



November 2016 | Member Newsletter

Phil Kozera

Letter from the Executive Director



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## AS LEADERS CHANGE, BIO NEBRASKA ENGAGES THE DECISION MAKERS

I hope that everyone had an enjoyable, safe, and relaxing Thanksgiving Holiday.

With the historic nature of the November 8 election, I thought it only right to start with a few observations on the changing faces of both the state and federal legislatures.

In Nebraska, there will be 17 new lawmakers in the upcoming session and a new Speaker of the Legislature. Five incumbent senators - all Republicans - were defeated, and in two instances, they were defeated by their Democratic challenger. Those incumbent senators not returning include Tommy Garrett (Bellevue), Dave Schnoor (Scribner), Jerry Johnson (Wahoo), Les Seiler (Hastings) and Al Davis (Hyannis).

On the federal side, the GOP retains both chambers of Congress. With the Senate, the breakdown is now 51 Republicans and 48 Democrats, with the Democrats experiencing a net gain of two seats. There will be a special runoff election for Louisiana on December 10. Appropriations, Banking, Environment and Homeland Security committees will likely see changes in leadership.

**"With the flurry of activity, Bio Nebraska has been busy this month engaging our elected officials at both levels of government."**

Republicans retained control of the House of Representatives, but Democrats gained six seats. There will also be new committee leadership, with Appropriations, Education, Energy, and Veteran's Affairs likely to change. The lame duck session must pass government funding for 2017 and may look at the 21st Century Cures, repeal of CMMI Part B Demo as well as an energy bill.

With the flurry of activity, Bio Nebraska has been busy this month engaging our elected officials at both levels of government. On the state level, we are collaborating with Sen. Morfeld's office to complete the Nebraska Bioscience Report. We also coordinated with John Bode, CEO of the Corn Refiners Association, on an editorial published in the Omaha World-Herald on the virtues of ag biotechnology.

Finally, Bio Nebraska has begun invoicing for 2017 membership. Our membership is the foundation of our organization; it is through your support and collaboration that our organization can be a strong advocate for the life science industry in our state. In addition, we have opportunities for sponsorships. We thank you for your continued support, and we encourage you to reach out to other organizations that have an interest in our life science community. To learn more about engaging with Bio Nebraska through sponsorship or membership, please contact me.

Best regards,



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## Upcoming Events

 [Nebraska Chamber Economic Summit](#)  
November 30  
Embassy Suites  
LaVista, NE

 [Bio & Beers](#)  
January 26  
Upstream  
Omaha, NE

 [BIO CEO & Investor Conference](#)  
February 13-14  
New York, NY

 [Partnering for Growth](#)  
March 21-22  
FFA Enrichment Center  
Ankeny, IA

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## Bioscience Leader Spotlight



*Omaha biotech start-up Prommune has a new tool to fight antibiotic resistance. Founder Sam Sanderson, Ph.D., says the technology can harness the body's defenses to fight bacterial, viral and fungal infections.*

## **Prommune is taking on the challenge of antibiotic resistance**

**Q: Bio Nebraska readers often are curious about our research ecosystem. Have you been able to find good partners?**

A: We have worked closely with two other Bio Nebraska members, including Dr. Kelly Lechtenberg of Midwest Veterinary Services, to demonstrate therapeutic effectiveness in production animals, and with Benchmark Biolabs to demonstrate potential to fight bacterial infections in fish.

**Q: What are some of your successes?**

A: An early application is greasy pig syndrome. This type of staph infection causes serious skin lesions and is becoming antibiotic resistant. Prommune's technology, known as EP67, activates the pigs' own immune cells to consume the bacteria. This evades a normal pathway that leads to antibiotic resistance. Our company has seven U.S. patents, with another pending, and we are working to optimize formulation, dosing and scheduling, and will complete safety and toxicity studies as part of a new animal drug application.

**Q: New regulations aim to cut use of antibiotics in animal feed. How might this impact antibiotic-resistant microbes in human-health settings?**

A: The goal of this new FDA regulatory requirement is to reduce the mutational pressures placed on bacteria from overuse of antibiotics. Some uses are fed to production animals not to fight a specific infection but rather to prevent the occurrence of infections and increase animal-product harvest. This use of antibiotics has created concern about the risk of antibiotic-resistant strains of bacteria that could have a detrimental effect on treating and maintaining food-animal health and could result in the transfer of those resistant strains from animals to humans.

**Q: Does this new regulatory emphasis enhance the market need for your immunology approach in animal health?**

A: Absolutely. The ability to use our lead therapeutic candidate EP67 to activate the animal's own innate immune responses against an infection (resistant or not) would provide a novel means to treat infections without the use of antibiotics and reduce the likelihood of the pathogen developing resistance

against the antibiotic. Also, since EP67 activates natural host innate immune defenses and does not target the pathogen directly, as an antibiotic does, it can complement conventional antibiotic treatments and provide a powerful dual therapeutic assault on the infective pathogen. We don't compete with antibiotics so much as we will provide a complementary treatment.

