalition of community health clinics in the South Bay and could be a valuable resource in helping the project establish a network of clinics in this area. She also has a deep understanding of the constraints under which community clinics and their clients operate and could provide valuable advice for the design of a successful program.

Raegene Castle, President, Self Help for the Hard of Hearing, Redwood City Chapter

Raegene Castle lost her hearing four years ago from an illness. Since then, she has become actively involved in collecting and distributing information about hearing loss and the options available to the hard of hearing population. Most notably, she is currently organizing a library of ALDs for those with hearing loss to learn about and test these devices. As a woman with substantial interest in educating herself and others about different types of devices and programs that are available for those with hearing loss, Raegene could be a valuable resource in helping to promote and disseminate information about the project’s programs.

Laura Clark, Health Educator and Counselor, Hearing Society for the Bay Area

Laura Clark was invaluable for our empathy work and human factors research. She actively promotes hearing education in low-income and multi-cultural communities in San Francisco. We had the opportunity to be with her in one of her information sessions for seniors with hearing loss. Her thorough knowledge of low-income communities makes Laura a valuable resource in helping to determine the project’s community partners and program locations. In addition, her extensive experience with adults and seniors would make her very helpful in designing the counseling and informational sessions to be held at senior centers and community health clinics.

John Gressman, President and CEO, San Francisco Community Clinic Consortium

John Gressman has worked with the San Francisco Community Clinic Consortium for 13 years. The Consortium serves as a convener for 10 clinics in San Francisco that serve a total of about 65,000 patients per year. These clinics target the low-income communities, particularly those who are uninsured. The clinics are well established and have earned the trust of the patients they serve. John has already informed several of his most suitable clinics for this project about the possibility of providing audiological services. These particular clinics include the Curry Senior Services Gerontology Health Center, which serves mostly seniors, and the North East Medical Services (NEMS), which serves mostly the Asian population. Many of the clinics are ethnicity targeted to help provide a comfortable environment where the physicians speak the patients’ native languages. Also, the San Francisco Community Clinic Consortium operates a mobile medical outreach van to the homeless community, which the project could possibly learn from. John is very supportive of the project and could be very helpful in establishing relationships with community partners.

Jennifer Lathrop, Audiologist and Owner, Pacific Hearing Services

Jennifer Lathrop has served as an advisor for the project, providing us the perspective of a private practice audiologist and has given us key insights into products and practices. Her business, Pacific Hearing Services, is very highly regarded in the Bay Area and is known especially for its high quality (geared more toward high-income patients). However, until recently, Jennifer accepted Medi-Cal patients as a “community service.” She had to stop due to the high costs and personnel demands that such patients placed on her practice, but she is always looking
for new ways to help the community. Jennifer has been very helpful in evaluating ideas for process streamlining and cost cutting. She could be an outstanding resource in the next phase of the project, providing insight into the best way to find a “win-win” solutions with private practice audiologists as well as commenting on the quality of the project’s products and processes.

Helen Luey, Program Director, Hearing Society for the Bay Area

Helen Luey has helped the team with information and advice for proper counseling procedures. Her work with the Hearing Society includes managing the counseling not handled by an audiologist. She works with a diverse population of patients, and has provided insights and revelations in terms of empathy of our population as well as ways to classifying those with hearing loss. She could be a valuable resource in providing recommendations and feedback for the counseling that would take place in the mobile outreach and community clinic programs.

Bob Madory, Director and Chief Audiologist, San Francisco Hearing and Speech Center

Bob Madory is the chief audiologist at the nonprofit San Francisco Hearing and Speech Center. This organization fits over 1000 new hearing aids per year, with a large percentage to low-income patients. His experience with low-income patients and his interest in providing quality hearing healthcare in a cost-effective manner make him a valuable resource for designing and evaluating a delivery model for community clinics.

Carla Pagotto, Director of Marketing, Tympany

Carla Pagotto is the director of marketing at Tympany and is in charge of research initiatives. We spoke to her to discuss Tympany’s product, the Otogram. The Otogram is a machine that performs automated hearing tests and does not require a soundproof booth but merely a quiet room no louder than 50 dB SPL. The Otogram can perform air and bone conduction tests, speech recognition tests, masking, manual audiometry, tympanometry, and has NOAH integration. There is also a mobile Otogram that can fit in a container the size of a average piece of luggage. Automated testing with a device such as the Otogram is key to the efficient processes developed for the mobile outreach and community clinic program.

