CRS Leading Delivery Science and Technology

Newsletter

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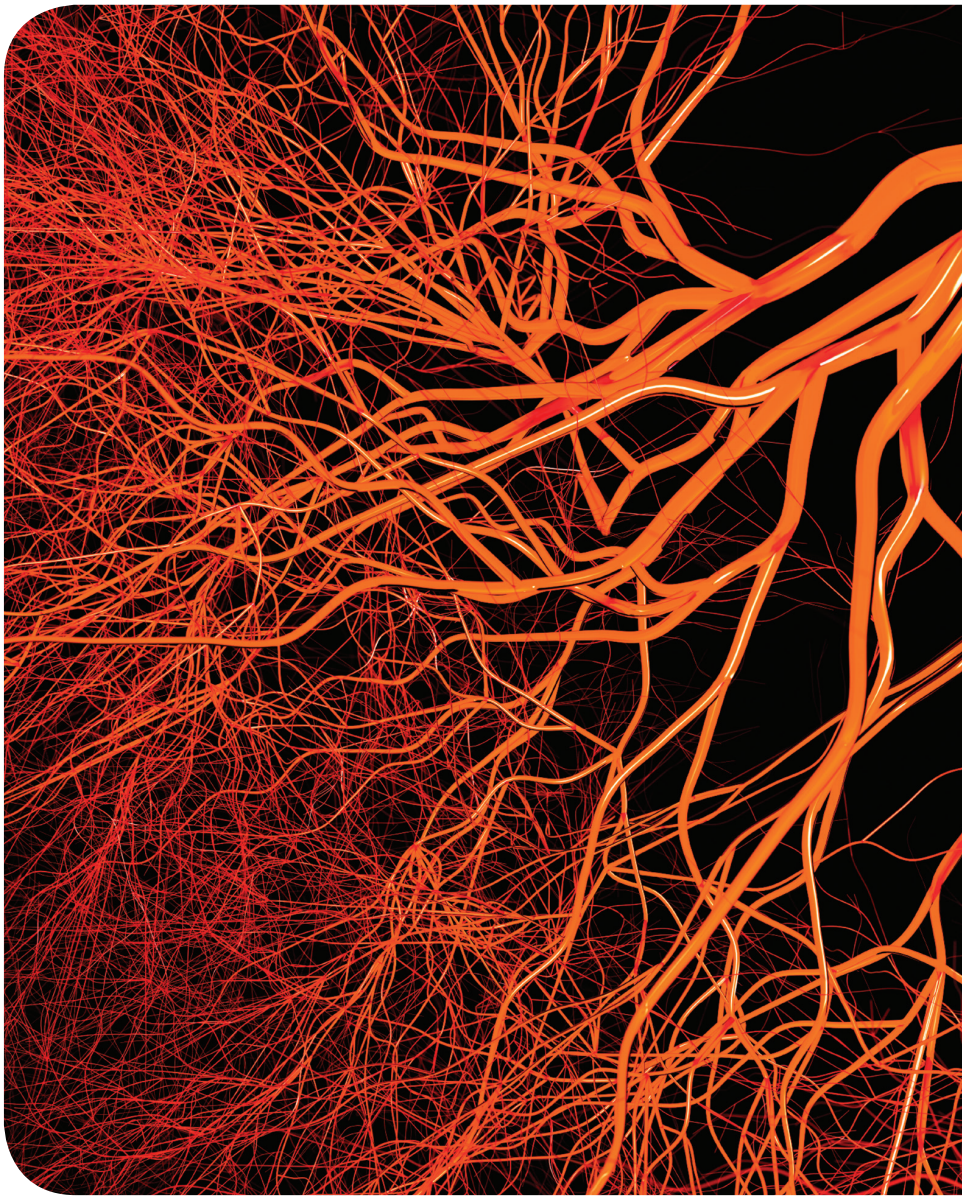

What's Inside

Join CRS in the Ultimate Global Gathering Place

Hawaii

REGISTRATION AND HOUSING NOW OPEN

REGISTER BY MAY 2 AND SAVE

40th Annual Meeting & Exposition of the Controlled Release Society

July 21–24, 2013
Hawaii Convention Center
Honolulu, Hawaii, U.S.A.

