



Oregon House Legislative Briefing: Bioscience Industry


Presenting Companies:




BIOTRONIK
excellence for life



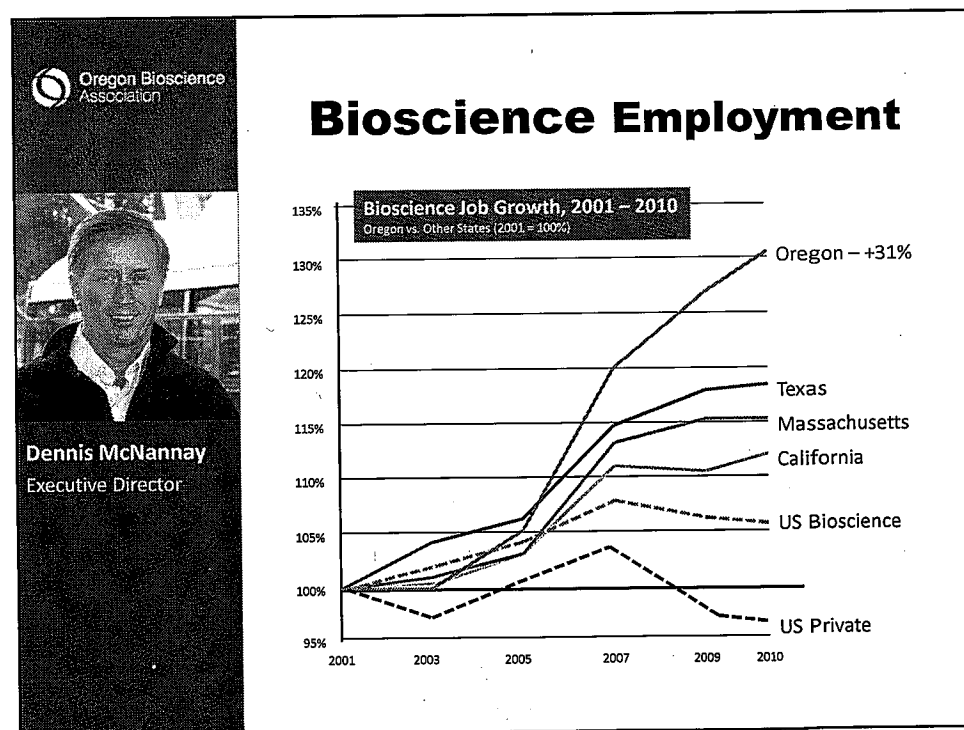
GALENA
BIOPHARMA



SAM MEDICAL
PRODUCTS®



REVMEDX





Juergen Lindner
General Manager

BIOTRONIK excellence for life

Since 1963, BIOTRONIK has been devoted to saving lives and improving the quality of life for patients and their families. Our research and development of cardiovascular medical devices exemplifies our commitment to maximum safety and top quality – and has ever since we developed Germany's first pacemaker in Berlin in 1963.

During the last half-century, more than two million of our devices have played a critical role in improving the health and well-being of patients. We have earned the trust of both physicians and patients, just as we trust in the skills and expertise of our over 5,600 employees in more than 100 countries.

Market Segment: Medical Implant Device

Oregon Employment: Over 500

Location : Lake Oswego, OR



Ryan Dunlap
Director, Controller &
Principal Accounting
Officer



Galena Biopharma, Inc. (Nasdaq: GALE) is focused on discovering, developing and commercializing innovative therapies addressing major unmet medical needs using targeted biotherapeutics.

Market Segment: Biotechnology

Number of Employees: 17

Location : Portland, OR

Market Capitalization: \$126,000,000 (created 2010)

REV MED X

Andrew Barofsky
President and CEO

RevMedx, Inc. is dedicated to saving lives by creating groundbreaking medical products designed specifically for combat medics and civilian first responders.