**"Thus, the development of therapeutics within the veterinary medicine realm has tremendous potential for treating analogous disorders in humans - not to mention maintaining the health status of humans via maintaining the health status of the animals they rely on as food sources."**

**Q: Is comparative veterinary R&D an effective avenue to create new therapeutics in animals that also result in new treatments for people?**

A: Yes, and this is the result of a relatively new and highly championed concept in veterinary medicine called "One Health," the idea that both animals and humans share a common environment, are exposed to common infective pathogens, and, consequently, have a common disease etiology. Thus, the development of therapeutics within the veterinary medicine realm has tremendous potential for treating analogous disorders in humans - not to mention maintaining the health status of humans via maintaining the health status of the animals they rely on as food sources.

**Q: Do we as a society fund enough of that work to take advantage of the efficiencies?**

A: No, but that's an answer that you'd hear from just about anybody in our position - there never seems to be enough money. However, the funding priorities from the various federal agencies and private/corporate investment always ebbs and flows and with the heightened awareness of the global public health crisis that can come from antibiotic resistance, there is every indication that funding from public and private sources will now flow rather than ebb.

**Q: In addition to staph infections, are there other major cross overs between animal and human health?**

A: The use of EP67 to induce/activate the host's own natural innate immune responses - i.e. host-directed immunotherapy (HDI) - is a platform technology for any type of normal or resistant infection (bacterial, viral, fungal) in multiple species of animals, including humans. HDI has the potential of a very broad therapeutic sweep.

**Q: What are some key challenges bridging from more academic R&D to commercialization?**

A: I've always felt that one's research doesn't mean much if it does not get out of the lab and into the hands of the people who could benefit from it. Establishing a business within the world of academia can be difficult, as can obtaining investment funds. Therapeutic proof of concept has been clearly established and the steps to getting out of the 'valley of death' stage of development are straightforward, albeit expensive, so it is aggravating when investors see this as too early for any investment.

**Q: Have you been successful finding more funding and capital?**

A: Yes. Nothing in the bank just yet, but suffice it to say that those avenues have been opened up to us in the last couple of years from the results we've generated with EP67 and its use in HDI.

**Q: What is your advice to other scientific entrepreneurs?**

A: Move with confidence toward your dreams and don't let the issues, problems and difficulties — and they will be there — dissuade you. Just bull your way through them and be persistent. Win the war of attrition.

Thank you Dr. Sanderson. Readers can learn more at [www.prommuneinc.com](http://www.prommuneinc.com).

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## State News

### **Celerion launches new web portal for Phase I Clinical Trials**

Celerion introduces Celexus®, a first-in-class web portal which offers clients a look at clinical research data in real-time, as it is collected in clinics and laboratories. Views can analyze trends in clinical data, screening, recruiting, adverse events, pharmacodynamics, pharmacokinetics and bioanalytics.

### **Neogen selected by Scottish Gov't for beef herd improvement program**

Neogen's Scotland lab was by selected to perform genomics testing to improve the country's beef herd. Scotland aims to improve herd profitability and sustainability, economically and environmentally. The five-year project is a partnership between Scottish Government, Scotland's Rural College (SRUC) and Neogen.

### **New kitchen council to support area food startups**

The Greater Omaha Chamber and the Council Bluffs Area Chamber of Commerce have a unique food startup incubator. The Kitchen Council was founded to lower the barriers to entry for new food companies while spurring economic development, job creation and entrepreneurial growth. Members can access a fully licensed commercial kitchen with tools, resources and production space.

### **NatureWorks Wins Two 3M Supplier of the Year Awards**

NatureWorks was honored with two 2016 3M Supplier of the Year Awards in recognition of the company's contribution to competitiveness and sustainability. 3M recognized 11 suppliers among thousands in its global-supply base for world-class performance. Suppliers were rated on strategic spend, contract compliance, actions taken to improve 3M's relevance and overall performance (quality, delivery, responsiveness, cost, technology roadmaps).

### **Workforce again a top concerns of business leaders**

Workforce availability is again a top concern for Nebraska employers, per a Nebraska Chamber of Commerce survey of business and civic leaders. The survey was conducted this fall during 30 Nebraska Chamber legislative forums in 28 communities. The forums were attended by more than 1,500 Nebraskans, including 55 state lawmakers and candidates for Legislature.