Emerging Challenges for Global Delivery

Join your delivery science colleagues for the latest information on emerging issues in delivery science and technology, including ocular and oral delivery, drug combination products, nanotechnology, interspecies variability, nutraceuticals, peptide and protein delivery, and more.

- Register by May 2 and save
- Hotel reservation deadline is June 19
- See a list of invited speakers and the full program online
- Exhibit space and sponsorship opportunities available

Location photo courtesy of the Hawaii Convention Center / David Cornwell.

CRS
Leading Delivery Science and Technology

www.controlledreleasesociety.org/meeting

CRS Newsletter
Leading Delivery Science and Technology

Vol. 30 • No. 2 • 2013

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The CRS Newsletter is the official newsletter of the Controlled Release Society. The newsletter is published six times annually, providing scientific and technical information pertinent to the controlled release community and news about society and chapter activities. Members can receive the newsletter via mail. The newsletter may also be viewed online at www.controlledreleasesociety.org.

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Visit www.controlledreleasesociety.org or e-mail crs@scisoc.org on questions about membership, meetings, publications, and services.

Contact dwoodard@scisoc.org for information about exhibiting, advertising or other visibility opportunities.

Steve Giannos
University of Maryland,
Baltimore, MD, U.S.A.

An Amazing 40 Years

As I watch the evening news on TV, the wrap-up story is all about the first cell phone call, made in New York City 40 years ago. Now we have billions of cell phones and several very large cell phone manufacturers.

This summer, we mark 40 years of controlled release and drug delivery at the CRS Annual Meeting & Exposition. (The annual meeting preceded CRS, founded in 1978, by five years.) Just take a moment to think of all of the pharmaceutical, consumer, cosmetic, food, and nutraceutical products that employ controlled release principles and technologies. We have changed the world too. Although controlled release is not a common topic in everyday life, our work shows up in a myriad of places, and our colleagues who have invented, researched, manufactured, and marketed controlled release products over the years have a lot to be proud of.

So much for cell phones.

In this issue of the *CRS Newsletter*, there is a very interesting article from the Aston Pharmacy School, U.K., describing the use of microfluidics for the preparation of liposomes. There is also report from the New Zealand Chapter of the Controlled Release Society (NZCRS) about their recent conference, which was the 15th annual meeting of the Formulation and Delivery of Bioactives (FDB) research theme at the University of Otago.

An interesting article comes to us from Interspeciesinfo.com, a helpful tool for the interpretation of interspecies differences and for choosing the optimal animal model. High-quality research using fewer laboratory animals is a major challenge in many research areas. In 2006, the National Institute of Public Health and the Environment (RIVM) in the Netherlands launched the website www.interspeciesinfo.com to support researchers in reducing and refining the use of laboratory animals.

Amy Hope is the newly appointed executive vice president of Scientific Societies, the operational headquarters for CRS and several additional scientific associations. Please welcome her in her new position. We also have nominations for the Board and for the Board of Scientific Advisors in this issue of the *CRS Newsletter* as well.

The CRS Foundation is looking for your support. The foundation started recently (2007), as we realized that we needed to honor the pillars of the society, and awarding postdoctoral fellowships is a way to build future leadership. To be sustainable, we need an endowment, instead of simply collecting for named fellowships as we go. Why give to the CRS Foundation? Many of the same reasons you give to your university. It keeps the CRS strong (future leaders) and contributes to solving challenging multidisciplinary problems (which is what CRS members do).

In closing, please try to get to Hawaii for the Annual Meeting. I attended the Hawaii meeting in 2004 and spent a few extra days sightseeing on the Big Island and staying at a coffee farm B&B. It was well worth the trip.