Soeren Louis Pedersen, CEO, Microsound

Soeren Louis Pedersen spoke to us about his company Microsound, a small Danish hearing aid manufacturer. We have learned a lot from this company’s unorthodox distribution methods in Europe (through optometrist chains and using pair-comparison programming). By partnering with them in the future, we could potentially add to their volume and obtain lower prices for our low-income customers.

Marcia Raggio, Director of Audiology Program, San Francisco State University

Marcia Raggio served as an advisor to the SES team. She is extremely knowledgeable and was very helpful; she generously made time to talk to us late in the evening on multiple occasions and was very interested in our work. We spoke with her about how audiology students could potentially work at a regional clinic, providing a win-win of good internship experiences for the students and free labor for the clinics. This idea was discussed in detail, but not included in the final reports due to the uncertainty of the continuation of the program at SFSU and more research needed on the amount of work students could do on their own to leverage the audiologists’ time.

Sharen Ritterman, Chief Audiologist, Stanford University Medical Center

Sharen Ritterman has a wide breadth of experience, including working in a mobile unit, working with Medicaid patients, as well as working in private practice. As an advisor she has helped us understand standard audiology procedures and helped us test and evaluate new technology. She
has been the project’s primary contact with Stanford Medical School and its ENT Department. Her years of experience as an audiologist have been an invaluable asset to the project.

**Joe Roberson, MD, CEO, California Ear Institute**

Dr. Joe Roberson is the medical director and CEO of the California Ear Institute, a leading otology center. The Institute was originally based at Stanford but recently became a private practice. As part of the outreach programs at the CEI, Dr. Roberson fits hearing aids and performs low-cost cochlear implants around the world. Additionally, the Institute offers solutions for low-income patients through a tiered pricing system and the Let Them Hear Foundation, which Dr. Roberson also directs. Dr. Roberson has also worked with several startup hearing device companies, including Sound ID. He has expressed his willingness to help the project and would be an extremely valuable resource, both in terms of business and product/process advice.

**Michael Valente, Ph. D., CCC-A, Director of Adult Audiology, Washington University**

Dr. Michael Valente is a leading expert on diagnosing and treating hearing loss. He has written several books on the topic and helped design the protocol of best practices for diagnosing hearing loss and fitting hearing aids for the American Academy of Audiology. Dr. Valente helped us develop an efficient fitting procedure, specifically the model for mobile diagnosis using automated audiometry and the model for high-volume, affordable audiology in community clinics. He is also an advocate of assistive listening devices. Dr. Valente has also expressed interest in testing our processes on his patients, of whom a large fraction are low-income, as well as our products, the affordable hearing aid and the new ALD.
9 Summary and Future Development

This report highlights the potential of recent advances in digital signal processing technology and automated audiometry to affordably extend hearing healthcare and treatment to underserved communities.

First, we discuss the hearing aid industry and the various distribution methods currently in place as well as the stringent hearing aid regulations. We then describe our target consumers as well as the various barriers that they face when seeking diagnosis and treatment of their hearing loss. We next describe the products currently on the market as well as potential products that our distribution strategies could utilize.

We then propose two integrated mechanisms for affordable hearing healthcare delivery: one a mobile program of hearing testing, diagnosis, and counseling; the other a program for treatment based in community health clinics. Further research with pilot efforts could further develop and demonstrate these models and hasten their adoption. Partners in such pilot efforts would include: academic researchers, audiology professional associations, manufacturers, community clinics and centers, and nonprofits that work with underserved communities.

We next suggest another delivery option for our affordable hearing solutions through the networks of audiologists and buying groups that currently exist. We have already built relationships with executives at large buying groups such as EPIC and HearPO who have expressed willingness in distributing high-quality, low-cost products. Other groups may be willing to provide referrals of low-income patients who cannot afford their products. The next steps would be to further develop and present our high-quality, tested products to these groups for internal review. After this review, the relationships would need to be formalized and then distribution could begin, bringing affordable products to thousands of audiology offices around the nation.

Finally, we list those advisors who have been especially helpful with our research along with a description of their expertise and potential help in the future.

The inspiration for our research was to seek ways to extend hearing healthcare to those who currently cannot afford it. A combination of new technologies and new approaches to hearing healthcare delivery holds the promise of dramatically reducing costs, while improving care. Our hope is that others will build upon and develop these ideas into affordable solutions that will reach the millions with untreated hearing loss and help them reconnect with the ones they love.