OptiOpia, Inc.

Affordable Quality Eyecare

Business plan submitted to JEE April 1, 2011

If you have a conflict of interest – for example, a business commitment in optometry, optician services, or refractive services -- please refrain from reading this document.

Introduction to OptiOpia – Affordable Quality Eyecare

OptiOpia is a for-profit social venture that will improve detection and correction of vision problems in less-developed countries (LDCs) and will improve vision screening, especially of children and under-served populations, in all countries. Between 500 million and one billion people, mostly in LDCs, are estimated by the WHO and other sources to suffer from uncorrected refractive error (near- and far-sightedness, astigmatism, presbyopia). Many of those in need are willing and able to pay a half to a week's wages ($4 to $40) for quality glasses. OptiOpia is lowering the cost of getting the right prescription and of filling it.

OptiOpia is a product development stage company based in San Francisco, California. OptiOpia's lead product addresses the biggest cost and access barrier: there are not enough people trained to perform an eye exam, specifically that part of an eye exam that measures refractive error and results in a prescription for corrective lenses. OptiOpia's second technology is a lens molding device. Our desktop-printer sized device (estimated initial COGS of $1,500 - $2,000) produces quality spectacle lenses on-the-spot, on-demand. This device will eliminate complex distribution systems. The molder also reduces the need for working capital (tied up in an inventory of lens blanks) and training (human capital) to make lenses, to cut lenses to fit a frame, and to manage a store's inventory. The reduction of the cost of setting up a mini-opticianry in turn not only serves some existing markets but also enables new channels for eyeglass dispensing, at general/pharmacy store kiosks and by mobile (even motorcycle-based) optician shops.

The name OptiOpia is a compound of *Opti*, as in Optics and Optimism, and *Opia*, as in Utopia and some of the vision disorders we address: Myopia, Hyperopia and Presbyopia.

Sustaining and Extending Healthcare Markets. OptiOpia is a for-profit venture in part because fitting and sale of eyeglasses is a profitable activity everywhere. Refractive services (diagnosing, fitting and dispensing corrective lenses) provide a major source of positive cash flow for non-profit and for-profit institutions alike, in all major less-developed countries. Though markets are used widely, these markets are not wide enough to serve everyone whose vision will improve with glasses or corrective lenses. A widespread lack of access to trained personnel (optometrists and ophthalmologists) has resulted in between 500 million and one billion people suffering from uncorrected refractive error, despite many having an ability and willingness to pay (and owning watches and other useful non-necessities). Extending the reach of existing markets and opening new markets for eyecare is OptiOpia's mission and its opportunity.

Product Opportunity 1: Low-cost Auto-refractor

Highlights.

Functions: Measures refractive error well enough to specify accurate prescriptions in less-developed countries; screens for refractive error in developed countries that license adequate numbers of eyecare practitioners; additionally screens for cataractous and other blinding opacities of the eye.

Comment [DHG1]: Coordinate this section with my BayBio handout page

Technology features ("special sauce"): Clever plastic lenses, see-through design for better accomodative stability, subjective refraction "override" capability, exploitation of cost curves that opto-mechanical and electronic components of consumer digital cameras are riding. Estimated COGS of less than $200.

Development status: Between benchtop prototype and a more complete prototype in development (adequate funding for that is not in hand – about **$115,000** is required); once that design is completed, about $750,000 to 1,000,000 is needed for design for manufacture (DFM) productization, testing and market development.

The low-cost auto-refractor is key for improving refractive services in less-developed countries

OptiOpia will de-skill the eye exam by completing development of a low-cost (~$200) auto-refractor (a device that measures refractive error) with low training requirements. Auto-refractors are a mature, well-understood technology, but the cost and fragility of existing devices have limited market penetration. Better auto-refractors will (NON-disruptively) increase profits of existing practitioners and enable entry of less-skilled providers. In regions where there is a drastic shortage or total absence of optometrists and ophthalmologists, there is also an absence of regulatory barriers to care by less-skilled providers. Until and unless the drastic shortage is addressed, extending eyecare markets by de-skilling the diagnosis of refractive error will significantly contribute to the improvement of quality care

Current devices cost between $5,000 and $15,000 and simply can't take much handling - even the portable ones. Most existing models are designed to be immobile in an optometrist's office or clinic; a technician uses them to obtain a starting point estimate of refractive error for the eye exam performed by the doctor. Having a good starting point saves the doctor's time, especially with children and those with communication problems (e.g., tourists who can't speak the language, the demented, autistic, disabled, etc.). Two currently marketed *portable* auto-refractors (Welch Allyn SureSight and Nikon Retinomax), which are priced at $5,000 and more than $12,000, are too fragile for use where most needed and are not as accurate as OptiOpia's is designed to be.

Vision Screening: an under-served market in the US and in more-developed countries.

In the United States and elsewhere in the developed world, increasing the proportion of preschool children aged five years and under who receive vision screening is a priority objective: this is emphasized in the Healthy People 2020 initiative of the US

federal government (http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=42). As a reviewer of this project's SBIR Phase I application noted, "The need for such a device is very high both nationally for the screening and early diagnosis of ametropias in children and rural populations, and internationally for the provision of optometric services in a wide range of locations."

The National Eye Institute (NEI, one of the National Institutes of Health) funded a research project, The Vision In Pre-schoolers Study or VIPS study, that showed that the two currently marketed portable auto-refractors are the present-day tools of choice for vision *screening,* a task that can be performed by lightly trained technicians and even HeadStart parents trained for a couple of hours. The key targets of public health screening efforts in developed countries are children and traditionally under-served populations (minority groups, urban and rural populations with poor access to healthcare). The autorefractor contributes to vision screening by determining whether a patient has more than a clinically or functionally significant amount of near- or far-sightedness or astigmatism. If positive, the patient gets a referral to an optometrist or ophthalmologist for a comprehensive eye exam. Of special interest are children, especially the difficult-to-examine young children 4-7 years old. Note that it is not feasible to provide every young child a comprehensive eye exam – even in a provider-rich city like Boston, there are not enough optometrists and ophthalmologists. Therefore, a low-skill screening step is essential.

