Business Plan

CONFIDENTIAL

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Company Overview

PhotoniCare, Inc., a C-corporation located in Champaign, IL, was spun out of the University of Illinois at Urbana-Champaign (UIUC) in 2015 to re-define the standard-of-care for screening, diagnosing, and treating middle ear disease. The founders recognized that current instruments' non-invasive visualization options are archaic, simplistic, and inaccurate for evaluating the middle ear, resulting in highly subjective decision making and a very unclear picture of the health of the middle ear. However, these methods are relied upon to diagnose and guide treatment for ear infections, which occur in nearly 100% of all children, and often lead to hearing and learning impairment [1]. **Middle ear infections are the most common cause of hearing loss in children and responsible for more surgeries than any other childhood disease.** In response to this clear need, the founders have developed innovative technology that can see through the eardrum to directly image the middle ear itself.

A compelling problem

PhotoniCare has identified an acute need for better screening and diagnostic tools for middle ear disease. The current state-of-the-art tool for diagnosing *otitis media* (middle ear infection) is the otoscope, which is a tool comprised of simply a penlight and a magnifying lens. The tip of this device is placed into the ear of patients to observe the surface of the tympanic membrane (eardrum) and gauge the health of the underlying middle ear. Physicians evaluate visual markers, such as the color, opacity, and placement (bulging vs. retracted) of the eardrum in a qualitative and subjective manner [2] (see Figure 2). Due to the subjectivity in this exam, research literature reports sensitivities and specificities ranging from 50-75% among expert physicians [3, 4], which is quite poor. Additionally, pneumatic otoscopy, a form of otoscopy that, when performed correctly, qualitatively evaluates the mobility of the tympanic membrane by modulating the ear pressure, raises the sensitivity and specificity to 70-90%, respectively. However, this type of otoscopy requires obtaining and maintaining a seal of the ear canal. Consequently, very few physicians actually use this exam due to the inherent difficulty in sealing the ear canal as well as the increased subjectivity of interpreting findings.

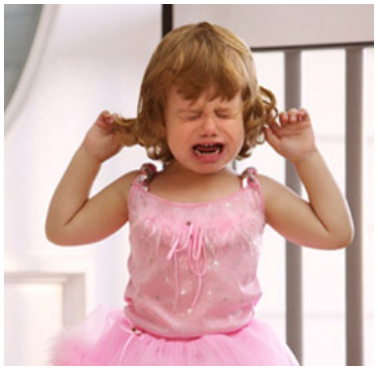


Figure 1. Virtually every child will experience an ear infection. And 40% of children will suffer chronic episodes of the disease.

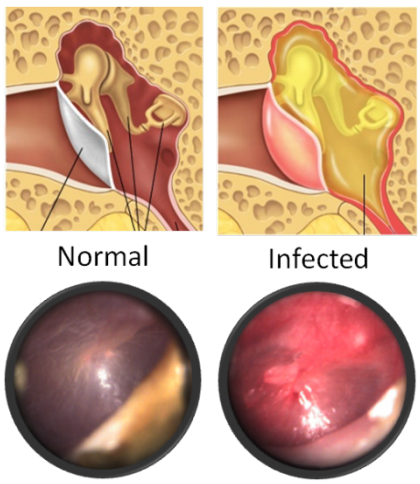


Figure 2. Otoscopy, the current gold standard for diagnosis, consists of a pen light and a magnifying glass. As a result, nearly half of all cases of these infections are misdiagnosed.

The limited diagnostic power currently available to physicians for assessing middle ear infection results in poor patient outcomes, and has contributed significantly to the over-prescription of antibiotics and the rise of antibiotic-resistant bacteria. Since there are no clear, objective rules or quantitative indicators to better govern the proper prescription of antibiotics, over-prescription of antibiotics is very common. In the ear, nose, and throat (ENT) specialist's office, children who have suffered repeat middle ear infections over many months will often receive strong antibiotics or, ultimately, surgical intervention to address the infection. **Myringotomy with tympanostomy tube placement is the most common surgical procedure performed on children under general anesthesia**, with more than 1M procedures annually in the U.S. alone [1]. This

represents an estimated $4B in healthcare expenses. The decision to place tubes is currently driven by the same subjective methods used to initially diagnose middle ear infections, thus it is widely believed that, like antibiotic prescription, this procedure is overused [5]. In fact, in 2013, the National Summit on Overuse named this surgical procedure one of the top five most overused procedures in the U.S. healthcare system (http://www.jointcommission.org/assets/1/6/National_Summit_Overuse.pdf).

An elegant solution

PhotoniCare has developed technology that increases clinical diagnostic accuracy by providing direct visualization and improved assessment of the middle ear for infection. The *ClearView*™ device has been designed to be used like a traditional otoscope, with one notable exception. The key distinction between this novel handheld tool and any other device available to clinicians is that the *ClearView* is capable of imaging THROUGH the eardrum and into the middle ear space. The underlying technology works similarly to ultrasound imaging, except near-infrared light is used instead of sound waves. This enables (1) higher resolution than ultrasound, with typical resolution on the order of 5-20 microns, and (2) easier imaging, by not requiring water or gel as a coupling medium. The result is high-resolution images of the middle ear space, without cutting the eardrum open. This unprecedented view into the middle ear enables physicians to visualize and characterize middle ear pathology, like effusions, biofilms, cholesteatomas, and retraction pockets, through the intact eardrum.

This fundamentally changes our ability to manage middle ear disease. Not only can effusions be accurately identified (currently, primary care providers do this with ~50% accuracy), our device can also measure and quantify the purulence, or amount of pus in the fluid--a parameter linked to the need for antibiotics, but very difficult to assess by looking at the eardrum surface with an otoscope. This new imaging technology will result in more accurate diagnosis of purulent fluid in the middle ear, and lead to more appropriate use of antibiotics and more efficient referral for surgery.

