Business Plan

November 26, 2015

For

InnovateHER

A critically needed medical device
Improving the lives of children and families
And greatly desired by physicians

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EXECUTIVE SUMMARY

Middle ear infections are ubiquitous in childhood, having a huge impact on children, their families, and their caregivers. Very nearly every child in America – 93% by age 7 – will suffer at least one middle ear infection severe enough to have to see a doctor, and the vast majority of those children will suffer repeat occurrences, up to a dozen or more in childhood.

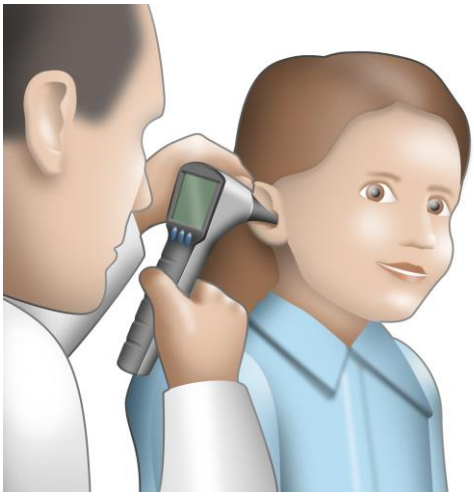
The impact on these children and their families cannot be overstated, yet there has been no real improvement in care in decades. Difficulty in accurate diagnosis leads to overtreatment and antibiotic resistance. Overprescription of antibiotics causes diarrhea, abdominal distress, and other side effects for the child; time is lost from work – usually, even today, by Mom or a female caregiver – to take the kids to the doctor and care for them while sick; and the lack of clear and accurate diagnoses leads to parental frustration and distress. So many children suffer repeat infections that it feels as if nothing has been, or can be, done to make matters better. In fact, there have been no major improvements in more than 40 years in the accurate diagnosis and treatment of middle ear infections.

Middle ear infections, called Otitis Media (OM), are the #1 indication for antibiotics in children, and the #1 reason for surgery in children, yet clinical studies show diagnostic errors averaging 50%, particularly in the key differentiation of viral vs. bacterial infections and the critical decision of whether an antibiotic is appropriate. The traditional response has been to prescribe antibiotics "just to be sure" because there is no clear way to differentiate when and when not to prescribe antibiotics. As we all know, it is critical that we reduce the use of antibiotics, and Otitis Media is an area of significant overprescription of antibiotics. We are now understanding that the effects are enormous for society and for the child. Antibiotic-resistant superbugs are on the rise, but for the individual child, it is worse; providing antibiotics when they are not appropriate can suppress the child's immune system response, meaning the child does not develop the antibodies necessary to build natural immunity and thus the child is actually predisposed to the next infection, and the next, and the next. Yet at other times, infections that need antibiotics go undetected, leading to surgery or permanent hearing loss. We desperately need a tool to instantly and accurately assess when and when not to prescribe an antibiotic for middle ear infections.

There has been little attention given to this significant medical issue with huge impact on families. Should we ignore this problem because it mostly affects children, and it is primarily women who deal with the consequences? We think not.

OtoNexus is developing the world's first medical device to provide the definitive, objective diagnostic data for the instant and accurate diagnosis of middle ear infections, called Otitis Media (OM), in children and adults. A simple and elegant solution, the device applies a well-known medical technology, Doppler ultrasound, in a completely novel way to achieve a key advance in differentiating when and when not to prescribe antibiotics. The device will provide data in seconds and will be easy to use by physicians or non-physician personnel (Nurses, Physicians' Assistants, etc.). Definitive, objective diagnostic data identifying both the presence and the type of fluid behind the eardrum **will lead to more accurate diagnoses, better treatment, better outcomes and significantly reduced costs.**

OtoNexus' ground-breaking, fully patented, transformative device uses a unique application of Doppler ultrasound through air to instantly and accurately diagnose middle ear infections in children and adults. *Otitis Media is the number one indication for antibiotic prescriptions in children, and is the number one cause for surgery in children.* 17.6 million cases of Otitis Media are diagnosed each year in the United States alone, at a cost that exceeded $5 Billion a year in 1996 data (the last year anyone cared enough to perform a full study), and clearly a much higher number now. Current diagnostic methods are decades old, highly subjective, and extremely ineffective; *clinical studies consistently show diagnostic error rates averaging 50%.*



As a result, patients often receive the wrong treatment and are referred to physician specialists more often than needed. As every parent can attest, recurrent middle ear infections are absolutely ubiquitous and have a huge negative impact on children and their families. Very nearly every child in America (93%) will suffer at least one instance of a middle ear infection severe enough to see a doctor, and the vast majority of those children will suffer repeat occurrences, up to a dozen ear infections or more in childhood.

The emotional and actual costs of the ubiquity of middle ear infections are tremendous. Time lost from work taking care of the sick child is just the tip of the iceberg. Frustration over inaccurate diagnoses or simply no ability to make a diagnosis adds to a parents' feeling of helplessness and frustration. **Both underdiagnosis and overdiagnosis lead to problems for the child, the parents, and caregivers.**

Overdiagnosis of Otitis Media is rampant; the CDC estimates that antibiotics are prescribed in approximately 85% of cases, yet should be prescribed in just 25% of cases, or less. Overprescription of antibiotics not only exacerbates the societal problem of development of antibiotic-resistant superbugs and significant individual side effects for the child such as diarrhea and stomach pain, but we are now coming to understand that giving an antibiotic too early or too often is actually making matters worse for the child. In these cases, the child's natural immune system response to the ear infection is suppressed, such that the child does not develop the antibodies needed to fight the infection, which then predisposes the child to the next infection, and the next, and the next. **We desperately need a tool that can clearly identify when an antibiotic is appropriate, and when it is not.**

The OtoNexus device is the first new technology in its space in over four decades and should dramatically improve the ease and accuracy of the diagnosis of middle ear infections, while significantly driving down cost of care. Unlike all current technology utilized for the diagnosis of Otitis Media, OtoNexus' ultrasound device is designed to objectively and accurately detect *both the presence and the type of fluid behind the tympanic membrane* (eardrum), allowing the physician or other practitioner to immediately make the correct diagnosis. While the appearance of the ear drum (as is commonly used for diagnosing OM) can be misleading in many instances leading to misdiagnosis, the OtoNexus device uses Doppler ultrasound to accurately determine the viscosity of fluid behind the tympanic membrane as means to more

precisely determine both the presence and the type of an infection, providing definitive diagnostic data to differentiate between states of no infection and various kinds of infection, including primarily viral or bacterial infections and "glue ear". No technology exists today (or that we could find anywhere, in existence or in development) that can provide these differentiations.

