



December 18, 2007

Dear NIO Members,

There is no mistaking the progress: 2007 was an excellent year for the Neurotechnology Industry Organization! Our public policy agenda and public relations efforts made significant headway throughout the year and we look to build on this momentum in 2008.

Since our founding just sixteen months ago, **over 60 organizations have joined our mission** to accelerate the development of treatments for the brain and nervous system. As the only trade association representing companies involved in neuroscience (drugs, devices and diagnostics), brain research centers and patient advocacy groups, NIO is quickly becoming a powerful agent for change.

NIO's primary purpose is to increase awareness of neurotechnologies, reduce barriers to innovation, and support industry growth. With this in mind, I'd like to share with you some of our key activities from 2007, NIO's first full year in operation, and preview what's to come in 2008.

2007

2007 Public Policy Tour: On March 29, twenty NIO executives came to Washington DC to participate in our first public policy tour. We met with dozens of elected officials and policy makers to discuss the opportunities and obstacles facing neurotech companies. A key topic of discussion at our meetings on Capitol Hill, the FDA and NIH was the National Neurotechnology Initiative. Overall, the NIO Public Policy Tour was an outstanding success and members found candid discussions with FDA officials particularly rewarding. [Read 2007 NIO public policy tour recap.](#)

National Neurotechnology Initiative (NNTI): A major focus of NIO's policy efforts for 2007, the NNTI is a \$200M/year Federal research and development initiative aimed at supporting innovation, accelerating translational neuroscience and improving the efficiency of the FDA review process for neuroscience drugs, devices and diagnostics. [More: Overview of NNTI.](#)

Crafted legislation – Members of NIO's Public Policy committee came together in the first half of the year to draft a proposed National Neurotechnology Initiative Act. Over the course of several months, numerous NIO members shared their priorities for neurotech research policy and made substantial contributions to the final draft bill.

Spearheading introduction – NIO members have joined me on six separate trips to Capitol Hill throughout the year to garner an ever-growing cadre of support for the NNTI legislation. These exceptional meetings were organized and supported by NIO's public policy team at K&L Gates. During these visits, we have spoken with the offices of over forty Senators and members of Congress. Nearly everyone has voiced support for the legislation and several Senators have expressed interest in becoming champions for the bill. [Read Op-ed in support of NNTI.](#)

NIO/FDA private-public working group: After meeting with Dr. Janet Woodcock, Deputy FDA Commissioner and other key staffers relevant to commercial neuroscience, members of our FDA policy committee built a consensus agenda whose goal is to get the FDA to improve the efficiency of the evaluation process for neuroscience products and to increase communication and clarity during the regulatory process. After vetting our strategy with a host of FDA consultants, we have recently decided the best way to achieve our objectives is to leverage the FDA's own Critical Path Initiative. We are in the process of choosing a specific initiative, which will yield meetings with the agency in 2008.

Public Relations: NIO actively outreaches to national media outlets to encourage coverage of neurotech, which will foster greater investor, policymaker, and consumer interest. Over the past year, NIO and its members have been highlighted in over 25 articles appearing in San Francisco Chronicle, BioWorld, Science magazine, Journal of Life Sciences, Reuters among many others. In August we launched a redesigned [website](#). In October we launched a [Neurotech Job Board](#). In November we unveiled the [top ten trends in neuroscience](#) that we expect will drive industry growth in years to come.

With the help of our public relations team at Feinstein Kean Healthcare we continue to develop relationships with influential reporters around the world. *Please keep NIO abreast of your corporate news so that we can weave timely information into our media pitches. Send press releases to memberpr@neurotechindustry.org. [More: Read NIO in the News](#).*

Events: In addition to our public policy tour in DC in March, NIO was involved in a number of highly visible events throughout the year.

- We hosted our first annual meeting on May 18 in San Francisco where NIO members shared their ideas for member growth, policy issues and financing.
- On September 25, NIO hosted a neurotech media tour in New York City in conjunction with the launch of the Nasdaq NeuroInsights Neurotech Index. Five neurotech CEO's joined me at meetings with the Wall Street Journal, Forbes and Scientific American Mind to discuss their recent success.
- On November 3-7, NIO had an exhibition booth at the annual Society for Neuroscience conference in San Diego. We also hosted a successful partnering social on the evening of November 4, which was attended by over 50 neurotech executives.

Also on behalf of the organization, I spoke at a host of biotech and neuroscience meetings across the US and abroad throughout the year including the annual Anti-Epileptic Drug conference in Florida, Committee on Military and Intelligence Methodology in the Next Two Decades in Washington DC, the Neurotech Reports conference in Newport Beach and the European Neuroscience and Society Network conference in London in late November. These types of visibility opportunities will gain increasing importance as NIO works to spread the word about neurotech far and wide.