Recipient of \$6 million R&D funding from US Special Operations Command and U.S. Army Medical Research and Materiel Command

Number of Employees: 9 (*8 with Technical Backgrounds*)

Location: Wilsonville, OR

Date of Inception: 2009

SAM MEDICAL PRODUCTS®

Adrian Polliack
President

SAM Medical Products is a developer and manufacturer of innovative medical products used for emergency, military, and hospital care.

For more than 25 years, we have represented innovation and quality to the medical professional.

Number of Employees: 35

Location: Wilsonville, OR

Date of Inception: 2009



Bernard Fox
Chief Financial and
Operating Officer



UbiVac

UbiVac is a development stage biotechnology company that is focused on discovering, licensing, improving and commercializing immunotherapy products that safely generate and augment the immune response to vaccines.

Based on these data a phase I clinical trial of UbiVac vaccine technology will be initiated in patients with non-small cell lung cancer (NSCLC) in the first quarter of 2008. UbiVac is also exploring the application of this approach to the development of an avian flu vaccine.

Number of Employees: 4

Location: Portland, OR

Date of Inception: 2005

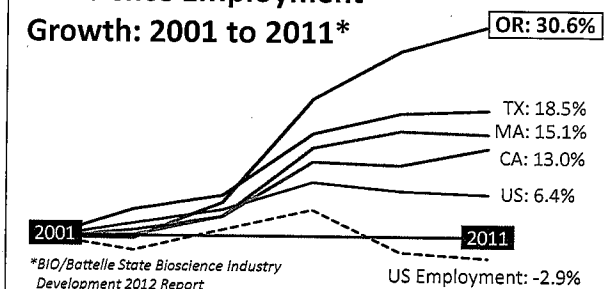
Oregon Statistics:

Oregon's bioscience industry is growing...

Highlights of Oregon's bio industry (as measured in 2009 data by ECONorthwest):

- Contributed \$7.1 billion directly and indirectly to Oregon's economy
- Employed more than 36,800
- Average Oregon bioscience wage: \$56,200
- Provided \$1.9 billion in cumulative personal income
- More than \$460 million spent on research, with most of this coming from federal funding sources
- Over 600 companies and research institutions
- Provides a 2.6 employment multiplier

Bioscience Employment Growth: 2001 to 2011*



Given the significant role bioscience plays in the Oregon economy, it is important that Oregon policy makers realize the aggressive efforts of other states to attract and retain these high-wage job producers. In order to compete for our share of these research, therapeutic, and manufacturing companies, Oregon must adopt more pro-active policies and incentives.

State-level Competitive Best Practices

- 12 States:** Match Phase One and Two SBIR grants
- WA:** Dedicates 10% of tobacco settlement to bioscience R&D
- GA:** Attracted more than 50 "Eminent Scholars" since 1990
- IL:** Provides workforce grants to companies hiring part-time graduate students for lab jobs while in school.

Members and Supporters

Airgas NorPac
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Biotronik
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Life Technologies
Medtronic
Moss Adams, LLP
Oregon Health & Science University
Oregon Translational Research & Development Institute
Pfizer
PhRMA
Portland State University
Precision Wire Components
Prolifiq
Publix Northwest
Schwabe, Williamson & Wyatt
Skanska
TE Connectivity—Medical
University of Oregon
Welch Allyn

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**Oregon Bioscience
Association**

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2013 Policy Guide

State and Federal Policy Priorities

The Oregon Bio supports public policies that foster job creation and promote growth of the life science industry by:

- Supporting productive business incentives that encourage traded sector industries, reward innovation, and stimulate research commercialization and entrepreneurship
- Promoting the creation of larger pools of investment capital to support emerging bioscience companies
- Advocating for the growth of health care markets and ensuring adequate access to health care products and services for all Oregonians, while avoiding narrow or punitive regulatory structures

www.oregonbio.org

Improve Business Environment



Policy Priority 1: Improve Oregon's Competitive Business Environment.