In 2013, the American Academy of Pediatrics issued strong new guidelines for the diagnosis, treatment and management of Otitis Media. These guidelines focus on reducing the use of antibiotics and increasing scrutiny on accuracy in diagnoses, stating, among other things, that antibiotics should only be prescribed when the diagnosis is unequivocal. The problem is that, **with current tools, the diagnoses are rarely unequivocal, especially in the difficult differentiation between viral and bacterial infections.** Thus, the physicians were given very clear guidelines, but no good tools with which to comply. The OtoNexus device will fill that gap.

OtoNexus has tested its device extensively with physicians who are the target market, to overwhelmingly positive response. Physicians struggle to comply with new American Academy of Pediatrics guidelines to only prescribe antibiotics when the diagnosis is unequivocal; the problem is, with today's technology and techniques, the diagnosis is almost never unequivocal, leaving the physicians with a very clear imperative but no good tools with which to comply. They clearly see our device as the tool to fill that gap. In market testing, they described its ease of use and the fact that it actually speeds the exam as excellent attributes, but were elated to finally find a tool that can definitively differentiate when and when not to prescribe an antibiotic for this ubiquitous, challenging medical problem. **100% of the more than 60 physicians studied said they will buy the device at the tested price.**

The Company also tested the device with insurance carriers, who are also strongly in favor. They clearly see the benefits of getting an accurate diagnosis from the very first caregiver the child sees, and estimate significant cost savings from the reductions in antibiotic usage and their side effects, reduction in the very high rate of referrals to specialists, and reductions in repeat infections and surgeries. Otitis Media is a major driver of cost in their healthcare systems, and they see substantial benefit from this device.

The OtoNexus ultrasound device will allow practitioners to increase the quality of care they provide to patients and improve patient outcomes by:

- **Greatly improving diagnostic accuracy and certainty**
- **Reducing unnecessary prescriptions of antibiotics**
- **Reducing antibiotic side effects and cost of their treatment, as well as societal effects such as the development of drug-resistant bacteria**
- **Speeding assessment time (while improving accuracy)**
- **Reducing unneeded specialist referrals and increasing quality of needed referrals**
- **Reducing repeat infections**
- **Reducing surgeries through earlier and better diagnoses**

In summary, in addition to improving patient outcomes through improved diagnostic accuracy, the OtoNexus device will have an enormous impact on reducing health care costs for this very common and highly disruptive medical problem, while having a very positive effect on children and their families.

OtoNexus Medical Technologies
Business Plan

THE PROBLEM

Medical practitioners diagnose 17.6 million cases of Otitis Media (OM: ear infections) each year, a condition which cost more than $5 billion in direct costs in the United States in 1996, the last year a full study was performed, and clearly a much higher number now. The current diagnostic methods are decades old, highly subjective, and extremely ineffective; clinical studies consistently show diagnostic rates averaging 50%. As a result, patients often receive the wrong treatment and are referred to physician specialists more often than needed, or worse, are not treated early enough.

Consequently, Otitis Media is both the #1 indication for antibiotic prescriptions in children and the #1 cause for surgery for children. Excessive antibiotic treatment from overdiagnosis of Otitis Media can lead to antibiotic resistance, significant side effects for the child, and increased drug costs. On the other end of the spectrum, under-diagnosis can allow the infection to progress, potentially requiring surgery or risking permanent hearing loss.

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Further, in 2014 the White House issued its *NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC RESISTANT BACTERIA*, which stated:

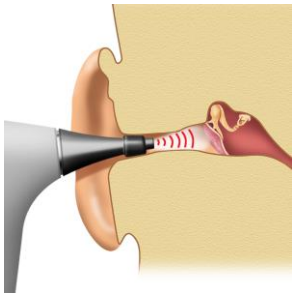
"The United States will work domestically and internationally to prevent, detect, and control illness and death related to infections caused by antibiotic-resistant bacteria by implementing measures to mitigate the emergence and spread of antibiotic resistance and ensuring the continued availability of therapeutics for the treatment of bacterial infections."

THE SOLUTION

OtoNexus is in the last stages of developing a Doppler ultrasound medical device (combined with the ability to visualize the ear drum) to *instantly and accurately characterize both the presence and viscosity of effusion fluid behind the eardrum* (the tympanic membrane, or TM). This vital information, represented as an image and a number reflecting viscosity, will improve diagnosis as well as allow practitioners to comply more closely with recently updated clinical practice guidelines of the American Academy of Pediatrics (AAP), such that antibiotics and/or specialist referral are provided only for the most appropriate cases.

This technology will be able to achieve a rapid, accurate assessment of both the presence and viscosity of any fluid behind the TM

even in an active, uncooperative patient. This would clearly be a significant improvement over all existing technologies, and is greatly desired by the medical community.



The OtoNexus system is a battery-powered hand-held "point and shoot" device – It is *Quantitative* (a numerical value is displayed); *Objective* (measurements are repeatable); *Simple* (no training required); *Fast* (exam under 5 seconds); and *Affordable.*

According to the AAP guidelines, *"devices that more accurately identify the presence of middle ear effusion and bulging that are easier to use than tympanometry during office visits would be welcome, especially in the difficult-to-examine infant."* The OtoNexus device will fill this gap and become the key tool for physicians to comply with these new guidelines.