All the best,
Steve ■

Kazunori Kataoka
University of Tokyo
Tokyo, Japan

Diversity and Innovation

Biologists have long understood the importance of diversity. Biodiversity boosts productivity because each species, no matter how small, has an important role to play; though uniquely specialized, each contributes to something bigger than itself. Most importantly, diverse ecosystems are much stronger and much more likely to innovate.

Social scientists confirm the same in human groups. American researcher Scott E. Page, a professor of complex systems, political science, and economics at the University of Michigan, says of such research, "There's a lot of empirical data to show that diverse cities are more productive, diverse boards of directors make better decisions, the most innovative companies are diverse. Breakthroughs in science increasingly come from teams of bright, diverse people. That's why interdisciplinary work is the biggest trend in scientific research."

For CRS, diversity is one of our core strengths. Our members utilize a shared technology, which brings a level of shared experience that is critical in our understanding of one another's work. Yet we each represent a unique expression of that technology—we each function within a certain niche of the biosphere (if you will) of delivery science.

As an association, we give considered thought to facilitating, encouraging, and expanding the diversity of our membership and our member leaders. This attentiveness starts with the election of our board members. The nominating committee carefully considers each candidate, looking for a mix of skills, knowledge, scientific merit, and experience that will enable that person to serve as both a leader and a collaborator within our governing structure.

We take this even one step further. To ensure that we have thoroughly examined the many possible candidates for leadership within the society, we ask our members to review our "findings" (candidates). Our bylaws call for a review and petition period in which members have the opportunity to review the candidates for both the CRS Board and Board of Scientific Advisors and to challenge the selection of a particular candidate if they feel called to do so, or they may submit alternate candidates for consideration. This ensures a broad and diverse perspective at the leadership level and sets the tone for open and innovative approaches to governing our association.

CRS local chapters are another reflection of the breadth and depth of CRS. The geographical structure of our chapters places them across continents and countries and provides a vital and important vehicle for members to interact, learn, and innovate. Many chapters hold their own conferences, have their own websites, and organize regular events. In addition to our chapters, the CRS divisions and focus groups also enable us to maintain our diversity while providing avenues of support for specific areas of specialization.

The diversity of our society and the platform for innovation that it creates are on full display at our annual meeting. This year in particular, our expansive scientific program and location in Hawaii (a center of commerce with global appeal) will attract an even larger and more diverse group of colleagues. The science and location are certain to boost the number of attendees from Asia, Australia, Europe, and North America. What's more, the emerging markets of China, India, and other Pacific Rim countries offer huge potential in the areas that delivery science serves, from pharmaceuticals to consumer and diversified products.

It is my honor to lead an association of such unique strength, resourcefulness, and accomplishment. When each of us has the opportunity to expresses our ideas and knowledge to the fullest, we all benefit. Your CRS leadership is here to create and facilitate these opportunities for connection and voice. Each of us is integral to the system and to the advancement of delivery science. I look forward to seeing you in Hawaii, where we will bring our diverse experiences and knowledge to bear on advancing and addressing some of the most exciting and emerging issues in delivery science.

Kazunori Kataoka ■

Delivery Science Meets Aloha Spirit: 40th CRS Annual Meeting & Exposition

July 21–24, 2013 • Honolulu, Hawaii, U.S.A.

Between the stellar scientific line-up, including 120 oral presentations, over 800 posters, six scientific workshops, and three insightful plenary speakers, this year's annual meeting is certainly not one you will want to miss! The program team is ensuring that the many diverse areas of delivery science are covered and that all attendees will have the chance to discover the latest findings in their area of delivery science plus expand their knowledge of and apply technologies from other areas. Read here about the offerings in Consumer & Diversified Products, Preclinical Sciences & Animal Health, CRS Innovation Sunday, and workshops that will add to your educational experience. Plus, learn a little bit about the host city—stunning Honolulu, Hawaii!