Create both productive business incentives and an entrepreneurial climate that boost Oregon's expanding bioscience industry by creating jobs, rewarding innovation, supporting company recruitment and fostering commercialized research. Oregon Bio points to these innovation initiatives:

- Support the \$1.7 million 2013-2015 biennium funding request (a 40% reduction from 2011) for Oregon Inc.'s bioscience Signature Research Center—the Oregon Translational Research and Development Institute's (OTRADI). Oregon Bio is also helping OTRADI stimulate job creation by supporting the new OTRADI Business Incubator (OBI), which opens in spring 2013. OBI will provide lab space and business mentoring for five "venture ready" bioscience companies.
- Complete, distribute and assist the implementation of an Oregon Bioscience Industry Roadmap. Created with participation from both public and private sectors, this roadmap will help Oregon compete nationally for its share of this high wage industry.
- Expand life science and biotechnology workforce development initiatives.
- Support the Governor's STEAM Access Task Force, which encourages students to pursue science, technology, engineering, arts and mathematics degrees.

Access to Growth Capital



Policy Priority 2: Improve Access to Growth Capital.

Oregon Bio seeks to help build the pools of public and private investment capital. Our goal is to coordinate the participation of all available state resources (e.g. state pension funds), providing Oregon companies increased access to funds, while simultaneously ensuring the fiduciary integrity of the funding entities.

- Support development and coordination of both the Oregon Growth Fund and the Oregon Growth Board to provide expanded and continued investment for Oregon bioscience companies.

Following the trend of other states (e.g. Utah, Wisconsin, Colorado, Connecticut), Oregon Bio will help state officials coordinate a more effective investment outreach effort. Investment fund managers would be encouraged to consider prospective Oregon bioscience companies when investing Oregon funds.

- Grow research and development funding/grants while protecting state, federal and private incentives.
- Use increased access to capital as a tool to recruit more bioscience companies to Oregon.

Sustain Health Care Products and Services



Policy Priority 3: Maintain Access to Health Care Products and Services.

Oregon Bio actively advocates for stable access to health care services and products for Oregonians by preserving reimbursements and monitoring health care reform actions and rules that impact public and private resources and financing.

- Support implementation of the Oregon health insurance exchange, due in 2014. Oregon Bio will help shape policy regarding how Oregonians who are covered by commercial, individual and public health plans will have continued access to new and innovative therapies and medical devices.
- Work in partnership with national device manufacturers' trade association, AdvaMed, to support rule changes for the HERC (Health Evidence Review Commission) to: (1) Create transparency in proceedings; (2) Require testimony from industry experts before commission renders decisions, and (3) Allow for sufficient notice of meetings and agenda items.
- Support the Biotechnology Industry Organization's (BIO) principles/platform regarding biosimilars, "Patient Safety in the Substitution of Biologic Products."
- Work with BIO and other national partners to repeal the federal medical device tax.

"Bioscience is a key industry driving Oregon's economy and long-term job growth. We have an opportunity right now to accelerate this innovative field by supporting capital expansion. We see the bioscience industry as a natural fit for Oregon."
Representative Tobias Read

"The Oregon Investment Act puts us on a path toward a smarter and more coordinated economic development strategy . . . this is the right approach to making key investments that will help invigorate our economy and increase wages."
Oregon State Treasurer Ted Wheeler

"We need more than an economic recovery to improve the lives of Oregonians for the long term. 'Recovery' implies going back to doing things the way we did in the past -- we need economic reinvention."
Oregon Governor Dr. John Kitzhaber

"The Oregon Investment Act puts us on a path toward a smarter and more coordinated economic development strategy... this is the right approach to making key investments that will help invigorate our economy and increase wages."