Delivering refractive services for kids who need them, as soon as they need them, will not only help improve school performance, but has been proven to be remarkably effective (see next paragraph) in preventing the development of amblyopia, a life-long, permanent un-correctable visual impairment currently affecting 3% of the adult populations of almost all developed and less-developed countries. The buyers for this market are primarily public health and primary educational institutions. These are admittedly difficult markets, but they have been gradually opening in the US and Europe as research has shown efficient, often auto-refractor based, vision screening drives referrals to licensed eyecare providers with optimal sensitivity and specificity. OptiOpia intends to own these markets in the US as they develop but cannot "bet the company" on waiting around for legislative allocations of resources during a time of budgetary pressure on existing education and health budgets.

The benefits of widespread and well-done childhood screening in Scandinavia are dramatic: prevention in more than 80% of children of the permanent, lifelong loss of good vision in at least one eye, amblyopia, by detecting and correcting near-sightedness, far-sightedness and astigmatism. OptiOpia believes that developing and deploying novel autorefractor technology is a great way, in the coming era of limited public health spending, to protect the health and quality of life of American children. Because recent NEI research has forcefully demonstrated the screening sensitivity and specificity of a portable, sensitive autorefractor that is operable by lay people and school nurses, and because of the national policy priority of this objective as a Healthy People 2020 initiative, now is a compelling time for investment to move

a low-cost autorefractor "to the factory door" to advance this important national public health objective. Why can't America match the Scandinavians' decrease in rate of amblyopia, from 3% to 0.3%? Why can't other developed countries that value their children's health and education?

Cataract Screening

Finally, and in addition, auto-refractors can be used to detect when the eye's optical media are not clear. Use of the OptiOpia auto-refractor will help de-skill the assessment of the clarity of the eye's optical media (cornea, humors, and lens), and thereby contribute to the detection of the common (especially in tropical regions) condition of cataract. (In cataract, the lens clouds up and impairs vision: this is the most common cause of legal blindness in the world, while uncorrected refractive error is the most common cause of what the WHO defines as "severe visual impairment and blindness" – see the Brien Holden article in the Appendix). There are even more inexpensive ways to screen for cataractous or other opacities if that is the only condition being screened for, but the fact that a lightly trained person with an autorefractor can perform opacity detection incidentally or in passing while working at an economically profitable/sustainable job is important for motivating partnerships between lightly trained refractive front-line refractive service providers (such as optician shops) and ophthalmology clinics, systems and hospitals that provide cataract surgeries.

Development Status.

OptiOpia acquired rights (from the precursor firm Low Cost Eyeglasses and Squid Labs, see History section below) to a benchtop prototype auto-refractor. The prototype's design embodied significant innovations of Saul Griffith that make it appropriate for low-cost production. Its performance on a model eye was shown to be well-suited for the needs of both less-developed and more-developed nations. The prototype was built by a contractor using a SBIR Phase I grant. Current funds in hand from The Lemelson Foundation are being used to advance that design to a more complete prototype suitable for limited human testing. Achievement of the milestone of a complete design (optical, mechanical, electronic, user interface) of this device and validation with limited human testing is OptiOpia's topmost priority. That milestone will be achieved in nine to twelve months with additional funding; design-for-manufacture and clinical equivalency testing could be completed in an additional ten months.

Auto-refractor Development Milestones (Pre-Marketing).

Publishing clinical equivalency studies using the completed and locked-down design-for-manufacture auto-refractor and presenting at international conferences in pediatric vision, public health, ophthalmology and optometry will be important steps in creating market interest and demand in all the market segments described below.

Operational in-field studies of the benefits of adopting the OptiOpia auto-refractor will be important and helpful in making the business case, by measuring the increased productivity of personnel engaged in delivering refractive services. Specifically, the key metrics associated with improved speed and accuracy of getting the right prescription are: more prescriptions per day, improved prescriptive accuracy (for personnel with a documented level of training and experience), improved customer satisfaction, maintenance records, bug reports and total cost-of-ownership, requests for new features and improvements.

Finding partners to perform such studies may seem ambitious. We are confident it's feasible. Ruthlessly efficient, well-managed eyecare systems of high international repute, such as Aravind and LV Prasad in India, have expressed interest in evaluating the OptiOpia auto-refractor. These institutions and other NGOs in vision care have in-house operational consulting competencies. Institutions partnering with OptiOpia on operational studies will be motivated to participate both in order to earn a long-term discount in OptiOpia's tiered pricing policy and to have a voice in guiding the product development priorities of OptiOpia so that they will align more closely with their own needs.

The low-cost autorefractor is a low-cost version of a familiar and well-understood device; therefore, the market risks for this product are less than those facing many innovative technologies

Product Opportunity 2: Lens Molder

Highlights: Desktop device, estimated initial COGS of ~$2,000, to make top-quality single-vision plastic lenses in five minutes. Especially useful for "minifying" the optician lab/shop (in capital and physical volume) and enabling mobile eyeglass dispensing. Prototype-proven; additional financing needed to productize. There is option value in advancing molder technology to certain lucrative developed-world markets, a value not discussed further in this document. (We have just concluded a phase one project exploring feasibility of molder technology for non-spectacle lenses.)