Doppler ultrasound technology is well-established, and has been used for decades for the noninvasive measurement of blood flow, as well as other medical indications. While this application is novel, the team at OtoNexus is very experienced with Doppler technology and has been producing and marketing an FDA-cleared transcranial Doppler diagnostic device for several years.

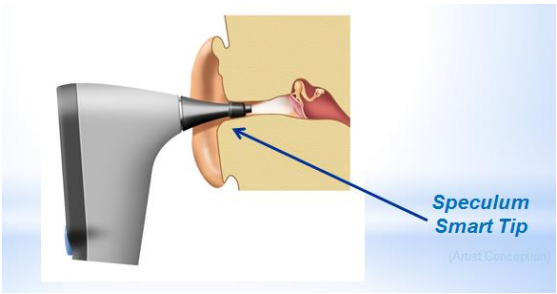
THE MARKET

The target market for the OtoNexus device is the clinics, offices, hospitals, and other sites with healthcare providers who treat children and provide pediatric care. Some examples include pediatric care offices, family practice offices, general practitioner offices, Primary Care clinics, Children's Hospitals, emergency rooms and emergency care clinics, rapid care clinics, and the drop-in treatment clinics that are becoming more and more common at Walmarts, large drug stores, and other venues. Our device is designed to be utilized by a variety of end-users (clinicians) at all levels of the medical care provision system, including physicians, ARNPs and NPs, physician assistants, nursing assistants, and other providers of care.

Our target market is large and can significantly benefit from the technology being brought to market. According to the CDC, 17.6 million doctor visits are coded directly to Otitis Media (OM) each year in the US by primary care physicians and emergency room physicians. Additionally, Otitis Media is the second most common childhood disease, second only to upper respiratory infection (the common cold), with a cost of over $5 billion spent on treatment in the US alone (1996 data).

Also according to the CDC, children make more than 205 Million doctor visits each year (2007 data, the most recent available). The two most common causes coded for these visits are Upper Respiratory Infections (common cold) and Otitis Media, together accounting for nearly 60 million visits. More than 100 million doctor visits are coded directly to disease states requiring an ear check, and that doesn't even count all of the cases where ears were checked but no dysfunction found, for example, Well-Child Visits. It is estimated that there are 150,000 to 180,000 ear checks per year; this is a market where OtoNexus can have a very positive impact.

Physician Perspective



OtoNexus' market analysis includes literature review as well as extensive conversations with more than 60 practicing pediatricians and other clinicians (including ENT/Otolaryngologists/Audiologists; Family Practice/Primary Care Physicians; Nurse Practitioners; and Physician Assistants) who would benefit from this device. 100% of those in the discussions indicated they would

buy the device at the tested price. A busy pediatrician can see 25 to 30 children a day, and the majority present with conditions requiring an ear check. The speed and simplicity of the device is seen as a benefit, and the ability to instantly know the answer, with a high degree of accuracy, is seen as a huge improvement over current practice.

Price and market elasticity have been positively validated, and there is an existing CPT code for clinicians to use for reimbursement. The expectation is that this device will become a regular part of patient care in clinical offices treating children, including pediatricians, family practitioners, general practitioners, doc-in-a-box clinics and in-store clinics, and Emergency Departments. In addition to use when OM is suspected, we believe it is likely that the device will, over time, become a standard part of any well-baby exam, greatly increasing the market potential. Use in preventative care will also identify asymptomatic OM, driving down instances of surgery and permanent damage to hearing.

The current revenue and pricing model is based upon a standard device priced below $1,000 with 'use-once' speculum seal tips (Smart Tips) priced starting at $4.75 each. These prices fit very well within the competitive product landscape, and have been positively validated with the market.

Importantly, there have been recent changes in the politico-economic landscape that may further enhance adoption of OtoNexus' device, including intense pressure to reduce healthcare costs, non-physician contact, added importance placed on accuracy in diagnosis and a net reduction in the frequency of antibiotic prescriptions. It is also noteworthy that of over 60 relevant physicians interviewed, all gave favorable reviews. Physicians specifically noted the ease of use as a benefit in addition to dramatically improved clinical outcomes.

Of note, the use of this device represents a new income stream for Primary Care Physicians. The otoscopy that they perform today is included in the charge for the office visit, and cannot be billed for separately. Since there is a separate reimbursement for the use of the device, on a per-patient basis, the physician as well as the patient benefits from its use. Pediatricians, who are primarily women, are the least-compensated of all physicians. As noted previously and below, the costs of this reimbursement are eclipsed by the overall healthcare system savings generated through better patient care via this device, so it seems appropriate that pediatricians and family practice physicians also benefit.

Reimbursement

The Company has been advised that it will be able to use an existing CPT reimbursement code. This eliminates the concern of not having an approved code at product launch. Use of the OtoNexus device can be coded to the existing Tympanometry CPT code for reimbursement, which provides a new revenue stream for the practicing primary care clinician, as they cannot bill separately for the otoscopy performed today.

Insurance Company Perspective

OtoNexus has also tested the device and its reimbursement model with insurance carriers. Otitis Media is one of the largest cost drivers in their systems, and carriers are very interested in a device that has the potential to significantly reduce those costs. They see potential cost savings in the reduction of antibiotics, the reduction of costs of treatment of adverse side effects and new infections as a result of suppressed immunity resulting from the use of those antibiotics, and large savings in the reduction of unnec-

essary referrals to specialists and elimination of expensive surgeries as a result of earlier and better diagnosis and treatment. While they recognize that there is a reimbursement associated with the test, they also recognize that the cost savings will likely be many, many times these costs. Better diagnosis and better care in this case also drive reduced costs, creating tremendous support and pull from insurance carriers.

Go-To-Market Plan

Sales will commence as soon as the device is FDA cleared. Since no clinical trials are expected to be needed for Clearance, this should be a relatively straightforward process. Children and their families will begin to benefit immediately from the device.