Figure 3. The PhotoniCare ClearView handheld imager (top) is used in the same way as the traditional otoscope to view the surface of the eardrum (bottom left), but also see through into the underlying middle ear (bottom right).

Customers and market

PhotoniCare's *ClearView* otoscope will be of interest to any of the 400,000 healthcare clinicians trying to diagnose ear infections each day in the U.S. This includes pediatricians, family practitioners, general practitioners, physician extenders (nurse practitioners and physician assistants), and ENTs. Assuming four clinicians in a given clinic share one of these devices, there are a potential 100,000 placements for the *ClearView* otoscope in the U.S. This represents >$80M annual recurring revenue (ARR) at ~25% penetration of this market.

The target customer segment for the *ClearView* otoscope is the pediatrician. There are more than 50,000 pediatricians in the U.S. Pediatricians hold the responsibility of screening, diagnosing, and

treating ear infections until they worsen to the point that specialty intervention is necessary. The value for this market is more accurate diagnoses in order to more optimally target the use of antibiotics, which are currently highly overprescribed, resulting in wasted resources and the promotion of antibiotic resistance. Improving the ability of a clinician to determine the presence of fluid will improve treatment and outcomes by ensuring chronic fluid diagnosis (largest reason for long-term hearing loss) is not missed, and by ensuring that ears that do not need antibiotics do not receive them. This could greatly improve patient outcomes in chronic cases where hearing fidelity and learning development are at risk. This target market represents ~$10M ARR at 25% penetration.

Competitive advantage

Intellectual property & research and development: PhotoniCare has exclusively licensed four patents to technology developed at UIUC and invented by PhotoniCare's founders. Additionally, PhotoniCare has filed four patents of its own. These are strong, broad patents that cover the full scope of our differentiating technologies, and provisional applications have been filed for complementary technology. The Biophotonics Imaging Laboratory, where this technology was invented, is considered among the most innovative labs in the world in the field of biomedical optics and imaging. It is expected that further IP developed out of the founders' lab at UIUC to support this technology will also be licensed in the future. We are not currently aware of any other technology on the market that can non-invasively visualize the contents the middle ear, safely. In addition to a competitive advantage through IP, the founders are the leading experts on this near-infrared optical imaging handheld technology, having helped to pioneer the field and drive innovations essential to successful translation of this technology to many clinical applications.

SBIR & contract funding: Since 2015, PhotoniCare has successfully received more than $2.3M in non-dilutive grant and contract funding from the NIH, NSF, FDA, and others. Cumulatively, the founders have won more than $50M in academic and business grants over their careers. We have a very good track record for grant funding, and will continue to leverage this strength and competitive advantage moving forward. This enables us to pay for technological and clinical de-risking without using investor capital. This enables investor capital to be focused exclusively on growing and scaling the business.

A technology platform to grow from: While initial efforts are focused on the *ClearView* otoscope as our first product, we have shown in peer-reviewed publications that this same handheld technology can also be used to image other tissue sites, such as the anterior and posterior segments of the eye, the skin, the oral cavity, and the teeth and gums [11]. These additional applications could be developed as a future line of separate products, or as attachments to the base imaging unit. We have previously developed working prototypes (and corresponding IP) able to image all of these tissue sites with a single base imaging unit in a single clinical setting, by using interchangeable tips for each new tissue site.

A world-class development team

PhotoniCare has assembled a team of top engineers, physicians, regulatory and reimbursement specialists, business development, and sales and marketing experience. Our team is detailed further below, but we have made a point to go out and fill in expertise gaps in the founding team with relevant experience, either in direct hires, consulting, or advisory roles.

PhotoniCare has competed in many competitive contests and received many awards since its inception, including an early funding award from a national award-winning technology incubator, an NSF I-Corps award, selection as a mentee company of Chicago Innovation Mentors, an NIH Commercialization Assistance Program award, first place award in the CIMIT CRAASH program (an accelerator out of Mass. Gen. Hospital, Boston), second place award in the 2016 Chicago Innovation Awards business plan competition, and acceptance into a top-10 venture accelerator: Dreamit Health, Philadelphia. Our participation as a Fall 2016 Dreamit company provided significant value to our growth by facilitating connections to executive teams at many large providers, payors, and large medical device and pharma companies. Additionally, Dreamit helped us refine our story and go-to-market strategy and facilitated curated introductions to dozens of investors on the east and west coasts.

InnovateHER

Ear infections are the leading cause of hearing loss in children and the most common reason children are taken to visit a doctor. While the clinical costs to manage the disease are high, at $6-10B, the indirect costs to the families that have to suffer them are nearly as high. It is estimated that more than $3B is sacrificed each year in the U.S. by mothers, fathers, and other caretakers that must miss work to take care of a child with ear infections, take them to the doctor, etc. As the most common reason for pediatric office visits, it is a huge burden to families around the world financially, emotionally, and physically.

The worst part is the helplessness felt on the part of the mother or father, who must settle for a staggeringly low standard of care for such a highly prevalent and potentially life-altering disease. If we were told when we walked in for a colonoscopy that there was only a 50% chance it was going to yield the correct diagnosis, there would be many fewer colonoscopies and many more cases of undiagnosed colon disease. While children rarely die from ear infections (severe cases can lead to meningitis), this disease still has an incredible impact on their quality of life. Imagine wearing earplugs when you are trying to learn to speak and interact with those around you. How incredibly frustrating that would be. This is reality for ~30% of all kids, who suffer from chronic fluid in their ears. When this fluid goes undiagnosed, it is often not caught until months later, because the child is often too young to articulate the problem properly. It is incredibly sad that we don't have a better solution so children can get the care they need, and mothers and fathers can be spared the frustrating process of a child with chronic ear infections.