OptiOpia's second product in development is a desktop-printer-sized lens molder that can fabricate top-quality prescription spectacle lenses in just five minutes. The device controls the shape of a membrane filled with the liquid acrylic monomer plastic most commonly used for lenses; then the plastic is cured with ultraviolet light. (The technology applies to low-shrinkage thermoplastics as well.) With a low-cost auto-refractor to make it easy to obtain a prescription and a lens molder to fulfill the prescription, OptiOpia is creating a new integrated solution to providing affordable and convenient refractive service.

The molder can make lenses on site, on demand, in a desktop device while reducing the need for capital (tied up in inventory of lens blanks and in-store machining at shops like Lenscrafters) and in training (because the molder is easier to use than the

current machines). The molder is highly novel and patented. Prototypes have been built and used to make a small number of lenses that met or exceeded commercial standards of spectacle lens quality. A SBIR (Small Business Innovation Research) Phase I grant was awarded to Squid Labs to advance this technology to make progressive advanced lenses (multi-focal lenses for smooth transition from far to near vision in patients with presbyopia); one result from that effort is a determination that advancing the technology in that direction is riskier and more capital-intensive than productizing the molder to make single-vision lenses (conventional sphero-cylindrical lenses to correct for near- and far-sightedness and astigmatism).

It is important to emphasize that spectacle lenses are already inexpensive to produce in factories and in many places inexpensive to distribute from factories to retail outlets. The availability in American retail pharmacy chains of reading glasses for less than $10 demonstrates that plastic lens manufacture is already quite efficient: making spectacle lens blanks (to be cut to fit a particular frame shape) in a factory costs only pennies per lens. OptiOpia's prototype lens molder is particularly helpful where rapid service is valuable to the customer or provider, where portability is valuable, and where the costs in space, working capital, training or administrative overhead of managing many drawers full of lenses -- and the supply chain to deliver them -- are burdensome. The lens molder is simpler in several dimensions as well as faster. That simplicity of "pour plastic in, type prescription in, make lens in five minutes" is particularly well-suited for small shops, kiosks within shops and mobile providers, and in regions that have uncertain supply chains. For those reasons, the molder will find a market in many regions of many less-developed countries.

Development Status. The next step is to test performance of the existing prototype with a large batch of sample lenses. If that is successful, work will proceed, subject to financing, to advance the commercial development and add proprietary technology for certain functionalities not disclosable here. The testing step requires $10,000 and some management time – essentially, a summer project with an engineering student and part-time technician. Financing is sought to productize the molder as well as to complete the productization of the auto-refractor. We estimate that approximately $1.75 million and 18 months will result in production of a small number of beta-products for extensive testing, evaluation and use in marketing to lead customers and in driving partnerships. We believe that the initial COGS will be $2,000 and then will decline with experience and scale. (It's an essentially mechanical device, likely susceptible to numerous incremental process and component improvements that will lower cost.)

Markets for the Auto-refractor and Lens molder

Summary. There are several markets for the auto-refractor (AR), the lens molder, and the bundled pair. Eyeglasses are sold profitably to the end-user (unlike condoms & vaccines), even by charities. We find from informal and formal market research in different regions that people are usually prepared to pay ½ - 1 week's wages for exam + glasses ($4 - $40) in very large "base of the pyramid": markets.

The AR is an established, mature, and well-understood part of eyecare around the world; OptiOpia's is less expensive, less fragile and more portable. Ours won't displace current practitioners, but help them improve productivity. Our device also allows new entrants in under-served markets, because of the reduced training requirements.
AR market segments:
• In US & developed world (MDCs): licensed professionals who do eye exams, replacement of existing stock and supply of new exam rooms. 20% share in 7 years: 3100 units/yr
• MDCs: schools and primary care offices that perform screening of children. 10% share in 7-10 yrs: 3000/yr
• LDCs: pharmacies, primary health clinics, micro-entrepreneurs, and non-governmental organizations (NGOs). 10K/yr in 10 years
• LDCs: professionals, especially opticians. 25% share in 7 yrs: 2100 units/yr
Lens molder market in LDCs: rural & edges of expanding cities

In this plan we have chosen not to discuss the marketing of the lens molder to developed world markets and focus only on its usefulness in LDCs.

Traditional Customers in Developed World

Although OptiOpia's low cost autorefractor has not to date been designed with the needs of the U.S. or European optometrist or ophthalmologist foremost, this group is likely to appreciate several benefits that such a device can bring to their practice for three reasons. First, it is inexpensive, and so could serve in a second exam room, as a back up, or as a replacement product to a broken autorefractor. Second, it combines subjective and objective refraction in a manner that is more convenient than using a two-step process, and thirdly it is novel.

There are 50,000 optometrists and ophthalmologists in the U.S., and an equivalent number in Europe. Japan has an additional 10,000. The vast majority of these practitioners has at least one autorefractor, purchased at an average cost, including accessories, of between $5,000 and $13,000 (sometimes bundled with keratometry or other functionality) and will require another only as an upgrade for new capabilities, replacement for a broken unit, or for a second location. We estimate between 10-20% may be interested in the low cost autorefractor, resulting in a potential market over 7 years of 11,000 to 22,000 units assuming good conversion from interest to purchase and a relatively static competitive landscape (see below). The initial market-launch success (several years ago) of the Welch Allyn SureSight, which sells for $4,995, against more expensive rivals gives support to a high potential demand for a less expensive easy-to-use product.

This group of customers can be reached using a combination of direct marketing and established sales and fulfillment channels.

Direct marketing and promotion. Identifying and communicating with the potential customers is relatively easy. Equipment purchasing managers for major optical chains, such as Lenscrafters and Pearle will receive free evaluation devices as well as personal visits from OptiOpia personnel. Independents (the "3 O's") can be

effectively informed about the device through simple direct mail offers and trade-journal articles and advertisements (in Vision Monday or Vision 20/20). However, unlike typical direct marketing organizations that also involve themselves in fulfillment, low-cost autorefractor marketing will utilize existing distributor networks. Because of the existence of marketing databases to reach optometrists and ophthalmologists, simple informative campaigns will enable affordable awareness building.