Amicus Brief: NIO also advocates for our members on intellectual property issues. In particular, we believe that certainty in the patent system is critical to encourage investment in neurotech R&D. On December 13, NIO filed an amicus brief in support of the patent owners in a pending patent law case before the Federal Circuit Court of Appeals in Washington, DC. Our amicus brief in this case supports reversal of a recent district court decision that questions a quarter century of settled law and leaves patent owners subject to challenges for simply following the rules laid out by the PTO.

Membership: NIO's membership more than doubled in 2007 with nearly 40 new companies, academic brain research centers and patient advocacy groups joining together to "give the brain a voice." NIO's growth is a testament to the fact that there is tremendous common ground among industry participants and that by working together we can increase awareness of neurotechnologies, reduce barriers to innovation, and support industry growth. [More: View all NIO members](#).

2008

Looking forward, 2008 promises to bring another year of exciting growth and continued momentum. We have plans in place to not only build on all of our existing programs but add a few more as well. Here is an overview of what you can expect in the coming year:

National Neurotechnology Initiative 2008: Our K&L Gates lobbying team is squarely focused on getting the NNTI bill introduced early in 2008. After introduction, Congressional hearings will be held on the legislation. The NNTI will be the primary focus of our meetings on Capitol Hill during the 2008 public policy tour in March. It is important to note that several forces are

converging which might accelerate the passage of this bill, even as Congress struggles to pass other legislation. Here's how you can help:

- Attend the NIO public policy tour in March
- Attend the Congressional hearings whenever possible
- Contact your local representatives in support of the legislation, and galvanize your various partners, vendors and investors to do the same
- Agree to byline an editorial piece for submission to your local news paper, urging Congress to pass the NNTI. Feinstein Kean Healthcare and NIO will supply the text and contact the editors, we just need the weight of your signatures to promote publication

Neurotechnology Development Foundation: To help further promote neurotechnology development we are in the process of creating a new 501(c)(3) non-profit entity whose objective will be to stimulate neurotech investment and promote treatment development. The NDF will be able to apply for grants that NIO is not eligible for. The NDF is currently working on a \$2M grant for 2009 that will enable it to place individuals who have expertise in the translational development of neurotechnologies in matching programs with neurotech companies. This *Neurotechnology Fellowship Program* (NFP) will fund fellows to provide up to six months of training and advice regarding general start-up issues, strategic business development, grant and venture financing, preclinical drug development, clinical trial planning, and insurance reimbursement. The NFP will be an additional focus of our meetings on Capitol Hill during the 2008 public policy tour in March.

Bay Area Neurotech Media Roundtable, San Francisco (January 22): NIO is hosting a special two-hour Bay Area neurotech CEO roundtable with the editors of the Pink Sheet Daily. As you're probably aware, The Pink Sheet is a well-read and respected news service devoted to the pharmaceutical industry. As NIO grows we will be hosting more of these media roundtables in more regions.

SAVE THE DATE: 2008 Public Policy Tour, Washington DC (March 12-13): On March 12th, we will canvass Capitol Hill and meet with leading Senators and members of Congress in support of neurotechnology. We will target Congressional hearings if the NNTI legislation has been introduced. On Thursday morning we plan to head to the FDA to meet with FDA Commissioner Andrew von Eschenbach and staff from key offices across the agency relevant for neuroscience to discuss NIO's critical path initiative project as well as share in a free form discussion individual company issues. Still in planning, is a meeting with CMS that will revolve around reimbursement for neurodevices. In order to make our voice heard, it is critical that we have as many members on the Hill, from as many Congressional districts as possible. Please email me if you would like to attend. *Formal invites for this event will go out in mid-January.*

NIO/YouTube Brain Awareness Week global competition (March 16): NIO is teaming up with the Society for Neuroscience and the Dana Alliance for Brain Initiatives to sponsor a competition for Brain Awareness week (March 10-16). K-12 students will post 30-60 second videos on YouTube based on the theme "Brain Power." Posted videos can take the shape of a poem, cartoon, a short movie, parody, song, drama, or experiment as long as it is relevant to the theme. Last year nearly 1 million people at 2,000 partner organizations in 69 countries participated in Brain Awareness week.

CIMIT/NIO Epilepsy Innovation Summit (May 7): NIO has teamed up with the Center for Integration of Medicine and Innovative Technology (CIMIT) to host a one-day working group summit focused on next generation treatments for Epilepsy. CIMIT is a non-profit consortium of Boston area teaching hospitals, engineering schools and research laboratories where clinicians, engineers, industry leaders, scientists and the military, work in interdisciplinary teams to generate promising, leading-edge translational technologies for healthcare. If you are interested in attending please contact me. Attendance is limited.