Part of the story and motivations behind PhotoniCare is a personal one. Ryan Shelton, our CEO and co-founder, has three children under the age of five, and all three have suffered through chronic ear infections. Ryan's three-year-old son is still in speech therapy because of the chronic fluid that he dealt with in the first 18 months of his life. And Ryan's 1-year-old daughter was recently scheduled for tube surgery. Dr. Shelton understands this disease from the patient's perspective and is extremely passionate about building a better solution.

ClearView product line

Product description

PhotoniCare's vision is to empower clinicians at the front lines of healthcare with tools that enable fast and accurate diagnosis of common diseases. We are starting by revolutionizing care for ear infections with the *ClearView* otoscope product. This product is a small, portable base unit with a screen that can be hung on a wall or placed on a flat surface using its stand. The handheld device resembles and is used exactly like a traditional otoscope, so very little training is required.

The user is presented with two streaming video images on the display. One is the standard otoscope view they are used to. The other is the depth-resolved image showing the contents of the middle ear in real time. Using a button on the handheld, the user can easily save data when they see something interesting. The device saves retroactively, so a small delay from the user won't result in missing the data they wish to capture.

Improvements we plan to make to the device in the coming months before our FDA submission include a small circular screen on the back of the handheld so users can see the image of the eardrum without having to look over at the screen on the base unit. This will improve ease-of-use and enable the user to focus on the patient. Another improvement is ergonomics of the handheld device. We are currently conducting user feedback studies to ensure our aesthetic and ergonomic design of the handheld is consistent with our users' needs. Additionally, we are working on algorithms to automate analysis of the images to further simplify ease-of-use of the device and data interpretation.

A demo of the device on a child with un-diagnosed (and therefore untreated) chronic fluid can be found at the following address: https://www.youtube.com/watch?v=JXVmy6Amo7s&feature=youtu.be

This demo was taken quickly with an iPhone, but shows one of our current prototypes used by a physician on a 5-year-old patient. A voiceover explains the demo, so sound is recommended.

Intellectual property

PhotoniCare currently has eight patents, four of which are exclusively licensed from UIUC. These cover the full scope of our product, including proprietary consumables and attachments for additional tissue sites for future expansion. Additionally, we have other patents for complementary products to fill our pipeline as we grow the company.

Competitive Analysis

Our unfair advantage is that we are the only technology we are aware of on the market or in development that is actually visualizing and measuring the disease in the middle ear. All other technologies are looking at or measuring the surface of the eardrum in some way, which will always have accuracy concerns, because the disease lies behind the eardrum. Here are some descriptions of our closest competitors:

OtoNexus - Developing a point-measurement Doppler ultrasound device to measure motion of the eardrum. This technology requires a seal of the eardrum (significant adoption barrier) and only measures information from the eardrum surface. Additionally, the measurement is confounded by amount of fluid in the ear--a huge challenge. Has yet to be validated in human studies.

Welch Allyn - Market leader of otoscopes and tympanometers, devices that measure the characteristics of the eardrum. While tympanometers can achieve reasonable (~80%) accuracy, they are very difficult to use and as a result have very poor adoption amongst primary care clinicians. Otoscopes are ubiquitous, but lead to very poor (50%) diagnostic accuracy.

CellScope - Smartphone otoscope. Attachment to turn a smart phone into a video otoscope. While this is an interesting concept for at-home applications, it still results in the poor diagnostic accuracy standard otoscopes suffer.

Pricing Strategy

Through extensive market research and customer feedback, we have decided on a razor/razorblade pricing model. We will lease the device to customers for free or for a nominal annual fee (e.g. $500), then charge for our premium proprietary disposables, which must be used for each exam. This reduces the barrier for adoption by enabling a clinic to trial a device without a capital purchase. As part of the lease, we will require a minimum annual purchase agreement on tips to reduce our exposure on the contract. While final pricing per-tip has not been finalized, from ongoing market research we expect it to fall between $3-10 per tip. Assuming reimbursement of $16-30 per exam using our new codes (described in a further section), this pricing is quite reasonable to the physicians we've spoken with.

Go-To-Market Strategy

PhotoniCare has three primary markets for its *ClearView* device: primary care clinics, ENT clinics, and retail clinics (e.g. Walgreens, CVS, etc.). Each of these markets will require different channels, so it is very important that we choose how we will focus our resources. Our initial target market will be pediatric clinics in teaching and research hospital settings. We've received strong feedback from this early adopter segment, and many of the thought leaders and key opinion leaders in the otitis media space are in this segment.

We will begin with a missionary direct sales team of 2-3 reps, and focus hard on this first target market. The razor/blade model we are planning allows new customers to evaluate the technology at lower risk than if they were to purchase outright. The missionary approach is important early on, as this technology provides new information to the users. It will be most effective to establish some adoption and product interest that a distributor can then leverage to fuel an effective scalable distribution strategy. We expect to transition to distribution channels within 18 months of product launch. We are currently building relationships with several potential channels, such as Henry Schein, Welch Allyn/Hill-Rom, and others with significant channels in the primary care markets.

Marketing will be driven by tradeshow exhibitions, ads in trade magazines, and direct calls and visits to larger institutions. We have already generated significant interest from most of the key opinion leaders in otitis media across the globe after a successful booth expo at the world's largest meeting on otitis media, held in Australia in June 2017. We intend to capitalize on this momentum as we maintain these relationships through our product approval and market release.

Our OUS strategy includes early interest from distributors and physicians in Japan, UK, and China. We will expand to these markets after CE marking, expected in 2018.