### **Novozymes a Nebraska manufacturer of the year**

Novozymes of Blair was named one of Nebraska's Manufacturers of the Year by the Nebraska Chamber of Commerce & Industry. The award is presented to manufacturers that are innovative in new products, processes, technologies and strategies.

### **NUtech Celebrates Successes**

NUtech Ventures recognized UNL innovators and technologies during a Nov. 1 celebration of achievements at Nebraska Innovation Campus. Chancellor Ronnie Green and interim vice chancellor for research and economic development Steve Goddard highlighted this year's NUtech Ventures Innovator Celebration award recipients.

- **The Prem S. Paul Innovator of the Year** award went to Donald Weeks, emeritus professor of biochemistry, for developing a novel approach to engineering herbicide-resistant soybeans and cotton, licensed to Monsanto.
- **The Career Innovation** award went to Stephen Taylor, professor of food science and technology, for his research and founding the Food Allergy Research and Resource Program. FARRP scientists developed the first assay for peanut residues, which was licensed to Neogen Corp.
- **The Breakthrough Innovation of the Year** award went to Jinsong Huang, professor of mechanical and materials engineering, and postdoc research associates Haotong Wei and Wei Wei for improved X-ray detectors in medical imaging, security and quality control applications.

- **The Startup Company of the Year** award went to Virtual Incision, a privately held medical device company focused on developing an advanced, miniaturized robot for general surgery abdominal procedures. Virtual Incision was founded on NU-licensed technology by faculty members Shane Farritor, professor of mechanical engineering at UNL, and Dmitry Oleynikov, chief of minimally invasive surgery at the UNMC.

#### Streck featuring antibiotic resistance kits

Streck showcased its ARM-D® Kits at the Association for Molecular Pathology (AMP) annual meeting in Charlotte, NC. The two multiplex real-time PCR kits together target a comprehensive list of Gram-negative bacterial genotypes conferring resistance to the B-Lactam antibiotics. (AMP advances the clinical practice, science and excellence of molecular and genomic laboratory medicine.)



*Calidum Chairman Sam Al-Murrani, Ph.D., addresses a standing room only crowd during the National Council of Entrepreneurial Tech Transfer's Best University Startups of 2016.*

#### Two Nebraska biomed startups pitch at national demo day

Two Nebraska biomedical startup companies were among the “Best University Startups of 2016,” an event that featured 35 companies. “There were more than 200 companies nationwide who applied for this opportunity,” said UNeMed President and CEO Michael Dixon. “Getting two Nebraska startup companies into the room demonstrates the University’s commitment to growing the state’s biomedical economy.” The Nebraska startup companies—Calidum Inc. and Orion BioScience—met with elected officials after addressing a standing-room crowd of venture capitalists, angel investors and industrial representatives. Calidum technology targets certain types of cancer for more effective treatments and diagnoses. Orion is built around a platform technology that looks to restore immune tolerance to cure autoimmune diseases.



*Donde Plowman nominated for new executive role at UNL*

#### **Plowman set as new UNL executive vice chancellor**

Chancellor Ronnie Green announced that Donde Plowman is sole finalist for executive vice chancellor. Plowman is dean of Nebraska's College of Business Administration. In the new role she would report directly to the chancellor and act as the chief academic officer. Plowman has raised over \$150 million for the college, including more than \$80 million for the new business college building. She was also instrumental in forming the Don O. Clifton Strengths Institute, made possible by a \$30 million gift from the Clifton Family and Gallup organization.



*Boehm joins UNL in 2017*

#### **Boehm named new vice chancellor at East Campus**

The UNL Institute of Agriculture and Natural Resources' new vice chancellor is Michael Boehm, currently professor of plant pathology and vice provost for academic and strategic planning at Ohio State University. The 51-year old Boehm will join UNL in January. In the dual role of IANR vice chancellor at the UNL and NU vice president for Agriculture and Natural Resources, Boehm has leadership of the campuses for all agricultural, natural resources and related affairs in the NU system.



*Ranchers hear Juan Enriquez, futurist and bio tech investor, at an Angus genomics symposium.*

#### **Neogen GeneSeek sponsors international genomics symposium**

Over 1,000 leading Angus producers heard world-class speakers describe how genomics improves beef production, reduces environmental impact and increases food production. At the American Angus Association's International Genomics Symposium, in Indianapolis, leaders of the association also announced hitting the milestone of selling over 1 billion pounds of Certified Angus Beef. Ranchers use genomics to pick breeding stock. The symposium was sponsored by Neogen GeneSeek Operations.

#### **Modest growth predicted for state**

Nebraska will experience modest economic growth in the first half of 2017, according to the latest UNL leading economic indicator report. The indicator, a composite of economic factors that predict economic growth six months into the future, fell by 0.14 percent in October. "The October decrease, while small, reduces optimism for 2017," said economist Eric Thompson, director of the Bureau of Business Research at the university. "The Nebraska economy, however, should continue to grow next year."