Over time, the company makes more money from the disposable tips, one use per patient, than the devices – a classic razor/razor blade model. The company's financial estimates assume capture of only a tiny fraction of the total of more than 200 Million doctor visits by children each year in the US alone. We consider this to be a conservative growth rate considering physicians' statements about the revolutionary features of the device, and the strong pull from the target market.

Pre-Launch Activities

The Company has already begun building the company brand and developing market awareness prior to the general release of the product. Opinion leaders such as ENTs and centers such as Children's Hospitals have a strong role in promulgating new technology. Thus, having the endorsement of ENTs and practitioners and researchers at Children's Hospitals and other research facilities will be important in the view of Primary Care and ER physicians. Importantly, OtoNexus already has partnerships in place with the Children's Hospital of Philadelphia and Seattle Children's hospital, two of the Top 10 Children's hospitals in the US (there are about 85 total).

- **Publications:** The Company is planning to release a series of papers and peer-reviewed journal articles targeted to the ENT and pediatrician communities prior to the launch date. Importantly, the Company was recently given a very prestigious grant from the Philadelphia Pediatric Medical Device Consortium, a joint partnership of the Children's Hospital of Philadelphia (CHOP) and the FDA. CHOP will perform OtoNexus' clinical marketing trials, so that papers resulting from the research will be jointly published by CHOP and OtoNexus. The credibility provided by CHOP, one of the premier Children's Hospitals in the world, is very significant for the company.
- **Industry Events:** The Company will present at a number of conferences and trade events prior to launch to build credibility and awareness. These include the meetings of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), combined meetings of the American Society of Otology Rhinology Laryngology and Allied Societies (COSM), meetings of the American Academy of Pediatrics, and meetings of the Family Practice Academy. OtoNexus management is familiar with all of these events and has been attending them for years.
- **Product Placement:** Certain notable physicians in primary care and the ENT community will be provided an "investigative" pre-production version of the product. These Key Opinion Leaders will then have the personal experience to help OtoNexus market the product. The company has already engaged key ENTs to hold meeting for pediatricians to share the benefits of the device.
- **Clinical Research Program:** Data will be collected from marketing human-use trials to evaluate the effectiveness of the product. This data will be published in peer-reviewed journals and other publications. An initial usability study will be conducted in the Seattle area, to be followed by in vivo clinical marketing studies at Children's Hospital of Philadelphia (CHOP), as noted above.

Sales Plan

The sales organization will have three distinct target markets with sales resources appropriate for each segment. Importantly, the company already has a waiting list of physicians awaiting the launch of the device, as well are key partnerships with Children's Hospitals.

- **Children's Hospitals:** Sales will start with Children's Hospitals. The Company already has partnerships with two of the top 10 Children's Hospitals in the US (of about 85 total): Children's Hospital of Philadelphia (CHOP), which will be performing OtoNexus' Clinical Trials and who gave the company a grant under the Philadelphia Pediatric Medical Device Consortium, and Seattle Children's Hospital, whose head of Pediatric ENT is on the Company's Medical Advisory Board. These successes will then be leveraged to other Children's Hospitals and to the pediatric community at large. Initial selling efforts will be very focused, and executed by a small and tightly focused internal sales force with a selling model targeted for this subset. The fact that Seattle Children's Hospital is on OtoNexus' Medical Advisory Board, and that OtoNexus is working with Children's Hospital of Philadelphia for the clinical trials, is a huge boon to marketing. The company will of course start with these hospitals.
- **Broader Marketing to Pediatricians, GPs, and Family Physicians:** As penetration is achieved in larger markets, sales will be expanded to large clinics and multi-physician practices in those same markets, again with the targeted internal sales teams. Later, after sufficient sales traction is achieved, certain proven, carefully selected distributors will be brought in to broaden sales reach to smaller clinics and smaller cities.
- **Large Medical Institutions:** The Company anticipates it will develop a direct sales organization to pursue large, multi-site clinics and hospitals. This assumes, of course, that the company has not already exited via acquisition before reaching this stage.

OtoNexus will first leverage its own wide network of ENTS, pediatricians, and other physicians to leverage inside support for new products. OtoNexus is already building support in the ENT community (with great success), and will leverage these key opinion leaders to broader acceptance. A similar effort will involve the many Children's Hospitals, leveraging the significant support there that the company currently enjoys.

In addition, the company plans to attend relevant Primary Care Meetings and Tradeshows in order to promote their product and to generate leads and sales. Examples include:

- American Academy of Family Physicians
- American Academy of Pediatrics
- American Association of Nurse Practitioners
- American Academy of Otolaryngology – Head and Neck Surgery

Pricing & Revenue Model

OtoNexus derives revenues both from the initial sale of the device, and from a recurring revenue stream driven by the ongoing sales of one-use-per-patient Smart Tips. The Smart Tips are a disposable speculum seal tip, used once per patient for hygienic purposes (standard of care), and incorporate patented, proprietary technology, so that they can only be sourced from OtoNexus. The device is planned to be sold for $995, and the tips for $4.75. These prices fit well within the competitive product

landscape, and have tested well with targeted physicians.

Taken together, the OtoNexus sales and marketing will serve the company well in fostering a successful product launch that will result in rapid adoption of the technology and in turn, an attractive revenue stream.

THE COMPANY

OtoNexus has a mature, experienced management and leadership team, whose pooled expertise has built multiple successful companies, brought dozens of med-tech products to market, and bought and sold medical devices successfully in the physician segment of the medical industry. The team has extensive expertise in Otitis Media, in Medical Ultrasound, in product development and management, sales and marketing, and in building successful businesses.

With this team in place, the Company as been able to attract Board members, business advisors, scientific advisors, and medical advisors who bring great strength and significant background and expertise to assist the company in completing development, performing clinical trials, managing the FDA and CPT/Reimbursement processes, and bringing the product to market, and when appropriate, in approaching large medical device manufacturers and others as potential acquirers of the company. In addition, the company's Medical Advisory Board consists of the world's leading experts in the diagnosis, treatment, and research of Otitis Media. This MAB has been a very active Board, and has been very helpful to the company.