Fulfillment. Orders will be able to occur directly, through a web site, or indirectly through a distributor, such as Lombart. Although distributors on the lens and frame side of the ophthalmic industry charge very high margins, the equipment distributors have more moderate margins, and they provide substantial savings vs. an internal strategy due to their existing catalogs, customer access, inventory management, billing, fulfillment, and customer service capabilities.

Risks. There are two significant risks in this approach. First, although equipment distribution in the U.S. and Europe is independently controlled from equipment designers, some very large companies with multiple product lines may be able to unduly influence distributors to not carry the low cost autorefractor. Obviously such competitive tactics would violate anti-trust laws, but they may occur anyway. The second major risk is the threat of customers being deliberately "diverted" by distributors from the low cost autorefractor to higher priced competitive products. If either of these threats occur systematically, we may be forced either to raise the end price (giving the increase in price to the distribution channel) or to use an alternative general product fulfillment house – such as the many outsourcing fulfillment firms located near Federal Express' Memphis hub.

With regard to regulatory clearance to market In the United States, a layman's reading of the Code of Federal Regulations Title 21, Subchapter H, Sections 886.1760, 886.9, and 812.3 indicates that the proposed low-cost autorefractor is a Class I device, exempt from the premarket notification procedures in subpart E of Title 21, Subchapter H, part 807 (See for yourself at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm). If upon consultation with regulatory experts and/or the FDA we determine that that interpretation is incorrect, then 510(k) clearance from the Food and Drug Administration will be applied for at the appropriate time.

Traditional Customers in Developing World

Unlike in the U.S. and Europe, only 25-45% of opticians, optometrists, ophthalmologists, and market peddlers in the developing world own autorefractors. Instead, they rely on standard visual acuity, retinoscopy, phoropters and trial lens kits for diagnosis. For many of these professionals, this is all that is needed, but for others, an autorefractor would be a good addition to their practice.

There are three reasons for a refractionist to acquire an autorefractor:

1. If the refractionist is poorly trained, the autorefractor offers the ***refractionist*** more prescriptive accuracy, thus increasing customer satisfaction and reducing returns,

2. Autorefractors inspire ***customer*** confidence that the resulting prescription is accurate, and so refractionists with autorefractors in the developing world have higher revenues,
3. Autorefractors facilitate ***higher throughput*** – both because of speed and also because of the use of non-professional help during the refraction, enabling the refractionist to focus on other issues, such as disease diagnosis.

We estimate that once the autorefractor is established in an area as a signal of quality service, most practicing refractionists would like one. For example, in Nicaragua, India, and China it has been observed that when multiple optical shops offer "computer testing", the rest of the shops buy an autorefractor to stay competitive. As such, we believe that we can capture a significant share of the 65,000 optical shops that currently do not use autorefractors. Assuming half of them purchase an autorefractor over the next seven years, and we capture one quarter of these new customers, we will achieve sales of 8,125 units. Additionally, many of the 35,000 stores who already have autorefractors are likely to need replacements as a result of wear, providing additional volume. Our pro forma financials conservatively estimate cumulative sales of 8,400 units over the first 7 years.

We will begin with targeting large economies with many potential customers. Attractive target countries include: India, China, Brazil, Mexico, Indonesia, Russia, Nigeria, and South Africa. The most attractive *initial* markets at this point appear to be India, in partnership with Aravind and LV Prasad, and Mexico or Brazil.

Direct marketing and promotion. We will take a similar direct marketing and distribution approach in the developing world as in the developed – approaching large chains, using direct mail to smaller entities, and partnering with distributors. The main difference will be that in the developing world we will try to achieve high market share using saturation methods instead of "skimming" for niches, as in the U.S. Identifying and communicating with the potential customers is relatively easy, though not as easy as in the developed world. In each country, major optical chains exist, typically with local outlet shares of 15-40%. For example, in Nicaragua Munkel had 30 of 60 outlets in the country. The largest one in Mexico has 550 stores, of roughly 5,000 in the country (data from ~2003 -- and needs to be updated). This pattern is repeated in many parts of the world, offering a good way to begin in any specific country. We will then try to create a standard of service that local competitors will strive to match. This can be done by including small window signs or customer information cards about the autorefractor.

Fulfillment. We will always seek to find a local distribution partner who will deal with product importation, legal registration, fulfillment, customer access, inventory management, billing, and customer service capabilities. We anticipate that the local partner will require 35-50% margins.

Non-Traditional Customers in Developed World:

As identified in the significance section of this grant, not enough children in the U.S. and other developed countries are screened early enough to treat impairment due to

refractive error and prevent amblyopia. One solution to this problem is to increase screening by non traditional personal – such as by pediatricians, school nurses, and child counselors.

There are an estimated 50,000 pediatricians in the U.S. While recognizing that every child should also have an eye exam (appropriate to age), a pediatrician may want to give a simple eye test as part of an exam. Such doctors (as well as nurse practitioners) are already trained in the basic functions and possible refractive errors of the eye, and so would be very comfortable with the device. Only the Welch Allyn SureSight is positioned to sell into the pediatric market[1]; few or no pediatricians appear currently to own a device. We estimate that with the proper education and marketing, a 10% penetration of this market over 7 years is possible, resulting in a cumulative volume of 5,000 units in US and an equal amount in Canada, Europe and Japan. How best to reach the pediatrician market requires further research but possibly sales, fulfillment, customer service, etc. can be performed through the product distributors who are already routinely selling to pediatricians such devices as otoscopes and visual acuity charts.