Finally, to briefly address the other markets mentioned above, we have strong relationships with channels into both the retail clinic market and ENT market. Walgreens approached us earlier this year, and, after multiple meetings, they indicated that they desire to pilot our device in their Healthcare Clinic setting once we have secured our FDA approval. This market is very interesting, as there are only a few very large customers, so sales into this market can be very efficient. The ENT market can be reached through direct sales, and several distributors we have spoken with have channels into this market. We anticipate to have early adoption and pull from this market, as the ENT market is generally always interested in new tools and have been very positive in their feedback to us thus far.

Additionally, Joel Weinstein, one of our board members, was the founding VP of Sales & Marketing at Hologic, a large medical device company. He is advising us in our go-to-market strategy and will be instrumental in helping build our sales team, distributor relationships, and sales strategy.

Communication

We will utilize several methods of communication to reach our customers. For all customers, direct sales will be driven by an experienced sales team who will make **direct contact** with customers through phone calls and demonstration visits. Our **website** will be used to inform potential and current customers of our products' capabilities, provide initial customer support through technical support inquiries and live chat, and educate potential users of the problems concerning middle ear disease, as well as the unique solutions our products can provide for these problems. **Trade conferences** frequented by our customer groups will be consistently attended and product demonstrations will be brought for additional exposure. In fact, earlier this summer we held our first booth at the largest ear infection conference in the world in Australia. These shows are an excellent way to connect with our customers. Due to the technical nature of our products, we will work with early adopters and the Boppart lab at UIUC to **disseminate scientific findings** related to our products at annual meetings and through peer-reviewed publications. This will generate additional exposure and communication channels to our customers. Finally, **social media**, such as Facebook and Twitter, will be used to generate interest from the general population and potential patients for our products. This will also be a way to better connect with parents and patients in order to build brand awareness, create demand, and tell our story as it unfolds.

Revenue forecast

Figure 4 projects annual revenue for the *ClearView* otoscope over the first three full years of sales. The forecast assumes 12% cumulative penetration in 2021. Revenue is driven by recurring purchases of our proprietary disposable tips, although ~10% of revenue comes from annual lease agreements for use of the device.

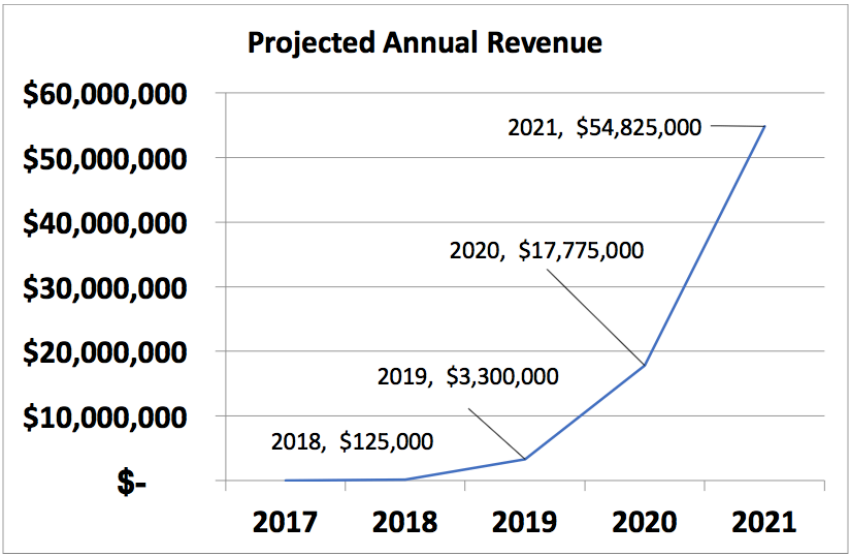


Figure 4. Five-year projected annual revenue.

Operations

PhotoniCare roadmap

The following table shows major tasks and milestones across all areas of business activities over the next five years. Alongside these anticipated activities and milestones are expected financings and potential exit events. This data has been compiled based on our current business development, product development, reimbursement, and regulatory strategies and is consistent with our pro-forma financial projections.

	H1 2017	H2 2017	H1 2018	H2 2018	H1 2019	H2 2019	H1 2020	H2 2020	H1 2021	H2 2021
CPT III codes obtained	■									
Seed Preferred financing	■									
Beta prototype		■								
Production prototype		■								
FDA approval			■							
Potential Exit #1			■							
Series A financing			■							
Clinical trials			■	■	■	■				
Product launch				■						
CPT I codes obtained					■					
>$1M ARR					■					
Potential Exit #2					■	■				
Series B financing						■				
>$10M ARR							■			
Break-even								■		
Potential Exit #3									■	■

To accomplish the activities above, we expect to staff up according to the hiring plan shown in the table below. Note that this model assumes direct sales as our sole sales channel. We expect to transition to distribution partners in 2019, but we left the full direct sales buildup to ensure our projected capital needs are conservatively high. Sales and marketing payroll will be much lower after a transition to properly leverage distribution channels.

HeadCount	2017	2018	2019	2020	2021
CEO	1	1	1	1	1
COO	0	0	1	1	1
CTO	1	1	1	1	1
CFO	0	0.1	1	1	1
Director of RA/QA	0	0.5	1	1	1
Director of Clinical Dev.	1	1	1	1	1
Director of Sales/Marketing	0	1	1	1	1
Engineers	2	2	2	2	2
Technical Sales	0	1	3	10	25
Administrative	0	1	2	3	6
Technical Support	0	0	1	2	3
Total	**5**	**8.6**	**15**	**24**	**43**

PhotoniCare team

Ryan Shelton, PhD | CEO, co-founder

Dr. Shelton is a passionate and motivated business-focused engineer with a profound personal connection to the problem PhotoniCare is solving. He received his B.S. in Electrical Engineering from Oklahoma State and his Ph.D. in Bioengineering from Texas A&M University. He has been building optical imaging systems for 12 years and managing engineering teams for 10 years. He leads PhotoniCare as its CEO and drives the company's long-term vision and strategic plan. He has experience negotiating and executing various research contracts, license agreements, and other business development activities. Dr. Shelton is full-time in PhotoniCare.