Animal Health and Preclinical Sciences Will Be Highlighted in Hawaii

The Preclinical Sciences & Animal Health Division (previously the Veterinary Division) is celebrating its first full year in its newly established form, which was created to meet not only the needs of scientists involved in the development and regulation of drugs and biologics intended for veterinary use but also the interests of pharmaceutical scientists working in preclinical drug development. There will be plenty of opportunities to discover top science in both preclinical sciences and drug delivery in animal health at this year's CRS Annual Meeting.

Attendees deep in discussion at the 2012 Preclinical Sciences & Animal Health Get-Together.

Invited speaker Jim Klostegaard, of the University of Texas, U.S.A., will lead a session on "Drug Targeting, Pharmacokinetics, and Biodistribution: Differences Between Species." While animal models are often used to explore the potential therapeutic application of targeted therapeutics, little information is available on the potential pitfalls associated with interspecies extrapolations. This session will highlight the challenges encountered when using animal models for therapeutics designed for use in humans. The challenges of optimizing the predictive capabilities of these animal model studies to support the development of human therapeutics and imaging products will be emphasized. Invited speaker Margareta Hammarlund-Udenaes, Uppsala University, Sweden, will likewise lead the "Challenges Around Brain Delivery: Sampling Site Issues and Interspecies Extrapolations" session. It will highlight the difficulties associated with estimating brain target site concentrations, errors associated with the use of cerebral spinal fluid concentrations to estimate concentrations in brain extracellular fluids, and the complications associated with interspecies extrapolation of drug delivery to the brain. Many other sessions will explore drug delivery in animals, including examining tropical/transdermal drug delivery, delivery to the brain, ocular and pulmonary delivery, and RNAi and DNA delivery. Peruse the more than 800 posters to see the latest technologies in animal health and preclinical sciences, and discover research that applies to your work. Be sure to hear the latest research during the mini-symposium on "Breakthrough Technologies in Drug Delivery in Asia," and learn about drug delivery in developing countries and the global challenges around our science.

All meeting attendees interested in preclinical sciences and animal health are welcome at the annual Preclinical Sciences & Animal Health Get-Together, cosponsored by Merial, taking place on Monday, July 22. This is your opportunity to finish off a day full of science by meeting colleagues with the same interests in a more relaxed setting.

From Food to Skyscrapers: Consumer & Diversified Products Sessions to Deliver a Wide Range of Delivery Science Applications

This year's Consumer & Diversified Products program is exceptionally strong, emphasizing the many areas that delivery science influences. The strong panel of presenters echoes that sentiment, representing industry and academia from around the world.

The "Food, Nutraceuticals, and Personalized Diet" session will cover recent developments in food research such as the addition of health-promoting ingredients like probiotics and vitamins, enhanced experience with long-lasting release of energy-providing ingredients, natural and less-processed food, and more. Invited speaker Martin Kussmann of Nestlé Institute of Health Sciences, Switzerland, will speak on personalized diet and bioavailability. From microencapsulation of ingredients for animal feed to intramammary delivery of drugs, "Modern Agriculture and Aquaculture" will focus on new possibilities for encapsulation and controlled release products in agriculture and aquaculture. The "Personal and Home Care" session attempts to capture current work and applications across skin care, personal care, home care, cleaning agents, and more. The optimization of microcapsules in home and fabric care will be the focus of the presentation by invited speaker Jiten Dihora from Proctor & Gamble, U.S.A. "Smart Building and Construction Materials

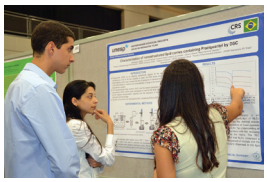
and Coatings" will look at how building materials can be made more sustainable, highlighting controlled release in new-age building materials and smart materials for construction and renovation.

James Oxley, C&DP Division Chair, addressed C&DP Luncheon attendees at the 2012 CRS Annual Meeting.