Management Team

Caitlin Cameron, Chairman and Chief Executive Officer, Board Member
Ms. Cameron is a highly accomplished senior executive with 30 years' cross-industry expertise in the Life Sciences, Biotech, Technology, and IT industries. She is a specialist in building successful start-up companies and taking them through to successful exit. She was previously Chairman and/or CEO of Presage Biosciences, CellNetix Pathology and Laboratories, and several technology companies, with successful private exits. She is an active investor with Keiretsu Forum and other Angel groups, and has served as Keiretsu Due Diligence Lead or support for life sciences and technology companies. Prior to choosing a life as a serial entrepreneur, Ms. Cameron spent the first half of her career rising rapidly through the ranks at AT&T, ending in running its Business Local Services unit, and growing it from $300M to $1.2B.

George A. Gates, MD, Founder, Chief Medical Officer, Board Member
Dr. Gates is a nationally recognized clinician and medical researcher in his field, with 40 years' experience in the diagnosis and treatment of otitis media. Dr. Gates is an otolaryngologist and neurotologist, and is currently an Emeritus Professor at the University of Washington (UW) and former director of the Virginia Merrill Bloedel Hearing Research Center at the UW. In his career, he has authored over 220 peer-reviewed published articles directly related to our medical area of interest. Dr. Gates is the inventor the OtoNexus technology.

Mark A. Moehring, PhD, Vice President, Research & Development, Board Member
Dr. Moehring is an internationally recognized Medical Ultrasound and Signal Processing Engineer and Innovator, and was formerly Director of R&D for Spencer Technologies. More recently, he has formed and managed his own consulting organization, Broadview Labs. Along with Dr. Gates, he was instrumental in

developing the design, testing the proof-of-concept, and successfully completing the patent process for the Company's technology.

Danny Kreindler, Vice President, Product Development
Mr. Kreindler (MBA, BSEE) is seasoned leader with 22 years of experience in hi-tech and medical device industries in both engineering and marketing positions. His areas of expertise include a proven ability to manage multiple complex projects from concept to production engineering design and management background – extensive system-level design experience. He has a solid understanding of both engineering and marketing processes, requirements, constraints and trade-offs. He has experience with hardware, software, IC and transducer specification and design, and was part of the design team at Cephasonics that created an ultrasound platform that is used throughout the world. His expertise is in project management, biomedical engineering, ultrasound device development, and device verification and validation.

Marc Fine, Vice President, Marketing and Business Development
Mr. Fine (MPH, BSN) has more than thirty years of experience in product development, strategic planning, business development, regulatory, and clinical trials. He has a successful track record of bringing medical devices to market. Mr. Fine has had a hand in several major breakthrough initiatives, including Interson's SeeMore USB ultrasound probe; Diasonics (first digital ultrasound imaging system); Teknar (first bi-plane prostate imaging system); SRI International (da Vinci Robotic Surgery System); and Siemens (first 3D C-Arm), among others.

Board of Directors and Advisory Board

Board of Directors

In addition to Caitlin Cameron, Chair and CEO, George Gates, MD, Founder and CMO, and Mark Moehring, Founder and CTO, all described above, the OtoNexus Board members are:

Rhonda F. Rhyne, Board Member
Ms. Rhyne has more than 25 years of experience in health care with both public and private industry companies, as well as experience as a clinical pharmacist. She is President and CEO of Prevencio Medical. She was previously President of CardioDynamics, a publicly-traded medical device company sold to SonoSite Inc. in 2009. Prior to CardioDynamics, Ms. Rhyne held positions of President & CEO, VP of Sales and Marketing, and Board Director at Culture Technology, Inc., a privately-held biotechnology company, as well as positions at GE Health Care and Cardiac Science. Rhonda is principal of Rhyne Life Sciences Consulting, a consultancy practice focused on emerging life science technologies. She also serves on the Board of Directors and Audit Committee for La Jolla Institute of Allergy and Immunology, Deeds from the Heart and Washington State University College of Pharmacy Dean's Advisory Council.

Ms.Rhyne is also the author of ***Keys to the Corner Office: Success Strategies for Women by Women,*** a reference guide providing strategic career advice for women seeking to rise to the highest levels of management and overcome the "glass ceiling" effect.

Marion R. Foote ("Robin"), Board Member
Ms. Foote is an experienced business executive and consultant, who is now fully engaged as a private investor and corporate director. In her corporate career, she ultimately served as Group EVP/CMO for Bank of America. In previous positions, she led an ever-expanding portfolio of specialized financial services and strategic initiatives for First Chicago. She began her consulting career with McKinsey & Com-

pany, and, in 2001, established her own firm (Randolph Partners) which she subsequently merged into Novantas, where she served as a partner through 2012. Throughout her career, Ms. Foote has focused on creating customer and shareholder value. Collectively, she has led development and implementation of analytically-driven strategic initiatives and programs worth billions in bottom-line improvement. Ms. Foote serves on the Boards of Avalara, Inc., and Saturna Trust Company, as well as the PeaceHealth St. Joseph Medical Center Foundation and St. Paul's Academy. She is a past Director of several other public and private companies, all of which have been successfully sold or merged.

Harris Brody, Board Member
Mr. Brody is a Partner of Blue Fog Capital, a private investment company focused on equity and debt investments in early-stage and lower-middle market companies. Mr. Brody's transactional experience with Blue Fog Capital, J.P. Morgan, and Prudential Financial includes more than $4 billion of private equity investment and $50 billion of M&A activity across a variety of sectors, including technology, healthcare, consumer and retail, industrials, and real estate. Mr. Brody brings a wide variety of experience in strategy, general management, finance, accounting, and operations to the portfolio companies he works with and partners closely and constructively with management to maximize shareholder value. Previously, Mr. Brody spent time in industry at the Clorox Company in a marketing and general management focused role on the Kingsford Charcoal and Combat Insecticides businesses.