One approach in the US might be to partner with large managed care organizations (both governmental and private) that increasingly dictate and evaluate best practices in primary care. Depending on where the costs of an unnecessary (false-positive) or missed (false-negative) comprehensive eye examination "land," some payers may have a strong economic incentive to adopt a device that offers the best sensitivity and specificity without requiring expensive doctor time for the screening step. In this regard, a recent 2003 comparative study of screening technologies (Miller, 2003) found that a dramatically lower-cost auto-refractor would be significantly superior to current-technology autokeratometry and photorefraction in sensitivity and specificity for detection of serious astigmatism (threshold between 1.50 and 2.00 D) in a population of 3- to five-year-old children with a high prevalence, at a Native American tribal Head Start program. Successful equivalency trials *and* analysis of sensitivity and specificity with a dramatically lower cost auto-refractor might motivate initial adoption for populations such as these. As a *caveat,* there are different approaches to quantifying economic benefits: quality of life associated with prevention of amblyopia, reduced false-positive referrals for a comprehensive exe examination, etc. Working with large managed care organizations on these analyses may facilitate bulk sales by virtue of savings due to reduced false-positive referrals and reduced office time in screening children and adults for ametropias and opacities.

There are 56,639 public and private elementary and secondary schools in the United States. There are 4.401 Nursery schools, 3.832 Kindergarten, 32,867 elementary, and 15.,539 high schools, teaching 8.2 million nursery and kindergarten students, 32.9 million elementary students, and 15.3 million high school students[2]. Because refractive error can emerge throughout a child's education, all of these schools are possible targets. Although this market is notoriously difficult to penetrate due to scarcity of discretionary funds in U.S. school system, a low cost, easy to use device

[1] Welch Allyn has offered a $4.500 "pediatrician" version of their wave front autorefractor that diagnoses the presence of astigmatism, but does not provide the axis.
[2] U.S. Census Bureau, U.S. Department of Education, courtesy Varsity Books

might have better success than previous attempts. Potential penetration into this market is hard to estimate, but could amount to 10% over 7 years, or 5,600 units in the U.S. Penetration may be more successful with financing packages that lower the initial purchase cost of the product. Additional sales to schools and national health services and non-specialist eyecare providers in Europe, Japan and other countries with strong governmental clinical care networks for primary care and vision screening are estimated to be about the same as the US market and, conservatively, to adopt at the same rate. In the pro forma financials, however, we only include sales in the US for this channel and do not include (due to a gap in our research on market sizing) expected sales elsewhere in developed world.

Marketing, promotion, and fulfillment. Non-traditional channels will require significant education, awareness building, and marketing to penetrate. Although direct mail marketing should be tested and response rates measured, it is likely that magazine articles, conference speeches, and general awareness building will be required in addition. Furthermore, someone familiar with supporting the school market (and its unique purchasing approaches) will be needed. As such, the best approach will be to partner with a firm already selling into the education market, such as a publisher, book distributor, or software provider. Major publishers selling into the educational market include McGraw Hill ($1.1 billion), Pearson ($1.1 billion), Harcourt ($755 million), and Houghton Mifflin ($751 million) [3], who would likely carry the product more to build their brand (esp. a private label option) than for the incremental sales. Such a partner could also access the opaque state-level and district level purchasing processes, introducing a scalable marketing approach.

Expansion of the vision screening market in the US alone will involve selling to slow-to-buy, cash-strapped state health and education agencies. We believe that meeting the American people's public health needs by developing this product in an American company like OptiOpia is best accomplished by developing a product for production and marketing that can benefit from economies of scale, for a global marketplace, to meet global needs, and to focus our best energies on entering markets with nimble private actors that can appreciate and act swiftly (i.e., buy) upon a pure economic value proposition. This market segment is attractive but will mature slowly.

Non-Traditional Customers in Developing World:

The hardest customers to tap will be the non-traditional customers in the developing world including primary health care workers, pharmacists, and micro-entrepreneur retailers. However, it also represents a very large potential market and the single best hope for reducing uncorrected refractive error globally.

The influential book *The Fortune at the Bottom of the Pyramid* by C.K. Pralahad persuasively emphasizes the power of entrepreneurs and private markets in developing countries to create wealth and customer/client/patient satisfaction in response to market-enablers such as lower financing costs/creative financing, new

[3] Open Book Publishing and Education Market Research. Sales to educational market reported. These numbers are from a document OptiOpia prepared in 2008 and may be obsolete.

ways to add information to markets, and reductions in market-destroying information asymmetries. The vast underserved market of emerging economies is very different from the American and European vision screening market,

In summary: without licensed eyecare personnel, an accurate and affordable autorefractor in lightly regulated eyecare markets that are starved of trained optometrists and ophthalmologists will help improve access, quality and affordability of eyecare for populations with youthful demographics, which characterizes much of the developing world. We shall now detail the scope of the commercial opportunity in the developing world and the potential societal benefits of our project to these populations.

In the developing world, there are two important problems in addition to vision screening that the low cost autorefractor seeks to address: 1) the very large number of people in the developing world who need glasses but don't have them, 2) the low quality of prescriptive accuracy in the developing world.

In many countries – such as India, Bangladesh, and China -- eyeglass peddlers sell glasses with very low prescriptive accuracy. Astigmatism is frequently misunderstood, myopia is over-corrected, and hyperopia not properly diagnosed. This results in very low customer satisfaction. OptiOpia's precursor venture, Low Cost Eyeglasses, conducted a survey in Tamil Nadu, India, and found that 21% of current glasses users are highly dissatisfied with their glasses.

The problems described above are the result of 1) the dependence upon a limited resource: the trained optometrist or ophthalmologist, and 2) the lack of a reliable, cost efficient technology to provide refraction by less trained personnel.