Worldwide energy consumption continues to rise, and technological solutions are needed to increase energy production. The mini-symposium "Energy: Problems Within the Industry That Controlled Delivery Can Solve" will bring together top scientists on controlled release technologies used in the energy field. Included are the use of high-temperature phase-change materials for solar energy storage and methods for enhanced oil recovery and spill cleanup. Presentation scope will range from the state of the current art to the unmet needs in these fields to stimulate the discussion between scientists and end users.

These are in addition to 16 other sessions related to delivery in the pharmaceutical and animal health industries, five mini-symposia on various topics, and several workshops. The opportunity to meet with delivery scientists who are working in other areas is vital, as innovation often springs from the blending of ideas from diverse origins.

The personal connections within CRS can be a source of significant opportunity. The Consumer & Diversified Products Division will be holding its luncheon on Tuesday, July 23, during the meeting. It always features lively conversation, old friends, and a few surprises each year. Plus, meet with your colleagues during the C&DP business meeting while at the annual meeting.



The CRS Annual Meeting & Exposition offers a comprehensive snapshot of the current state of controlled release and delivery science with the opportunity not only to see what is being accomplished and how problems are being solved but also to be a part of the conversation and direction of this work. Make plans to engage in this rewarding experience July 21–24, 2013, in beautiful Honolulu, Hawaii!

Gain More from Your Meeting Experience with an Educational Workshop

Come early and attend one of the workshops at the 40th CRS Annual Meeting & Exposition. These workshops offer focused presentations on specific topics by noted speakers and are open to a limited number of participants for an additional fee. The educational workshops will be held Saturday, July 20–Sunday, July 21. You must register for all educational workshops in advance, and you do not need to attend the entire meeting to attend a workshop. See the meeting website for more complete details.

Oral Delivery of Bioactives Using Lipid-Based Drug Delivery Systems

Saturday, July 20, 08:55 – 17:00, and Sunday, July 21, 08:30 – noon

Chaired by Anette Müllertz, University of Copenhagen, Denmark, and Sarah Hook, University of Otago, New Zealand

The three major challenges in the development of oral delivery systems are poor aqueous solubility of low-molecular "classical" drugs, the development of oral delivery systems for modern biologics, and the development of oral vaccines. In all three areas lipid delivery systems have a lot to offer. In this workshop we will explore new developments in the formulation and delivery of small-molecular-weight drugs, proteins, and vaccines. Analytical techniques for the development, as well as the understanding of the mode of action, of lipid-based delivery systems are crucial in this process and will also be included in this workshop.

Controlled Release Dosage Forms and Product Development Strategy for Expected New Regulatory Trends

Saturday, July 20, 08:00 – 17:00

Chaired by Ubrani Venkataram and Yanning Lin, Food & Drug Administration, U.S.A.

A recurrent theme in FDA expectations is for the application of QbD principles in the development of controlled release solid oral dosage forms. The workshop intends to present topics relevant to demonstration of product and process understanding in regulatory submissions. Speakers will discuss new trends and technology approaches for robust formulations, a development strategy via *in vitro–in vivo* relationships (IVIVR), the use of spectroscopic methods for the examination of the solid state of controlled polymers, and a backwards look at scale-up for the Wurster process. FDA staff will discuss current expectations for regulatory submissions in the Office of Generic Drugs with a focus on application of QbD principles to the product development of controlled release solid oral dosage forms.

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Leadership Workshop for Women in Science

Saturday, July 20, 08:00 - 17:00

Chaired by Diane Burgess, University of Connecticut, U.S.A.
Organized by the CRS Women in Science Task Force

This highly interactive professional development workshop includes best-practice theory, personal reflection, and small group work. Each participant will leave with a clear understanding of their management strengths and challenges. Attendees will also learn how to enhance their ability to lead a team, build a coalition with peers, and effectively influence "up." Prior to the course, each participant will be asked to take two online personal assessments. Results from this pre-course work will be used to create personalized binders for each participant to use during the workshop.