Oregon State Treasurer
Ted Wheeler

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Peter Murray, Welch Allyn, Chair
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Jennifer Fox, Ph.D., OTRADI
Geoff Hall, Precision Wire Components
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Adrian Polliack, SAM Medical
Steven Prewitt,
Schwabe Williamson & Wyatt
Ron Sherman, Silicon Valley Bank
Nathan Gibson, Skanska USA
Matt Smits, TE Connectivity
Will Fox, Welch Allyn
Gordon Brown, Yecuris Corp.
Michael Phillips, Davis Wright Tremaine

Contributors to this report:

Dennis McNannay
Pat Coussens
Dianne Danowski Smith

Staff of Oregon Bioscience Association

Dennis McNannay, Executive Director
Dan Hill, Director of Member Services
Donna Chambers, Office Manager

Advocacy in action 2012

Oregon Bio established another active policy platform with high activation in 2012. Several key issues at the federal and statewide legislative levels warranted Oregon Bio's response. In continuing momentum from the 2011 legislative session, Oregon Bio's Government Affairs and Advocacy Committee and Oregon Bio's board adopted guiding principles to value public policies that encourage job creation, capitalize and encourage commercialization, and promote the growth of the life science industry in Oregon through:

- Productive taxation and business incentives that enables the expansion of industry clusters, rewards innovation and stimulates commercialized research;
- Avoidance of punitive regulatory structures while maintaining our customers' safety; and
- Advocating for the growth of health markets and ensuring adequate access to health care for all Oregonians.

Arguably the key effort founded by Oregon Bio was the impetus and eventual 2012 passage of the Oregon Investment Act. The act evolved the identification of capital gaps that exist in Oregon, and lack of investment in economic growth strategies across many key industries. The act seeks to better coordinate the attraction of venture capital, targeted tax credits and small-business assistance, and culminated in creating the Oregon Investment Board.

Another key priority was co-organized by the national medical device trade association. As partners, Oregon Bio and AdvaMed pursued potential legislation to require the Oregon Health Authority's Health Evidence Review Commission to transparently conduct product reviews and coverage determinations, and to include expert testimony and fair notice of hearings.

Important policy work also included active advocacy for continued funding of the Oregon Translational Research and Development Institute, and Oregon Bio's board adoption of BIO's

"Principles on Patient Safety in the Substitution of Biologic Products," setting forth a path as FDA and state policies emerge on biosimilars.

Medical device tax: Oregon companies face real impact

Despite efforts from Oregon Bio and alliances across the country seeking to repeal or delay its implementation, a 2.3 percent tax on the sale of certain medical devices in the U.S. went into effect in January, 2012.

The impact of the tax locally was illustrated by Welch Allyn, a New York-based manufacturer with operations in Beaverton. The company's Oregon workforce was dropped from 270 people to 110 as a result of its move to cut 10 percent of its 2,750-person global workforce as part of the firm's restructuring. Welch Allyn's CEO, Steve Meyer, said the cuts within his company, a manufacturer of patient monitoring systems and vital signs devices, were necessitated by the 2.3 percent tax included in the federal Affordable Care Act.

The Portland office of Oregon Bio member Moss Adams has helped companies to understand the tax's implications. In the national health care legislation, the tax applies to the sale of taxable medical devices by their manufacturer, producer or importer. Under the tax, the medical device manufacturing community pays an estimated average of \$194 million per month in medical device tax payments.

Despite widespread opposition, the implemented tax is a threat to the medical device industry that employs more than 400,000 workers nationwide, generates approximately \$25 billion in payroll and invests nearly \$10 billion in annual research and development.

In December, the U.S. Treasury published final regulations and additional interim guidance that define a "taxable medical device" as any device listed with the FDA under Section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 807. The statute provides some exemptions to the tax.

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Oregon Bioscience
Association

ANNUAL REPORT | 2012

2012: The Year of Bio's Growth in Oregon

Dear Members and Community,

2012 represented a noteworthy year for Oregon Bio and our member companies. It was a year of drastic and fundamental change. In many cases, progress came as the result of years of careful planning and effort. Whether it was the groundbreaking for the Collaborative Life Sciences Building or the passage of the Oregon Investment Act, the bioscience industry and Oregon Bio are having a greater statewide impact than ever.

Fortunately, Oregon Bio, since its genesis, has and continues to be a catalyst for growth and awareness of Oregon's bioscience industry. Now we are starting to reap the benefits.