The lower number of optometrists and ophthalmologists in the developing world enables optometrists to focus on wealthy urban customers. For example, a World Health Organization study of seven Anglophone countries in Africa found that the respective percentage of ophthalmologists who lived in their country's capital city was 66%, 30%,100%, 50%, 65%, 78%, and 74% (IAPB, 2002), yet the majority of the population of Africa lives in rural and in mid-sized towns (World Bank, 2001). In some areas, such as in Africa and Latin America, the lack of optometrists causes a restriction in supply and an artificially high price given the ability to pay. In Jamaica, where there are fewer than one optometrist per 100,000 people (World Council of Optometry, 2002), and 60% of the population lives in households with a daily gross national income per capita of less than $6 (Branko, 1999), the cheapest pair of glasses available costs $56 (Low Cost Eyeglasses, 2002a, 2002b; Help The World See, 2002) – more than nine times the daily income, and more than 15 times the factory cost of the glasses. Frames and lenses themselves cost very little to produce: plastic frames can be bought in bulk from Chinese factories for less than $0.50, and glass lenses can also be bought for less than $0.50 a pair. All of the expense (and profit) is in the channel. To understand this situation on a global basis, our precursor firm Low Cost Eyeglasses, Inc. conducted a global survey in January of 2002 (www.lowcosteyeglasses.net).

In other areas (such as in India) the price can be as low as $2/pair – closer to the actual manufacturing cost of glasses. However, this low price is achieved through the heavy use of market peddlers (Onyelucheya, 1993), who frequently mis-prescribe astigmatism and hyperopia and thereby erode public trust in the quality of the product. Enormous numbers of people can afford the lenses and the frames but they cannot afford or access the expertise to get the right lenses. **A low-cost autorefractor will help people get the right lenses.**

The maximum impact on the health of the most people will occur:

- where adoption of low-cost autorefraction technology in enormously populous developing countries helps both adults and children get glasses to see better,
- where adults and children with refractive error simply get a good set of glasses, and thereby can enjoy all the practical benefits (and pleasure) of visual perception.

OptiOpia conducted detailed research in this market, and has developed a plan to access these customers using a franchise approach that captures profits from ongoing eyeglass sales. Franchisees would attend a class to learn about refractive error and eyeglass delivery and would purchase a starter kit. The franchisee would be required to purchase frames and lens resin on an ongoing basis, providing a larger revenue capture and advantaged economics.

The starter kit would include a low cost autorefractor, the low cost lens molder, a selection of frames, and marketing and business management materials. The starter kit will cost between $1,500 and $2,000. Given the revenue potential from the sale of eyeglasses, the franchisee's investment is likely to be repaid, after salary, within one year.

The low cost molding device being developed enables the simple local production of pre-edged lenses in any basic prescription – including sphere, cylinder, and axis, by using a variable mold and off the shelf lens casting technology. The result of this is that the local franchisee does not require lens inventory or lab support. The result for OptiOpia is a much simpler distribution and inventory model, as well as a strong revenue model.

This approach was extensively analyzed by our precursor firm, Low Cost Eyeglasses (see History section). An early version of the plan won the Harvard Business School Business Plan Contest, social enterprise track. Plans were evaluated based on innovation, impact, scalability, financial sustainability, and several other criteria.

OptiOpia has evaluated a plan to create 10,000 franchisees in India over a period of 7 years. Each franchisee is predicted to sell on average 1,000 to 1,500 glasses per year, at an average price of $5 to $8 (in India). OptiOpia expects to receive approximately $.50 in profit (net of financing costs, plastic materials and frames) per pair sold. If successful, the plan could be duplicated in China, parts of Africa and Latin America.

For initial market entry, partners are essential. OptiOpia's preferred partners for entering a developing country market are best-in-class community eyecare centers with large operations, quality management, and tiered pricing. Such "seedbed" institutions will be motivated to work with them because they will be able to realize the benefits from the low-cost auto-refractor of (a) increased referrals, (b) reduced training requirements for refractionists (personal communication, Dr. Aravind Srinivasan to Dr. Grosof, 2006-9), and from the lens molding machine of (c) reduced lens costs (automated edging machines required by opticians to cut lens blanks to fit into lens frames now cost $25,000) and (d) reduced staffing costs to operate, learn, and maintain edging machines. As experience grows with such institutions, the knowledge obtained will be used to target "middle-tier" developing countries, especially in Latin America, where our market research indicates significant opportunity for using autorefractors to improve the quality of eyeglass prescriptions for (non-destitute) lower-middle and working classes who have the resources to spend 1-2% of annual income on a pair of eyeglasses.

In each market above, the low-cost autorefractor will face significant competition. The principal competing products are the Nikon Retinomax and the Welch Allyn SureSight autorefractors, because they are portable and are the lowest-priced autorefractors. Important NIH-NEI research, the Vision in Preschoolers Study (discussed in Background & Significance) has demonstrated their clinical value in sensitivity and specificity as screening devices. These devices are also associated with major recognizable brands with established distribution channels. These devices are already established in the developed world marketplace and have an (apparently quite modest) presence in developing world markets. These two devices are designed to measure refractive error more quickly than the first version of the device is likely to operate. Because of these products' focus (so to speak) on supporting a starting point for refraction, they have not, however, been designed to support highly accurate measurement of refractive error, as various biases have been detected but not corrected with a look-up-table (personal communication, Bruce Moore, 2006; see also operator manuals for these devices). OptiOpia's "see-through" presentation of fixation targets, however, provides a significant advantage in serving presently under-served markets and children, because pointing to familiar targets accelerates and better maintains stable fixation and accommodation than do virtual targets. OptiOpia believes the Retinomax and SureSight devices have been priced too high to support adoption in the US for the kind of widespread vision screening needed to meet the Healthy People 2010 objective, too high to drive a truly compelling case for screening (cf. Miller, 2003). There is ample evidence from OptiOpia market research – as well as some evidence from the devices' operator manuals, which are freely available online -- that the Retinomax and SureSight devices are not well-suited for serving the developing world's needs in challenging environments (dusty and humid), in settings where electricity is not continuously available and where supply chains for replacement parts, repair and calibration services are uncertain. There is little evidence that the RetinoMax and SureSight devices will soon be integrated with improvements in eyeglass provision – for example, an on-demand, on-the-spot system for making and dispensing lenses for huge developing world markets, or a new way to deliver made-to-order glasses from a traditional spectacle lens and frame

manufacturing facility. Without a means to create new markets for dispensing glasses, these products will be poor competitors against an integrated solution that gets both the right prescription and makes the right lenses on the spot.