Key Advisers

Butrus (Pierre) Khuri-Yakub, Ph.D., Distinguished Professor, Stanford University; Scientific Advisor
Dr. Khuri-Yakub is the acknowledged world expert on CMUTs, or Capacitive Micromachined Ultrasound Transducers, the type used by OtoNexus. He has been leading research and innovation on CMUTs in his lab at Stanford University for more than 20 years (since their inception), and is an expert in the development of micromachined silicon sensors and actuators such as airborne and water immersion ultrasonic transducers and arrays, medical ultrasound imaging systems, and other similar systems. Dr. Khuri-Yakub performed a complete Scientific Feasibility and Achievability Review of OtoNexus' plans and specification, and enthusiastically endorsed them.

Chris Rivera, President, Washington Biotechnology and Biomedical Association; Business Advisor
Chris Rivera is a key Business Advisor and sits on multiple boards in the biotech and medical device industries. Chris is president of the Washington Biotechnology and Biomedical Association (WBBA) and Chairman for the national Council of State Bioscience Associations (BIO), is a successful CEO in biopharmaceuticals, and has established a robust list of cohesive relationships throughout industry including potential acquirers for OtoNexus. Chris has provided advice on commercialization plans and schedules as well as other business aspects, and has connected the company with numerous important sources.

Medical Advisory Board

Charles D. Bluestone, M.D. *Distinguished Professor of Otolaryngology, U. Pittsburgh School of Medicine; Emeritus Director Pediatric Otolaryngology, Pittsburgh Children's Hospital*

Doctor Bluestone is the undisputed world's leading authority on Otitis Media through internationally cited research studies and books, as a conference organizer, and as an educator. His trainees have gone on to advance the sciences associated with Otitis Media in regard to diagnosis, pathogenesis, medical and surgical treatment.

Jerome C. Klein, M.D. *Professor of Pediatrics, Boston University School of Medicine, Boston Medical Center*
Doctor Klein is one of the world's foremost authorities on diagnosis and treatment of Otitis Media. He has collaborated with Dr. Bluestone in the second edition of their book "Otitis Media in Infants and Children." He lectures widely, has participated in national consensus panels, and has trained a generation of pediatricians in the challenges in Otitis Media management. He developed a teaching otoscope (Welch Allyn) to help train residents in Otitis Media diagnosis.

Scott Manning, M.D. *Division Chief, Otolaryngology Head and Neck Surgery; Program Director, Otolaryngology Education, Seattle Children's Hospital; Professor of Otolaryngology-Head and Neck Surgery, University of Washington*
Doctor Manning was trained by Doctor Bluestone. He has provided medical and surgical diagnosis and treatment of infants and children with Otitis Media for over two decades and has endeavored to improve patient care through organizing and training effective and efficient healthcare practices. He and Seattle Children's Hospital have been excellent partners for OtoNexus.

Michael Glasscock, III, M.D. *Professor of Otology and Former Director of The Otology Group at Vanderbilt University, Nashville*
Doctor Glasscock is internationally recognized as an innovative surgeon. He combines top tier knowledge in the surgical care of complications of otitis media with extensive business acumen. He has helped guide OtoNexus' path bridging innovative ideas and the development of new therapies.

Albert Berg, M.D. *Former Chair, Department of Family Practice, University of Washington*
Doctor Berg is a leading academic Family Practitioner who has participated in national consensus conferences relating to the diagnosis and treatment of Otitis Media in infants and children. He provides information on the needs of the primary care practice community in the diagnosis and treatment of Otitis Media.

Lauren Bakalatz, Ph.D. *Professor of Pediatrics and Otolaryngology, Ohio St. UCM; Director, Center for Microbial Pathogenesis, The Research Institute at Nationwide Children's Hospital*
As an active scientific investigator with an emphasis on bacteriology of Otitis Media, Doctor Bakalatz provides vital assistance on animal models for otitis media as well as researched data for design and testing for OtoNexus. Doctor Bakalatz is acknowledged in the industry as the leading researcher in Otitis Media.

INTELLECTUAL PROPERTY

OtoNexus has a strong intellectual property (IP) position, which consists of patented technologies, know-how and other trade secrets.

The Company holds two issued patents, and has filed additional provisional patents and is in the process of filing more to protect its innovations through additional multiple patents. Issued patents are US 7,771,356, which protects our method for acoustic observation of induced motions of the tympanic membrane and processing these observations, and is fully-owned. We also have exclusive license for our field of use to US 8,162,837, which covers additional elements of our technology. We have found no other technology existing or in development, anywhere in the world, that can provide this diagnostic data, by any method. Further, this technique presents minimal change to the physician methods and experience of otoscopic examination of the tympanic membrane, and therefore will present minimal effort for technology adoption.

OtoNexus is working with patent attorneys and a registered patent agent on additional intellectual property related to the device design, and on new IP related to the performance and other aspects of the design and function.

In addition to the patent and license noted above, the Company has implemented a robust IP protection program through utilization of appropriate IP agreements with employees, advisors, and third party contractors. This program also includes a formal, technology transfer agreement with the company from whom OtoNexus purchased its IP, which in addition to yielding the title and license to the U.S. patents noted above, has also provided an ongoing collaborative relationship between the companies.

The Company IP strategy consists of (1) Patent elements that are novel and will contribute to protection from competition from the viewpoint of OtoNexus and any company likely to give serious consideration to acquiring OtoNexus; (2) development and maintenance of trade secret information that will present a barrier to entry for competitors; and (3) emphasis on in-house command of the basic science and practical implementation of OtoNexus' technology, so that the Company does not become beholden to outside third party vendors.

REGULATORY CLEARANCE

This company will apply for FDA 510(k) regulatory clearance in the US, and C-Mark outside the US. It is expected at this time that no clinical trials will be required by the FDA for clearance to market, as the OtoNexus device is expected to be a 510k, Class II, NSR (Non-Significant Risk), non-invasive device with a predicate device. The company does plan to do its own clinical marketing trials, however, to produce data for publishing and to support marketing claims, and accelerate clinical acceptance.