https://www.linkedin.com/in/ryan-shelton-92289231/

Ryan Nolan, MEng, CCRP | Director of Clinical Development, co-founder

Mr. Nolan is an experienced biomedical engineer and clinical research specialist, and currently serves as PhotoniCare's Director of Clinical Development. He received his B.S. in Bioengineering from University of Pittsburgh and his M.Eng. degree in Biomedical Engineering from Cornell University. He is a CCRP-trained Clinical Research Specialist with extensive experience developing and managing clinical studies and trials using new technologies in various clinical environments, as well as interacting with physicians and hospitals to optimize device design for utility and quality data generation in the clinic. Mr. Nolan is full-time in PhotoniCare.

https://www.linkedin.com/in/ryan-nolan-23841438/

Stephen Boppart MD, PhD | Chief Medical Officer, co-founder

Dr. Boppart is a distinguished professor of engineering at University of Illinois at Urbana-Champaign (UIUC). He received his Ph.D. in Medical and Electrical Engineering from the Massachusetts Institute of Technology in 1998, followed by his M.D. from Harvard Medical School in 2000. He directs a highly interdisciplinary lab of 25 researchers at UIUC that is focused on developing innovative optical imaging and diagnostic technology and translating these to clinical applications.

Through successful federal, foundation, and industry grants, awards, and gifts, he has brought in more than $40M in funding for his lab since he started as a professor in 2000. He has previously co-founded two other start-ups, one of which was acquired by St. Jude Medical. He has authored 40 patents and over 300 publications in the areas of optical coherence tomography and other optical imaging technologies and is a world-renowned thought leader in biomedical optics and imaging. Dr. Boppart is full-time faculty at UIUC, but is also employed 10% effort in PhotoniCare.

Wei Kang, PhD | Director of R&D

Dr. Kang is a self-motivated biomedical engineer by training with more than 5 years of experience in the medical device industry. Prior to joining PhotoniCare, he was a Principle R&D Engineer in St. Jude Medical (now Abbott), responsible for prototyping and developing complex *in vivo* optical imaging devices, which are now commercially available. He gained hands-on knowledge on critical aspects of product development, including clinical affairs, quality control, regulatory affairs, manufacturing, and supply chain, etc. He is a nature fit to PhotoniCare team, organizing day-to-day development activities. Dr. Kang received his Ph.D. degree in Biomedical Engineering at Case Western Reserve University, OH. Prior to that, he received his M.S. and B.S. in Biomedical Engineering at Tsinghua University, Beijing, China. Dr. Kang is full-time in PhotoniCare.

https://www.linkedin.com/in/wei-kang-5b78b625/

Andrew Zhang, PhD | Lead Engineer

Dr. Zhang is a creative bioengineer with a broad range of knowledge. He has 10 years of experience in the development of optical and electrical systems for biomedical applications. He received his Ph.D. in Electrical Engineering from Oklahoma State University and spent 3 years of post-doctoral training in Johns Hopkins University and University of Washington. He has authored over 40 publications in the area of biomedical optics. He leads the prototype development at PhotoniCare. He is passionate about making a real impact on healthcare quality for children. Dr. Zhang is full-time in PhotoniCare.

https://www.linkedin.com/in/anqizhang/

David Rodgers | Lead Software Architect

Mr. Rodgers is an experienced software developer with over 10 years of experience developing a variety of hardware-dependent and hardware-independent projects with varying performance constraints. He received B.S.s in Computer Engineering and Computer Science from Iowa State University. He designs and develops the software core for PhotoniCare projects. Mr. Rodgers is full-time in PhotoniCare.

https://www.linkedin.com/in/david-rodgers-55bb2525/

Board of directors

In addition to Ryan Shelton, the following members are on PhotoniCare's board of directors.

Gary Durack

Mr. Durack is a seasoned entrepreneur with 30 years of experience in biological and medical device development. He received his B.S. in Electrical Engineering from Purdue University. After a successful career with Beckman-Coulter, he founded and grew iCyt, which he successfully sold to Sony Corporation in 2009, marking Sony's first acquisition in the biotechnology space. Gary is an investor in the company and contributes to the business development efforts at PhotoniCare.

https://www.linkedin.com/in/garypdurack/

Joel Weinstein

Mr. Weinstein is an experienced medical device executive, serving as Hologic's first VP of Marketing, and later going on to lead several startups to successful market entry and growth. He received his B.E.E. in Electrical Engineering from City University of New York and his M.B.A. from Western New England University. He now works with the CIMIT accelerator in Boston assisting early stage medical device companies with marketing and business development strategies.

https://www.linkedin.com/in/joel-weinstein-4311b41/

Clinical Advisory Board

In addition to Dr. Ryan Shelton, Dr. Stephen Boppart, and Ryan Nolan, the following members are on PhotoniCare's clinical advisory board.

Andrew Thorrens

Mr. Thorrens is a seasoned reimbursement executive with 27 years of experience developing and executing reimbursement strategies. He has experience in all aspects of reimbursement and market access and, until recently, was Head of Reimbursement and Market Access at Allergan, plc. He assists with PhotoniCare's reimbursement strategy and execution. He is also an investor in PhotoniCare.

https://www.linkedin.com/in/andrewthorrens/

Michael Novak, MD

Dr. Novak is a pediatric otolaryngologist with 40 years of experience, with a primary specialty in otitis media and related diseases. He received his M.D. degree from Baylor. He has been working with PhotoniCare's technology since 2009, when it was first prototyped in the academic lab of the founders. Dr. Novak is a member of the American Academy of Otolaryngology and has extensive experience working with early stage medical products.