Table 1. Overview of Competition vs. RetinoMax & SureSight
(**bold + +** means major advantage to in its targeted market segments; **bold - -** means major disadvantage to ; + and – means some advantage and disadvantage, respectively, to)

	U.S./Europe Traditional	U.S./Europe non-traditional	Developing World traditional	Developing World non-traditional
Price	**+ +**	**+ +**	**+ +**	**+ +**
Brand Name and Power	**- -**	-	**- -**	-
Established Distribution	**- -**	-	-	-
Speed of measurement	**- -**	-	-	-
See-through fixation target	+	**+ +**	+	**+ +**
Maintenance costs and product uptime/lifetime	+	**+ +**	+	**+ +**
Accuracy, correction of measurement biases	+	+	+	**+ +**
Integration with innovative lens dispensing to provide eyecare solution	+	n/a	**+ +**	**+ +**
Attention and focus on bottom-of-the-pyramid marketing	n/a	n/a	+	**+ +**

Pricing and Revenue Model

With the exception of the non-traditional developing world market, prices across the other three markets will be roughly similar. As actual cost of service and marketing information becomes available, prices to the distributor and buyer may be adjusted. The pro forma financials assume a uniform average selling price of $1,000, to simplify analysis. OptiOpia is, however, committed to tiered pricing and attaining economies of scale so that the most impoverished large-scale buyers will be able to afford and access our technology at or near cost. The stated commitment to do so was instrumental in obtaining a major grant from The Lemelson Foundation. The goodwill engendered by this commitment has also helped OptiOpia obtain a variety of

assistance and even assets; it will in the future help us recruit superior staff (including interns, informal advisors, board members, etc.) and excellent business and NGO partners.

Partnerships

OptiOpia has made informal contacts with numerous potential partners. Ongoing, discussions with eye care NGOs have helped us to define possible funding opportunities, paths and field testing projects for lens molding and auto-refractor technologies. Leading organizations with which we are engaging to deploy these technologies include: VisionSpring, Acumen Fund, Seva Foundation, ICEE, David Green of Project Impact, Helen Keller International and Eyesight International. For-profit entities interested in the lens molding technology have included Essilor (a leading French eyeglass frame and lens manufacturer), . VisionSpring's experiments in using markets in less developed countries to distribute reading glasses (which **can** be self-prescribed) are especially important to us. Much of our analysis of partnerships is appropriate to defer to a more confidential setting.

Proprietary Technology and Intellectual Property

There is an issued US patent #7,264,755 for the lens molder; we expect to file more during future development of both products. There is much prior art for auto-refractors but certain specific designs we develop will probably be defensible by patent in addition to trade secrets on certain design features. Trade secrets will provide a (temporary) defense while market and distribution relationships develop, relationships that OptiOpia expects to provide a sound basis for competitive advantage.

Business Model

OptiOpia will make most of its money by designing, manufacturing and selling auto-refractors, lens molders, and proprietary supplies for the molder; other sources will be device training, device maintenance and licensing molding technology for new applications. Existing channels of distribution and order fulfillment will be used to sell to trained eyecare professionals in more-developed countries (MDCs) and less-developed countries (LDCs). Direct marketing will sell to chains of LDCs' optician shops (e.g., the largest Mexican one has 550 shops). In the marketing section our planned marketing to US pediatricians and schools is described.

The largest LDC markets are harder to tap: primary health care workers, pharmacists, mini-entrepreneurs. We have detailed research and plan to access these customers using a franchise approach that captures profits from ongoing eyeglass sales. Partnering with large, market-influencing eyecare hospitals (e.g., Aravind) and NGOs is key for credibility and brand-building. Latin America offers promising "middle-tier" LDC markets for first entry. Mexico is accessible, large, logistically and legally easier, and a gateway to comparable middle-tier markets in rest of hemisphere.

OptiOpia will need to substantially increase its organizational capabilities in order to implement its business plan. Prior to completion of the design-for-manufacture (DFM) stage of auto-refractor product development, OptiOpia intends to add to its core executive team. As the product development approaches completion, a marketing group will be built to penetrate the different market segments targeted. For the roll-out of a franchise program, recruiting, management, and training staff will need to be added in the target countries.

Production Plan. OptiOpia will engage an identified product development contractor to perform manufacturing of early functional prototypes, and possibly to perform initial production and fulfillment. We will evaluate outsourcing of manufacturing to a contract-manufacturing firm when appropriate. Manufacturing entails the production of plastic parts and lenses, the production and assembly of the electrical components, assembly, packaging, quality control, inventory management and purchasing management. Many of these activities are commodity, low value added activities that are easily out-sourced to appropriate companies, such as Nypro or Flextronics. Some of these activities require careful control because the auto-refractor is a (lightly) regulated medical diagnostic device and because of industry standards in consumer optics. While an alternate and more capital intensive plan might involve acquisition of retail optician chains in cities in LDCs, at present management prefers to chart a path in which OptiOpia is a lean, capital-efficient operation using numerous contracted services.