*Meza new leader for global engagement*

### Jane Meza leading global outreach for UNMC, UNO

Jane Meza will begin a new role as interim associate vice chancellor for global and student support for the UNMC, UNO and Nebraska Medicine. Dr. Meza currently is senior associate dean for the UNMC College of Public Health and chairs its department of biostatistics. UNO, UNMC and Nebraska Medicine established the new position to collaborate on global engagement related to education, research and service.

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## National News

### Tie between human, animal health underlies biotech advances

BIO CEO Jim Greenwood writes that human health is "inextricably linked to the health of animals and the environment we share." Most elected officials aren't concerned with animal welfare because they're focused on human well-being, Greenwood writes, but appreciating the connectedness between animal and human health provides the basis for biotechnology research and product development.

### Trials for biotech wheat planned in UK

British researchers from Rothamsted Research, Lancaster University and the University of Essex have filed an application with the UK Department for Environment, Food and Rural Affairs seeking permission to conduct field trials of a biotech wheat variety that could increase yields by up to 40%. If approved, trials will start in April in Hertfordshire, England.

### Merck's new plant in China to churn out 10 billion doses by 2021

Merck has opened a pharmaceutical production plant in the Jiangsu province of China, and the plant will make drugs included on China's Essential Drug List. The first batch of drugs is expected to hit shelves by the second half of next year, and the company plans to be making 10 billion doses of diabetes, cardiovascular disease and thyroid disorder treatments a year by 2021.

### EPA proposes denial of RFS point of obligation change

The EPA intends to deny petitions from independent refiners to change the point of obligation under the Renewable Fuel Standard from refiners to the companies that blend biofuels into the transportation fuel supply. "While we do not anticipate a benefit from changing the point of obligation, we do believe that such a change would significantly increase the complexity of the RFS program which could negatively impact its effectiveness," the EPA stated.

### Alaska Airlines flight uses biofuel from wood waste

A jet fuel blend with 20% biofuel made from Pacific Northwest forest residuals powered an Alaska Airlines flight from Seattle to Washington on Monday. The biofuel blend was produced by Northwest Advanced Renewables Alliance, which is led by Washington State University.

### Novartis' leukemia drug under priority review by FDA

Novartis' new-drug application for PKC412, or midostaurin, has been accepted by the FDA for priority review as a treatment for newly diagnosed FLT3-mutated acute myeloid leukemia or advanced systemic mastocytosis in adults. The filing was backed by late-stage trial data involving AML patients whose risk of death was reduced by 23% compared with patients on chemotherapy, and a midstage study in patients with systemic mastocytosis that showed a 60% response rate to the treatment.

### Merck to collaborate with OpGen on antibiotic resistance Dx

Merck will partner with OpGen on the development of informatics technology and rapid diagnostics for antibiotic resistance in a collaboration with undisclosed financial terms. OpGen will gain access to Merck's library of 200,000 bacterial pathogens to support its database of antibiotic-resistant pathogens and rapid DNA test development.

### Will Liquid Biopsy Revolutionize Cancer Treatment?

Liquid biopsy technology and its potential impact on cancer diagnostics and therapies is covered in this paper from Novella Clinical: The Promise of Liquid Biopsy Technology

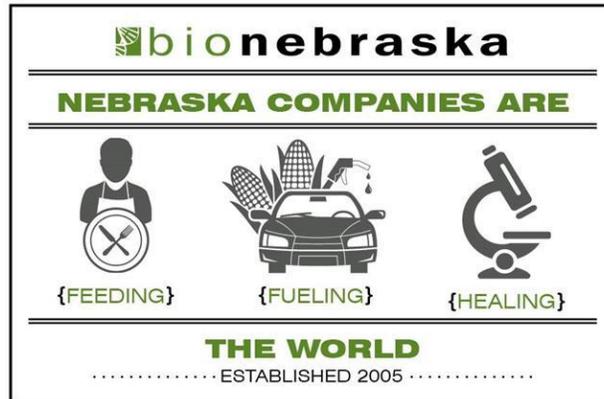
### Fla. OKs field trial of biotech mosquitoes

The Florida Keys Mosquito Control District's board has voted in favor of allowing a field trial of Oxitec's biotech mosquitoes. The board of the Florida Keys Mosquito Control District voted 3-2 to move forward

with the trial, with commissioners Stephen Smith and William Shaw opposing the measure, a spokeswoman for the mosquito control district said. Several steps remain before the trial can commence. First, officials need to find a new site after two-thirds of voters in the proposed location voted against the trial on a nonbinding ballot measure earlier this month.

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