Michael Pichichero, MD

Dr. Pichichero is a pediatric infectious disease specialist, and the most published researcher in the world on otitis media, per www.ExpertScape.com. He received his M.D. degree from the University of Rochester. He is a world-renowned key opinion leader in the otitis media field, having founded and run the Rochester Regional Research Institute for 8 years, raising more than $20M in this time to advance

research in otitis media. His work on vaccines and antibiotic use has had tremendous impact on the standard of care for otitis media.

https://www.linkedin.com/in/pichichero-michael-588660b4/

Clinical Validation

Presently, the *ClearView* technology has ~15 peer reviewed publications, around half of which are clinical. These can be found on PhotoniCare's website (www.photonicareinc.com). They cover various aspects of the work our team has pioneered in this field over the past several years. Our first commercial study is nearly complete, and the results are quite compelling, with 93% sensitivity and 97% specificity for detection of fluid through the eardrum across more than 50 ears. Comparing this to otoscopy, which is typically 50% accuracy, suggests our approach could be a very strong solution for middle ear diagnosis. Below is a description of the study protocol and initial results.

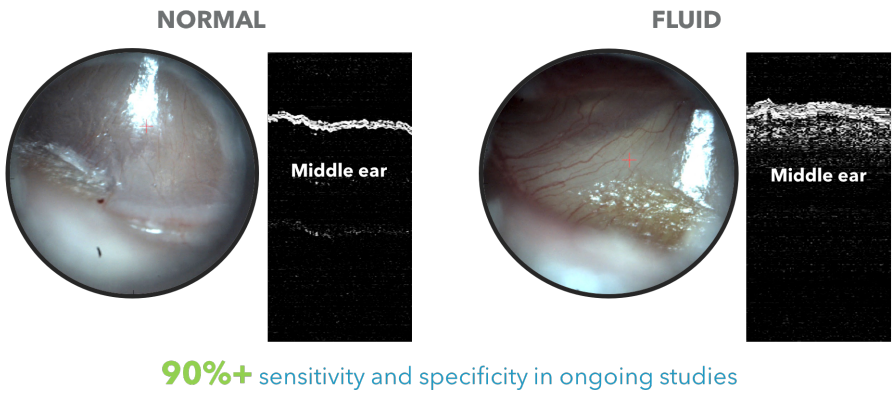


Figure 5. In our ongoing clinical study, preliminary analysis shows 93% sensitivity and 97% specificity for detection of middle ear fluid through the eardrum.

Goal: Conduct a clinical utility study using optical coherence tomography (OCT) to collect images of the middle ear space of subjects with middle ear disease to determine effusion presence.

Expected outcomes: Successful completion of this study will result in the collection and quantitative analysis of middle ear disease datasets. The data analysis is expected to demonstrate the feasibility, safety, and utility of OCT to directly visualize the middle ear space and the presence of middle ear infection effusions and biofilms.

Experimental Approach:

Primary care population: Subjects will be imaged with the PhotoniCare *ClearView* device on the day of their appointment with their pediatrician or family physician, particularly for appointments with ear-related complaint(s) and/or symptoms. Study control subjects will consist of otherwise healthy (no otitis media (OM)) patients undergoing a routine health appointment. Subject imaging results will be correlated with their medical records.

Otolaryngology population: Subjects will be imaged with the *ClearView* on the day of their regularly scheduled surgical intervention for recurrent or chronic OM while awaiting their surgical appointment. Study control subjects will consist of otherwise healthy (no OM) patients

undergoing standard cochlear implantation. Subject imaging results will be correlated with their medical reports, as well as confirmed post-myringotomy incision in surgery.

Initial Results:

Preliminary analysis on all collected data compares diagnostic use of the *ClearView* (read by an OCT expert) against clinical assessment by an otolaryngologist and post-myringotomy incision findings (fluid aspirated or not). Initial results demonstrate that use of the *ClearView* results in 93% sensitivity and 97% specificity for determining presence of fluid through the eardrum in an unsedated child prior to surgery. NOTE: In the cases that led to imperfect sensitivity and specificity, it was verified that the clinician imaged the patient in a location contrary to the prescribed use of the device (e.g. ear canal wall, earwax, etc.), resulting in an inaccurate reading. Removing these cases gives the ClearView device a perfect record thus far in the study for determining the presence or absence of fluid in the middle ear, through the in-tact eardrum.

Regulatory Strategy

PhotoniCare expects to submit its first 510(k) application for the *ClearView* product by the end of 2017. In preparation for this, we have met multiple times with the FDA CDRH review team, including one formal pre-submission meeting. In this meeting, the FDA agreed with our Class II 510(k) classification, our intended predicate devices, the study that will be required for our first claim, and the wording of our first claim. The wording of our first intended use claim will be:

> *"The ClearView imaging system is intended for use as an imaging tool in the evaluation of human tympanic membrane and middle ear microstructure by providing one-dimensional, real-time depth visualization."*

The study required for this claim is only a 25-patient observational study. We expect it to take 1-2 months at our local hospital, where we already have an ongoing collaboration established.

Table 1 Predicate FDA 510(k) approvals with reasonable equivalence

Date	Description	Number
05/11/12	Bioptigen - Ophthalmology	K120057
01/05/10	Vivosight - Dermatology	K093520
03/01/04	Imalux – Handheld (general)	K033783

Our first FDA claim, listed above, will allow us to enter the market and aggressively attack our target market beginning in 2018. Our second FDA claim will be adding quantitative analysis to our images to aid the user in diagnosis. This is expected to require a 150-patient study and will be completed in 2018 with an expected submission in late 2018. The ability to improve the ease of use of the device through this claim will increase adoption of our device and open up the broader general practitioner market.