Team

David Grosof, PhD, MBA, President and Founder.

Start-up consultant. Co-founder, Theregen. Assistant Professor, Ophthalmology, Washington University Medical School (St. Louis). NASA Ames research scientist (retinal imaging and eye movements). PhD (visual neuroscience), UC Berkeley; MBA, MIT Sloan School of Management. BA, Harvard College.

He is OptiOpia's one full-time employee. He was primarily responsible for the application to the Lemelson Foundation that resulted in OptiOpia's seed funding.

For five years, Dr. Grosof worked with entrepreneurs and investors as a biomedical technology start-up consultant. In that role he conceived and clarified financing strategy, introduced ventures to investors and made investor presentations, business plans, web pages, press releases, etc. He performed some business development tasks: partner selection/identification strategy, negotiation preparation, contract review and analysis, and directly participated in R&D collaborations. He improved legal support and helped bridge communication gaps between attorneys and non-attorneys. He performed competitive analysis. He identified candidates for co-marketing alliances, and for one firm directed and performed all facets of marketing an IT product to both academic computing centers and commercial drug discovery customers in biotech and pharma: marketing communications, advertising, sales force education and trade show sales.

Dr. Grosof has a useful and unusual combination of basic and clinical research experience in vision science and ophthalmology that he has specifically applied to retinal imaging, an important part of the auto-refractor development work. He has extensive experience with biomedical technology ventures and is directing corporate development for both the lens molding and low cost autorefractor technologies at OptiOpia.

Saul Griffith, PhD, Chairman and Founder

Saul Griffith. Founder, Inventor.

Founder & CEO, OtherLab (engineering / design studio - energy production (wind and solar), energy systems analysis, computational manufacturing, electric transportation, sustainable design, and science education).

Founder & former President, Makani Power (Google-funded wind power start-up).

Partner, Squid Labs. PhD: MIT Media Lab (Joe Jacobson advisor). Lemelson-MIT Graduate Prize winner. Inventor of smart electronic rope (Time Magazine top invention 2005). Co-founder ThinkCycle (open collaborative design). Co-author of book *HowToons.* Technical Advisor, Potenco.

On September 25, 2007, the MacArthur Foundation awarded Dr. Griffith a MacArthur Fellowship, popularly known as the "genius grant."

Dr. Griffith is the key inventor of both the auto-refractor and lens molder. He invented in order to meet the unmet needs he found in the field, after observing shortcomings of existing approaches. He continues to supervise, to supply ideas and attract great people to OptiOpia as Chairman, while engaged full-time on other projects.

Dr. Griffith's high-profile academic distinctions and first-authorship of a *Nature* paper on self-replicating robots, infectious enthusiasm for exciting children's interest in engineering (co-author of the 2007 book *Howtoons* http://www.instructables.com/group/howtoons/), his leadership of a high-profile Google-funded cleantech firm Makani Power and recent MacArthur Fellowship have attracted considerable press attention. The resulting publicity has proved to be helpful in securing the attention not only of journalists but also of philanthropic organizations and private investors for OptiOpia.

Bruce Moore, O.D., Clinical Consultant

(Doctor of Optometry). Marcus Professor of Pediatric Studies and Chairman of the Department of Specialty and Advanced Care at the New England College of Optometry, Boston, Massachusetts. Dr. Moore is an internationally recognized expert in children's eyecare and glasses, and has been active in both research and policy

formulation to help diagnose and treat children who need eyeglasses and eyecare early enough to help them learn and to prevent the permanent visual impairment called amblyopia. Dr. Moore is excited about leading the clinical equivalency studies and eager to get a field-appropriate auto-refractor deployed to maximum effect.

Daniel J. Laser, PhD, Consultant

Daniel J. Laser, PhD. CEO, Wave 80 Biosciences. PhD (Mech. Eng), Stanford. He led Wave 80's development of a fully automated, portable assay for malarial antigens, the first field-use modular instrument with full immunoassay multiplexing functionality. Dr. Laser is a good executive who has provided invaluable guidance in shaping OptiOpia's product development plans, implementation, use of contractors and numerous aspects of both project and general management.

Prior Financing

Briefly, grants have financed product development, totaling $650,000 and there have been various hard-to-quantify in-kind contributions. Details: OptiOpia has received and is spending a $300,000 grant from The Lemelson Foundation primarily to develop the auto-refractor. OptiOpia was founded in 2008 as a spin-out from Squid Labs, LLC, an engineering partnership. In 2005-6 Squid Labs secured a SBIR Phase 1 grant of $100,000 to develop the lens molder. OptiOpia also acquired various rights to the auto-refractor and lens molder, as well as market research, from the now-dormant Low Cost Eyeglasses, Inc., founded by Saul Griffith with Neil Houghton in 2001, which had contributed to initial development of both technologies by writing a successful SBIR Phase I grant ($100,000) for a novel prototype auto-refractor. The founders and Squid partners have also invested tens of thousands in various expenses.

Financing Sought and Use of Proceeds

OptiOpia seeks $3 million in additional financing. OptiOpia will use contractors for much of the auto-refractor's product development and contract manufacturers for initial production.
28% ($850,000) to complete the design for manufacture of the auto-refractor, make some prototype devices, and to perform and publish human clinical testing to establish the clinical equivalency of the auto-refractor to the clinical "gold standard" method of retinoscopy.
13% ($400,000) to establish international marketing operations in entry markets, including partnering on operational field trials of the auto-refractor (e.g., with Aravind Eye Hospital, NGOs).
58% ($1.75M) (possibly in tranches) to complete productization of the lens molder. Fewer funds would cause exclusive near-term focus on auto-refractor development.

Summarized Financials will follow shortly.