One clear indication of Oregon Bio's health and vibrancy was the success of both our annual conference and networking events. Newly expanded into a two-day event, the Oregon Bio 2012: Oregon Bioscience Digitization and Discovery conference attracted world-class keynote speakers and an average of 240 attendees each day. Based on the post-conference attendee survey, our 2012 event was easily the most popular and successful conference in Oregon Bio history. Not to be outdone, our "Bio On" series of networking events each sold out in 2012, averaging 140 attendees per event.

After years of consistent advocacy, Oregon Bio helped win support for renewed R&D tax credits, and passage of the Oregon Investment Act; and assisted OTRADI in its successful bid to construct a bioscience-specific business incubator. Achieving these important milestones add to the growing realization that Oregon's bioscience industry is on the move as an economic sector and employment engine.

Although our industry tends to follow a slow, incremental growth path, it may seem surprising to veteran industry watchers that the 2012 Battelle/BIO industry report documents Oregon's rapid employment growth. From 2001 to 2011, the 30.6 percent employment growth in Oregon out-performed employment growth over the same period in Texas, California and Massachusetts. This is a record of accomplishment far too few recognize.

And 2013 promises another exciting year. Thanks for joining with us in these efforts.

Dennis McNannay, Executive Director

Peter Murray, 2012 Board Chair
Vice President of Operations West, Welch Allyn

2012 funding and grants for Oregon's bioscience research

Oregon in 2012 expanded again with a strong and stable portion of federal funding with universities and academic organizations receiving grants and support from entities including the National Institutes of Health, Department of Defense and the National Science Foundation. Overall, Oregon's portion of the NIH funds increased over 2011.

NIH Extramural Awards for FY2012: \$304,571,134

According to NIH, these funds in FY 2012:

- Oregon received 713 awards, up from FY 2011
- 60 companies and research institutions received awards, up from FY 2011
- SBIR and STTR funding comprise \$25 million of the total
- Each NIH dollar invested in Oregon generates \$2.21 in new state business activity



"Oregon Bio has actively involved members and strong leadership which has created an organization that is growing in size, leverage and value."

Adrian Polliack, Ph. D.
President of SAM Medical Products
and Oregon Bio's 2012 Chair Elect



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2828 SW Corbett Avenue, Suite 115 | Portland, OR 97201

Oregon Bio: 2012 milestones

OTRADI: Bioscience incubator complex set in motion

In late November, the Oregon Translational Research and Development Institute (OTRADI) announced its plans to create a 13,000 square-foot bioscience complex in Portland's South Waterfront District.

Slated to be complete in Spring 2013, the OTRADI Bioscience Incubator (OBI) will house up to six companies. Approximately 50 percent of the OBI space has already been reserved by area bioscience companies. Among the future tenants is 13therapeutics—the Oregon Health & Science University-spawned drug company which has raised more than \$7 million in startup and venture capital funds.

Renovations to the existing space will include building out individual labs and offices, as well as shared equipment, conference facilities and administrative areas. The incubator will also include six wet labs—large research areas that include plumbing fixtures, lab benches and air ventilation systems.

According to OTRADI Executive Director Jennifer Fox, Ph.D., the bioscience incubator's shared space and entrepreneurial mentoring is designed to increase the chances of successful expansion for promising startups. She adds that in addition to the facility supporting the growth of new companies, it can also reduce the barriers between innovative bioscience ideas and successful commercialization.



Ultimately, Fox believes the OBI will play an important role in keeping successful bioscience startups in Oregon as they commercialize their research and ideas into products in the marketplace.

Projections of rapid industry growth over the next several years have further encouraged large scale investors to support OTRADI's vision, which includes the development of the OBI. Funds provided via the Oregon Innovation Council will cover the OBI's initial \$1 million buildout costs.

Oregon InC., the state-led effort to back startups and commercialize public university research, has allotted some \$10 million to OTRADI since 2007. The nonprofit OTRADI, currently located at PSU's downtown campus, plans to also co-locate its operations in the OBI.

FDA clearance propels Sonivate Medical

Founded by Dr. Ron Schultz and technologist Scott Corbett under the name BlackToe Medical, the newly named Sonivate Medical secured FDA clearance of its ultrasound-imaging SonicEye product last spring.