COMPETITION

The OtoNexus device represents the first significant technological advance in Otitis Media in 40 years. A key differentiator for OtoNexus will be the ability to distinguish among different types of middle ear effusion, something not available in any current technologies.

There is currently no product available to diagnose Otitis Media with the use of Doppler Ultrasound. Existing methods include inspection of the tympanic membrane using monocular visible light with an otoscope (the method of primary care physicians), binocular magnification using an operating microscope and pneumo-massage (the method of ENT specialists), and acoustic reflection (the home-use method). These methods are either too costly or provide incomplete or inaccurate results. These methods are implemented through the use of Otoscopes, Tympanometers, and an acoustic reflectance device, and are described below:

- The monocular Otoscope is the current standard of care. It was developed more than 80 years ago. Otoscopes come in a variety of models, the most widely used of which costs $350. Because this is considered part of the physical examination, there is no CPT code or separate reimbursement for this procedure. The addition of pneumo-massage of the eardrum began about 40 years ago, and is generally performed by specialists such as ENTs. ENT doctors use both eyes in their observation of the eardrum and thus achieve depth perception via the operating microscope. Failure of the eardrum to move briskly and synchronously with pneumo-massage is clinical evidence for middle ear fluid. Due to it difficulty and need for specialized training, pneumo-massage is rarely used in primary care offices.
- Tympanometry was introduced some 40 years ago, and is primarily used by specialists such as ENTs. It employs low frequency sound transmission while the pressure in the ear canal is forcibly increased and decreased. The resultant plot is generally accurate in determining the presence or absence of fluid/effusion in the middle ear. However, tympanometry is unable to differentiate the *type* of fluid/effusion, and therefore cannot differentiate between types of infections. Another weakness of Tympanometry lies in its requirement for specialized training in its use and interpretation of readings from the device. While Otoscopes are available in nearly all ERs, Tympanometers are most commonly used only in specialty clinics, such as ENT, audiology departments, and in a very few Pediatric offices. Very importantly, Tympanometers require pressurization of the ear canal, which is very painful for the ill child. And even with all of this, the Tympanometer cannot assist in making the key differentiation of whether an antibiotic is appropriate, as it cannot differentiate fluid type. The average price of the Tympanometer is $3000 to $5000 or more, depending upon functionality.
- An acoustic reflectance device for home use has been available for nearly three decades. It is not used by physicians. It was sold in pharmacies under the name “Ear Check” for around $60. The company has been sold multiple times and has yet to develop a substantial market presence, and the device was pulled from the market due to poor reliability. The Company appears to be planning to relaunch their product, according to their website (www.earcheck.com). Research has shown the device to be highly inaccurate, particularly in differentiating infection types, and the few pediatricians that the Company has found who know of the device recommend against it for their patients.

In addition, several attempts have been made to apply other technologies to the assessment of Otitis Media. None have been found to be able to determine both the presence and the type of fluid behind the eardrum, and thus cannot make the key differentiations needed to instantly and accurately diagnose otitis media. The Company has searched the world over, reviewing patents, research papers, grant applications, and other materials, and has not found any technology in existence or under development that can provide the key differentiation of whether or not an antibiotic is appropriate.

FINANCIAL

OtoNexus’ CEO has a strong financial background. The company has been able to achieve significant goals in a highly capital-efficient way, particularly making excellent use of outside experts to drive product development while retaining all engineering and design in-house. This allows the company to keep recurring costs low and turn on and off development projects as needed, and their associated costs. The largest development cost is for the development of the new, unique ultrasound transducer, while other development relies heavily on existing technologies, reducing overall costs.

OtoNexus expects to be able to generate $62 Million in sales in the United States alone in four years, with robust profit margins on both the device and the use-once tips. Revenues from the use-once tips quickly surpass revenues from the device, a classic razor/razor blade model.

Importantly, the company already has a waiting list for its device.

A robust, highly-detailed financial plan and pro forma forecasts are in place, and are available upon request to qualified investors.

TECHNOLOGY

It is expected that this technology will be able to achieve a rapid, accurate assessment of both the presence and viscosity of any fluid behind the tympanic membrane (eardrum) in an active, uncooperative patient. This would clearly be a significant improvement over the existing technologies, and is desired by the medical community.

Major Milestone Achieved – Proof of concept of Testing in humans!

Recently OtoNexus achieved a key milestone, substantially ahead of current plan. Having solved the fundamental technology issues and developed the essential elements, OtoNexus' prototype device has already demonstrated the ability to successfully induce movement in the tympanic membrane (eardrum) and also to measure that movement both safely and effectively. As well, OtoNexus has proven that that it can distinguish fluids with different viscosities using an artificial ear we created for that purpose. This achieves perhaps the single largest and most important milestone in product development, and thus removes the single largest barrier to success. The company is on track for successful launch.

OtoNexus has made very significant progress in a small amount of time and on very little funding. In addition to the high level of expertise on its own team, OtoNexus has engaged outside experts in completing its ultrasound technology. OtoNexus' VP of R&D, Mark Moehring, and VP of Product Development, Danny Kreindler, each have 25 to 30 years' expertise in designing, developing and bringing products to market, including dozens of medical technology devices, with particular expertise in ultrasound medical devices. In addition, Dr. Pierre Khuri-Yakub, a Stanford research professor and leading expert in ultrasound is a Scientific Advisor on this work.

The basic architecture of a MEMS ultrasound transducer is very similar to that used for MEMS microphones, which are used in all smartphones, hearing aids, and other applications requiring tiny microphones. These MEMS have proven performance and reliability in real world applications. For this reason, the OtoNexus CMUT transducer is expected to exhibit similar high reliability and performance.

Obviously, specifics of the technology are proprietary and of necessity are not described in detail here.