Reimbursement Strategy

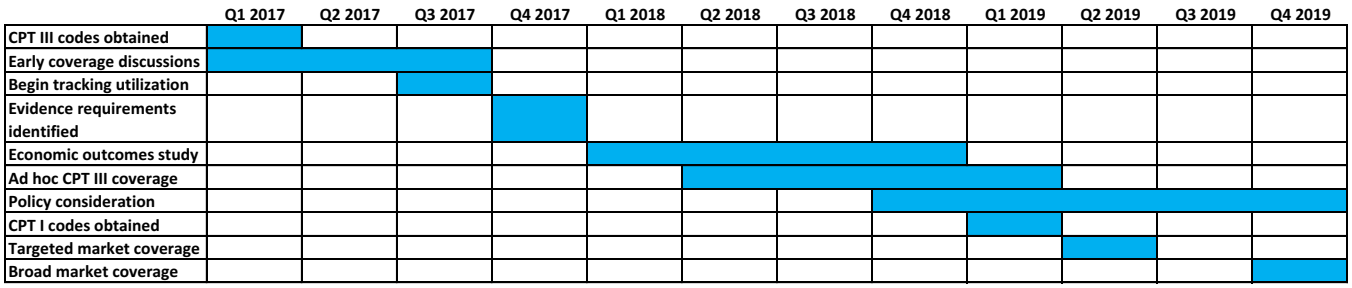
We recognize that widespread adoption of our *ClearView* device will be catalyzed by a billable reimbursement code to provide additional revenue to our customers using the device. We are addressing this immediately and in parallel to product development. In February 2017, PhotoniCare successfully presented two codes for consideration at the AMA's Current Procedural Technology (CPT) Editorial Panel Meeting. These codes were met with full support from all affiliated physician academies. The American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) co-developed the application with us. These codes were approved in March 2017 and will be active in July 2017.

We have excellent resources with which to develop and execute our reimbursement strategy. One of our founders has direct experience getting CPT codes for similar technology in other clinical specialties. One of our investors and clinical advisory board member was the former Head of Reimbursement and Market Access at Allergen, plc. Additionally, we work with Avalere, a top reimbursement and market access firm, located in Washington, D.C., to refine our reimbursement strategy and landscape assessment.

The *ClearView* device is capable of quickly and accurately assessing the presence of fluid in the middle ear, and characterizing that fluid to determine need for antibiotics. This feature alone is compelling support for coverage and payment of our reimbursement codes by insurance providers. Current tools result in 50% misdiagnosis of middle ear fluid by primary care physicians. This leads to significant antibiotic over-prescription, as well as failure to diagnose many cases that need intervention. Identification and characterization of fluid will be our first focus and the basis for our reimbursement and initial adoption.

By improving diagnosis early in the disease timeline, our device may decrease the number of surgeries required for otitis media, which is of great interest to payers. Otitis media was identified as one of the top-5 most overused procedures in the U.S. The *ClearView* device can quantitatively measure the amount of pus in an effusion. And in the cases of high pus content, stronger antibiotics may be more appropriate, even if it is in the first or second visit. Appropriately treating these infections based on direct information about the effusion contents will lead to faster resolutions of active infections and decreased chance for biofilm formation and chronic infection.

Timeline:



The above chart shows an expected timeline for reimbursement activities. Note that our codes can be used as early as July 2017, and once our product is FDA approved, these codes may be covered and paid on an *ad hoc* basis with commercial payers. CPT I conversion and widespread coverage is projected in 2019.

ROI analysis: It makes reasonable sense to model potential reimbursement for our diagnostic device after the use of similar imaging technology in the ophthalmologist's office. In ophthalmology, optical coherence tomography imaging systems are used to screen for and diagnose anterior and posterior eye disease. Depending on which portions of the eye are imaged, reimbursement can range from $36-45 in a single visit or up to $81 across two consecutive visits for imaging of both anterior and posterior segments. As a floor for our payment model, we can consider tympanometry reimbursement, which is paid at $16 per scan, but provides much less information than the *ClearView*. Tympanometry is a device that uses sound and pressure to measure the transmission of energy through the eardrum, but the device essentially measures mechanical properties of the eardrum itself, not a measure of the contents behind it. The *ClearView* would be a complete replacement for a tympanometer.

With this information, we can then perform ROI analysis. PhotoniCare plans to use a razor/blade pricing model, where the device is leased to the customer in a minimum purchase agreement for our proprietary disposable tips. While pricing for these tips is still being explored, based on market analysis data let's assume for this analysis they are priced at $5 each. Under this razor/blade model, the customer ROI is quite straightforward. Every time the clinician uses our device in a reimbursable exam, their profit would be the amount of the reimbursement, less the $5 they paid for the tip. This ensures a healthy ROI from the first day they use the device. If, instead, we assume a total value of the minimum purchase agreement, we can calculate a payback period required to recoup the costs of that contract. For instance, if we assume a minimum purchase agreement of 1,000 tips, the annual contract cost would be $5,000.

With a reimbursement range of $16-45 to consider, if we assume minimum purchase contract of $5,000 for the *ClearView* device we can begin to make estimates for the annual patient volume required for a 1-year or shorter return on investment of contract (i.e. <1-year payback period, which is considered acceptable by most hospitals and clinics). In the case of $16 reimbursement, the contract would pay for itself within 1 year if a conservative 1.25 patients were imaged per day ($5,000 / $16 / 250 days = 1.25). In the case of $30 reimbursement, use of the *ClearView* device would recoup the contract costs within 1 year if 0.67 patients were imaged per day. Finally, in the case of $45 reimbursement, the *ClearView* device would pay for itself within 1 year if 0.44 patients were imaged per day.

During the flu season, an average pediatrician or urgent care clinician may see 6-12 children per day with complaints of ear pain. We believe payback periods of 2-3 months will be achieved by our customers.