The finger-mounted SonicEye is a small probe device that the provider uses to scan for biopsies, nerve blocks, vascular access and numerous guided procedures and protocols.

In 2001, Schultz began work on a glove containing an ultrasound transducer. Eventually teaming with Corbett, they produced the finger-worn ultrasound probe, combining miniaturization and ultrasound transducer design.

Despite myriad challenges, funding was eventually acquired to reach the company's FDA-clearance goal. Earlier in 2008, funding dried up just as the product's design was nearing fruition. The company was on hold until winning a SBIR grant worth \$750,000 through the Department of Defense.

Starr continues his focus on feeding Sonivate Medical's funding hopper. In addition to its recent work on a \$1 million equity round, the company was awarded \$265,000 through the Bend Venture Conference in September. At October's Oregon Bio Conference, Sonivate was also awarded \$1,500 worth of patent work by the law firm of Alleman Hall McCoy Russell Tuttle.

2012 brings continued success for Tree Star's niche market

In the world of modern cell research, flow cytometry provides a prime example of an area where even though technologies are rapidly producing more and more results, processing the multitudinous data is a mammoth challenge.

Enter Oregon Bio member Tree Star, Inc.

The Ashland-based company continues to find success through its FlowJo software technology used to effectively analyze flow cytometry data. Cytometry refers to the measurement of the physical and chemical characteristics of cells, and flow cytometry is the process in which measurements are made while cells in a liquid suspension are

forced to flow one at a time through a measuring device. Doctors and scientists used to arduously count cells with a microscope. The invention of the flow cytometer and programs like Tree Star's FlowJo, has allowed researchers to count thousands of cells rapidly while obtaining much more detailed information.

According to Mike Stadnisky, Ph.D., application scientist at Tree Star, as the utility and power of cytometers evolved, a need arose for a more powerful and user-friendly analysis and display program.

Stadnisky said FlowJo was primarily written by Adam Treister, who founded Tree Star in 1989, and his teammate Mario Roederer. The company, then based near Palo Alto, developed several software applications devoted to data mining, analysis and display. Treister's work with the Stanford Department of Genetics brought him into contact with the Herzenberg Laboratory, where he and Roederer collaborated on the first prototypes for FlowJo.

The product was made available commercially in 1996. In 2003, Tree Star relocated to Ashland and continues its rise in its niche market today.

As the company furthers its growth of creations FlowJo, FlowDx and Fluorish (which Stadnisky calls an e-commerce solution the firm hopes will dramatically help users design, share, and improve their flow cytometry experiments), Tree Star is on the cusp of releasing its newest version, FlowJo vX.

Oregon Bio: 2012 Growth

BIO cites Oregon as a high percentage job growth state over a decade

The Battelle/BIO 2012 State Bioscience Industry Development Report cited Oregon with its decade-long employment gains at 30 percent, surpassing Texas, Massachusetts, and California as well as the U.S. bioscience industry. Each of these states also leapfrogged the U.S. private industry market in the past decade. The report cites Oregon growth in other ways.

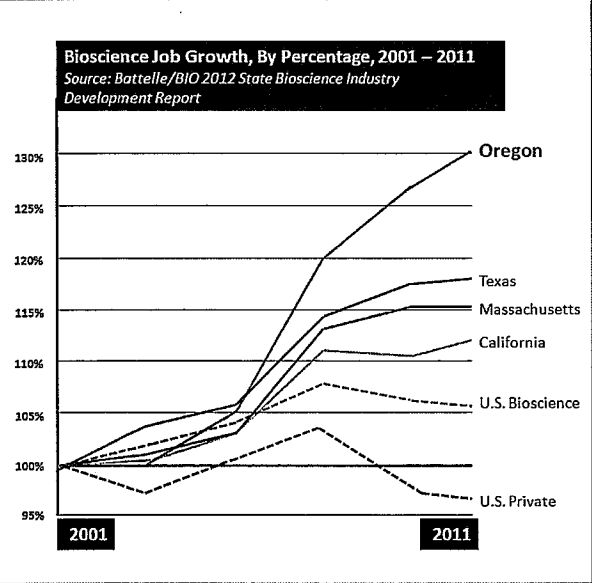
Oregon's bioscience sector:
Outgrew Oregon's total private sector employment by 20% since 2001.