EXIT STRATEGY

Our goal is to bring our device to as many people as possible as quickly as possible, and make a real difference in the world of Otitis Media. We will launch sales of our device immediately upon FDA Clearance. Then, OtoNexus anticipates being acquired by one of several Big Medical Device Manufacturers (BMDMs), and initial conversations with potential acquirers have indicated very strong interest. These BMDMs can quickly broaden distribution and availability to our device, as well as provide a great return for our investors. Acquisition would most likely occur at one of three points: At FDA clearance, meaning no final funding round needed; at profitability, anticipated to be 17 months after launch; or at Year 5, with anticipated $62M in revenues, the most likely exit point.

IMPACT AND BENEFITS

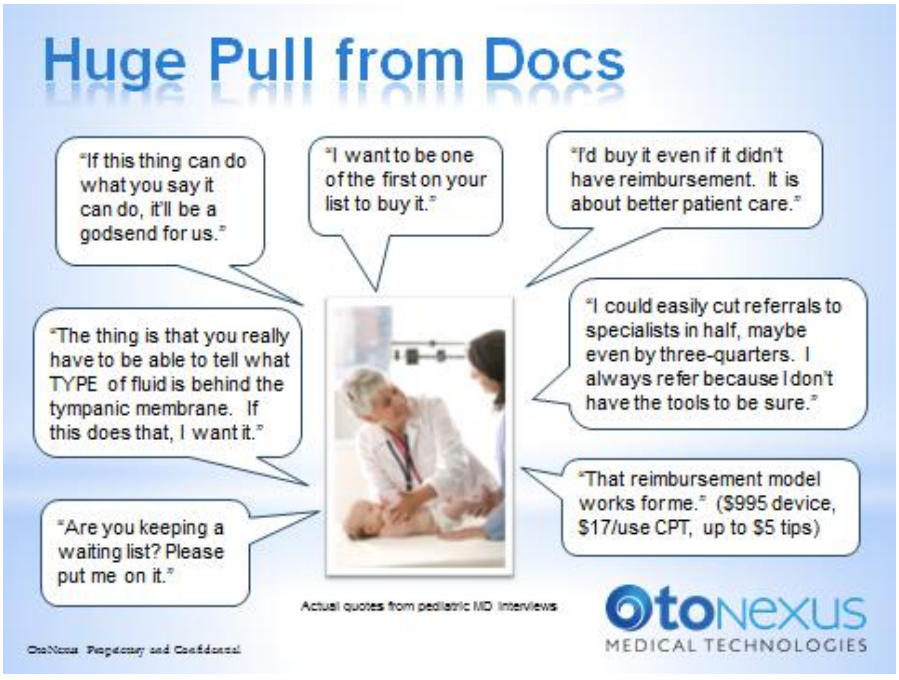
Children need it. Physicians want it. And insurance carriers love it.

Very nearly every child in America – 93% by age 7 – will suffer at least one middle ear infection severe enough to have to see a doctor, and the vast majority of those children will suffer repeat occurrences, up to a dozen or more in childhood. The impact on these children and their families is enormous.

OtoNexus' Doppler ultrasound device will be the first advance in this area in 40 years. OtoNexus is developing the word's first medical device to assess both the presence and the type of effusion behind the eardrum or tympanic membrane (TM), thus for the first time being able to clearly differentiate not only that an infection is present, but the type of infection, clearly differentiating the states of no infection, primarily viral, primarily bacterial, and glue ear. Thus, in just a few seconds, the clinician is given the definitive data required to make the key decision of whether or not to prescribe an antibiotic.

The benefits to children, their families, physicians, insurance carriers, the healthcare system, and society as a whole are very significant. The CDC estimates that antibiotics are prescribed in about 85% of Otitis Media (middle ear infection) cases, yet should be prescribed in 25% or less. Our device will provide the key data needed to determine when and when not to prescribe antibiotics.

The device is greatly desired by the physicians and groups where these kids land first; they want to improve the care they give their patients, eliminate the negative consequences of overprescribing antibiotics, and improve their ability to comply with the new guidelines from the American Academy of Pediatrics. The powerfully positive response highlights the great need for an easy-to-use, highly-accurate, inexpensive diagnostic device for Otitis Media.



Insurance carriers are also greatly in favor of this new device, as they can clearly see how the device can improve patient outcomes while driving down the overall cost of care. Otitis Media is one of the largest

cost drivers in their systems, and carriers are very interested in a device that has the potential to significantly reduce those costs. They see potential cost savings in the reduction of antibiotics, the reduction of costs of treatment of adverse side effects and new infections as a result of suppressed immunity resulting from the use of those antibiotics, and large savings in the reduction of unnecessary referrals to specialists and elimination of expensive surgeries as a result of earlier and better diagnosis and treatment. While they recognize that there is a reimbursement associated with the test, they also recognize that the cost savings will likely be many, many times these costs. Better diagnosis and better care in this case also drive reduced costs, creating tremendous support and pull from insurance carriers.

The OtoNexus ultrasound device will allow practitioners to greatly increase the quality of care they provide to patients and improve patient outcomes by greatly improving diagnostic accuracy and certainty, reducing unnecessary prescriptions of antibiotics, reducing antibiotic side effects and cost of their treatment, as well as societal effects such as the development of drug-resistant bacteria, speeding assessment time (while improving accuracy), reducing unneeded specialist referrals and increasing quality of needed referrals, reducing repeat infections, and reducing surgeries through earlier and better diagnoses.

In addition to improving patient outcomes through improved diagnostic accuracy, the OtoNexus device will have an enormous impact on reducing health care costs for this very common and highly disruptive medical problem, while having a very positive effect on children and their families.

For more information, please contact:

Caitlin Cameron
Chair and CEO
OtoNexus Medical Technologies, Inc.
206-919-2623
caitlinc@otonexus.com

www.otonexus.com

OtoNexus Medical Technologies, Inc. is a Delaware corporation, based in Seattle, Washington.
OtoNexus Medical Technologies, Inc.
1546 NW 56th Street
Seattle, WA 98107