Financial Plan

Past and current funding

In June of 2015, PhotoniCare closed on $250,000 in early seed funding. Since that time, the company has been funded primarily through $2.1M in non-dilutive grants. Presently, the company is closing on a $1.5M Series Seed equity financing, led by Almond Tree Capital. The first close will occur on June 26, with a final close by August 31. This financing will fund PhotoniCare through its first FDA approval, expected in Q1 2018.

Future funding requirements

In addition to the Series Seed round we are presently closing, we will expect to raise $4M Series A in Q2 2018 to support product launch, which will get us to $2M ARR in late 2019. At that point, PhotoniCare will either exit, or raise a Series B growth round of $6M to reach break-even in 2021.

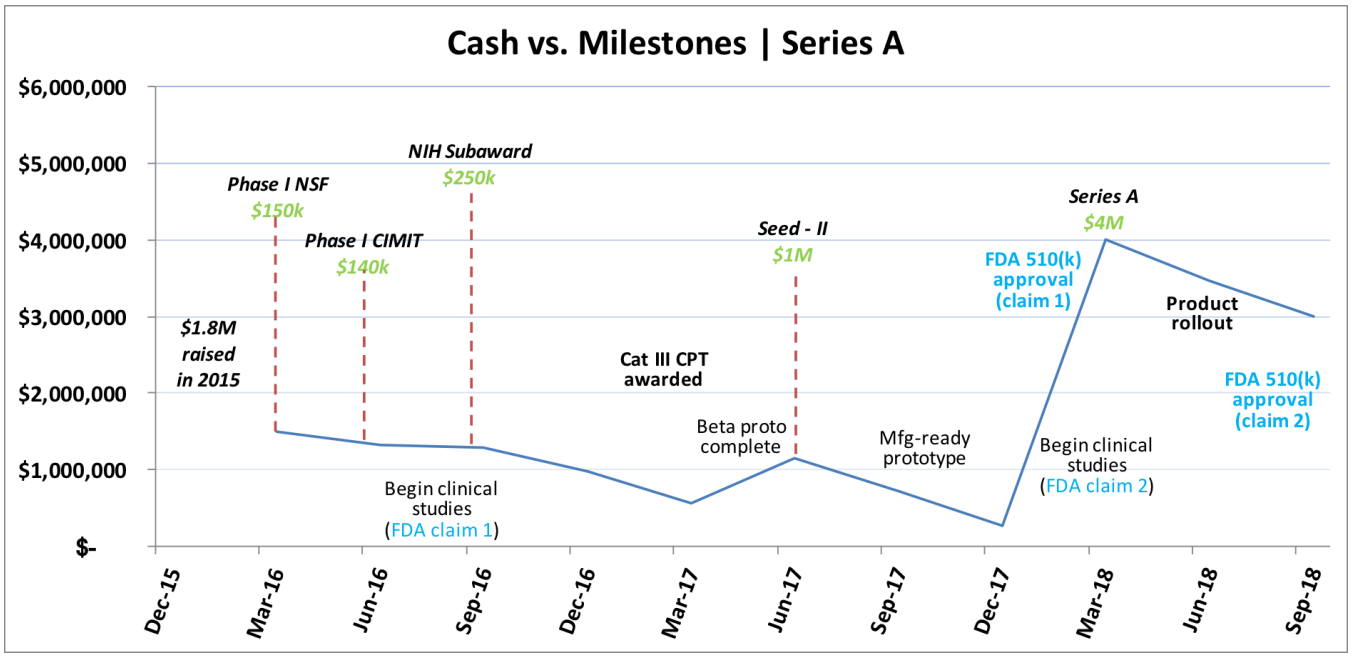
It is important to note that PhotoniCare will apply for a continuing renewal of our large NIH grant in September, providing an additional $2.5M for clinical and technical development, if funded.

Pro-forma income statement

PhotoniCare
Net Operating Income (Loss)

	2017	2018	2019	2020	2021
Revenue (Includes Grants)	$ 800,000	$ 1,375,000	$ 4,550,000	$ 17,775,000	$ 54,825,000
Cost of Sales	-	417,500	5,028,000	12,865,500	27,010,500
Gross Profit (GP)	800,000	957,500	(478,000)	4,909,500	27,814,500
GP %	100.0%	69.6%	-10.5%	27.6%	50.7%
Operating Expenses					
Sales & Marketing	7,500	448,876	1,141,556	2,756,748	6,112,052
General & Administrative	232,476	393,433	827,588	1,110,780	1,650,304
Research & Development	1,152,376	1,515,938	1,241,432	1,261,124	781,408
Total Operating Expenses	1,392,352	2,358,247	3,210,576	5,128,652	8,543,764
Net Operating Income (Loss)	$ (592,352)	$ (1,400,747)	$ (3,688,576)	$ (219,152)	$ 19,270,736

Cash flow vs. Milestones



Exit considerations

We have identified three logical exit points:

The first is immediately following our FDA approval, prior to our Series A raise. This would be a strategic acquisition to a medical device company that would want to leverage their channels to sell our innovative and disruptive *ClearView* device.

The second is just prior to our Series B raise (late 2019) with $2M ARR. This could be a sale to a medical device company (e.g. Welch Allyn), a distributor (e.g. Henry Schein), or even a clinical or retail partner (e.g. Walgreens/CVS).

The third potential exit is after we've passed break-even and are a profitable company in 2021. At this point, we project $50-75M ARR, which opens up a larger amount of potential buyers, such as medical device, distributors, retail, or private equity and holding companies. An acquisition at this stage would be driven by a multiple on trailing revenue. Comparable exit analysis we've done internally shows a multiple of 4-6x among comparable companies, yielding a potential exit of $200-450M.

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