Neurotech Industry Investing & Partnering Conference, Boston (May 8 & 9): NIO is co-hosting this premier partnering and investing conference for the neurotechnology industry including pharmaceuticals, medical devices and diagnostics. The conference is a global forum where investors, executives, entrepreneurs, scientists and others involved in the development of new treatments and diagnostics for the brain and nervous system come together to shape the future of their organization and the industry.

NIO Annual Meeting, Boston, MA (May 9): To correspond with the Neurotech Industry Investing & Partnering Conference, NIO members will come together to discuss issue critical to the success of the industry and their organization. An organized networking lunch will provide time for members to get to know each. Updates on current programs and future plans will also be discussed.

Membership: Size matters. NIO membership must continue to grow rapidly in order to achieve the critical mass necessary to support our current and future programs. *Please introduce me to two potential members in the next six months so we can reach our 2008-membership goal of 100 members.* As NIO's only employee, I spend a great deal of time recruiting new members. The more you can help put me in contact with the right person, the more time I will have to build on our strategic programs. Once we reach 100 members, NIO should have the resources necessary to hire a second employee, enabling us to be even more responsive to your needs.

Get Involved: NIO is a member-driven organization. If you would like to get more involved in the FDA Policy committee, the CMS Reimbursement committee, Public Policy committee or the membership committee, please contact me. I am also seeking members who are willing to take a more active role in helping drive these committees towards success.

“Giving the Brain a Voice”

Today, nearly 2 billion people worldwide and nearly 100 million American's suffer from a brain or nervous system illness. Brain-related illness generates more healthcare costs and lost income than any other therapeutic area: \$2.0 trillion annually worldwide, \$1.1 trillion annually in the US. This economic burden is accelerating as the population ages and expands, creating unprecedented demand for treatments that delay, prevent and cure chronic brain-related illness.

Despite the clear human need and significant global market opportunity, neurotechnology companies face unique investment requirements, research and development challenges, and regulatory milestones which can require more time and money to develop and deliver new treatments than in other life science and healthcare sectors.

NIO was formed in August of 2006 to provide commercial neuroscience organizations a collective voice to address these issues and to help patients, the public, investors and government officials understand the benefits of neurotechnology products and the unique needs of this industry.

With your continued support and dedication of our strategic partners at K&L Gates and Feinstein Kean Healthcare, we are well on our way to making an important difference.

Sincerely,

Zack Lynch
Executive Director
Neurotechnology Industry Organization

The Neurotechnology Industry Organization (NIO) is a non-profit trade association representing companies involved in neuroscience – drugs, devices and diagnostics, brain research centers, and advocacy groups across the world. More information: www.neurotechindustry.org

NIO Members Since Founding August 2006

Corporate -- Acadia Pharmaceuticals, Accera, Acorda Therapeutics, Acumen Pharmaceuticals, Adlyfe, Alseres Pharmaceuticals, Amarin, BrainCells, Inc., Brain Resource Company, Ceregene, Cogmed, Cognitive Drug Research, CoMentis, Cortechs Labs, CNS Response, Cyberkinetics

Neurotechnology Systems, CyberLearning Technology, EEG Spectrum International, Ellman Innovations, EnVivo Pharmaceuticals, Innovative Neurotechnologies, Medivation, Neurologix, NeuroNova, NeuroPace, NeuroProtect, NeuroScience Associates, Northstar Neuroscience, RemeGenix, Sound Pharmaceuticals, StemCells, Inc., Targacept, United Therapeutics, Xenoport, Xytis -- **Brain research centers** -- Allen Institute for Brain Science, Blanchette Rockefeller Neurosciences Institute, CIMIT Neurotechnology program, McGovern Institute for Brain Research at MIT, Mind Research Network, Van der Veer Institute for Brain Research -- **Patient advocacy groups and research foundations** -- Accelerate Brain Cancer Cure, ALS Hope Foundation, Alzheimer's Drug Discovery Foundation, Brain Aneurysm Foundation, Epilepsy Therapy Development Project, International Neuroscience Network Foundation, NAMI, NARSAD, Neurotech Network, Myelin Repair Foundation, Parkinson's Research Foundation -- **Venture capital firms** -- Brain Trust Accelerator Fund, NeuroVentures, Technology Partners -- **Strategic Partners** -- American Society for Experimental Neurotherapeutics, BiotechPartnering Solutions, Buchanan Ingersoll & Rooney, Feinstein Kean Healthcare, K&L Gates, NeuroInsights, NeuroInvestment, Neurotech Reports, Nixon Peabody, The Potomac Institute's Center for Neurotech Studies View brief descriptions of all NIO members.