Increased employment by 8% during the economy's 2007-2010 recession and nearly 31% in the past decade.

Showed job gains overall since 2001 in each of the industry's main five subsectors.

Grew average annual wages by 7.6% over 2011.

Increased the number of bioscience establishments to 762.



Oregon Bio's 2012 conference sets records

In early October, Oregon Bio hosted its fifth annual statewide conference themed, "Oregon Bio 2012: Bioscience Digitization and Discovery." Attendees reported high approvals of content, tracks, speakers, networking opportunities and location.

"This was easily the highest value conference we've ever assembled," said Dennis McNannay, Oregon Bio's executive director. Just over 40 percent of attendees said this was their first Oregon Bio conference and 30 percent had attended at least twice before, with overall attendance surpassing past Oregon Bio events.

A number of firsts were accomplished:

- Research Pavilion: The first effort to host a walk-through area highlighting locally-based innovation and research.
- STEM: This was the first opportunity that included Oregon high schools students in curricula focusing on science, technology, engineering and math.
- Gov. Kitzhaber declared October 9 as Oregon Digital Health and Bioscience Day, to kick off the conference's first day.
- Entrepreneur-a-palooza: Local start-up executives made pitches for a potential prize of patent counsel from law firm Alleman Hall McCoy Russell Tuttle, with the award going to Sonivate.
- Recommendation: 2012 marked the first year 100 percent of attendees said they would recommend attendance to others.

"The reception and dinner were highly popular with 'unplugged' perspectives from well known industry pros who gave no-holds-barred comments on the future of personalized medicine, commercialization and industry growth predictions," said McNannay. The 2013 annual conference will happen the week of September 16.

BioPro continues success

Celebrating its fifth successful year in 2012, Oregon Bio's BioPro, a comprehensive workforce training program created to upskill bioscience professionals, continues its growth and popularity.

The program, which for the first year, supported itself completely on user fees, targets the workforce development needs of Oregon companies and research institutions in biotechnology, medical devices, diagnostic tools and related technologies. BioPro features diverse offerings onsite at companies as well as community classrooms, with innovative industry-specific series curricula and well regarded instructors.

"We have a laser focus for the BioPro program, which is to enhance the talent and skills of the Oregon bio workforce to make the region an even more competitive, world-class bioscience landscape," says Dan Hill, Oregon Bio's director of training. Since 2007, the BioPro program has trained roughly 30 percent of Oregon's direct bioscience workforce.

BioPro's curricula address key bioscience areas through classes covering manufacturing; regulatory inspections; corrective and preventive actions; statistical process control; planning and time management; frontline management; problem solving; technical writing; records and documentation creation and maintenance; effective negotiating and business writing, as well as labeling, and product and service channel marketing.

The program received "gold" standard honors for cluster training in its industry through the Oregon Governor's Office.

Tailored to bioscience workers from quality analysts to program managers, 2012 was also the year BioPro offered its first-ever class for workers seeking to learn Six Sigma Black Belt methodology to help apply it in their organizations to make performance-improvement breakthroughs.

Highlights of BioPro in 2012:

- Trained over 2,500 bioscience workers since 2007
- Trained 520 students for a total of 5,920 training hours
- Deliver training in metro Portland as well as Bend and Corvallis
- Introduced 15 new classes and instructors
- Worked directly with 64 companies that participated in 2012.

"The BioPro program in 2012 had financial stability; the results of significant work and focus from board members and participants. The BioPro program has gone from an entity that relied on most of its funding from government grants to a self-sustaining program that has added better content and course topics to reflect the ever changing needs of the Oregon Bio membership."

Peter Murray, Vice President of Operations West, Welch Allyn and Oregon Bio's 2012 Chair