Taste-Masking Technologies and Formulations: Meeting the Challenges for Bitter Drug Actives

Saturday, July 20, 08:00 – 17:00

Chaired by Nigel Langley, BASF Corporation, U.S.A., and Tom Farrell, Colorcon Inc., U.S.A.

The workshop will discuss the growing importance and relevance of taste masking in pharmaceutical drug development. Areas such as life-cycle management, pediatric, and geriatric medicines and veterinary applications will be highlighted. The FDA will provide insight into the current requirements for pediatric medicines. Existing and new technologies for taste masking solid oral dosages and liquid formulations will be described. The workshop will finish with an open panel discussion providing the attendees an opportunity to debate this important issue within the pharmaceutical industry.

Using *In Vitro–In Vivo* Correlation (IVIVC) to Meet Challenges in Global Delivery

Saturday, July 20, 13:00 – 17:00

Chaired by Vivian Gray, V. A. Gray Consulting, Inc., U.S.A., and Tapash Ghosh, ONDQA/CDER/FDA, U.S.A.

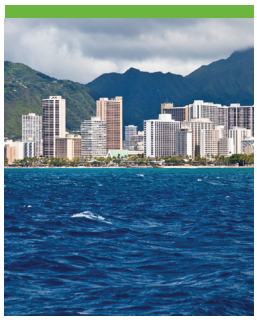
This workshop will provide a stimulus to develop *in vitro–in vivo* correlations (IVIVC), highlighting the utility of the correlation. There will be discussion on global expectations for the IVIVC by review of regulatory guidance, along with the experiences of the FDA. The key factors in developing the *in vitro* test and supporting the formulation will be explored, along with case studies of biowaivers using IVIVC. The traditional approach to IVIVC and *in vitro–in vivo* relationships (IVIVR) using deconvolution will be presented.

Hawaii

The Islands Are Calling: Exotic, Tropical Hawaii

The beautiful city of Honolulu lies on the island of Oahu, part of the chain of islands that make up Hawaii. Honolulu offers the pristine beaches and waters of Waikiki, historic landmarks, world-class shopping, a flourishing cultural scene, and a variety of dining options. Climb Diamond Head, visit Pearl Harbor, snorkel at Hanauma Bay, or simply swim in the warm waters of the Pacific while enjoying your time in paradise.

Why Hawaii?



Hawaii is an important business center, located in the middle of the Pacific with easy access to the Asia Pacific region and North and South America. This allows for a truly international meeting, which reflects the international nature of the Controlled Release Society. Chapters within China, Australia, India, and New Zealand have shown great growth in participation, and Hawaii offers an excellent opportunity for those chapter members to attend a CRS Annual Meeting. In addition, Honolulu is actually considered a less expensive city for travel than most major convention cities. The Aloha attitude pervades throughout the experience. The incredible year-round climate and hospitality make Hawaii the perfect meeting place, creating a meeting experience you are sure not to forget!

Island photos courtesy Hawaii Tourism Authority (HTA) / Tor Johnson; Hawaii Convention Center courtesy Dana Edmunds / HCC

CRS Innovation Sunday: Delivery Science Meets Business Opportunities!

CRS Innovation Sunday is all about the business of delivery science, taking innovative ideas and technologies into the commercial sector. Be sure to arrive in Honolulu in time to participate in a day devoted to innovation, with these must-have components:

- The right people there from industry, academia, and government
- Workshops related to industry and commercialization
- A platform for young companies or university departments to communicate their novel technologies
- Opportunities for one-on-one appointments
- An industry session that addresses Big Pharma's delivery science needs
- Open forum for industry/academic-related subjects
- Opening reception and exposition for networking

This is the start of the CRS Annual Meeting program—don't miss it!

"If you want to get information on the recent research from the leading scientists in drug delivery and you also want to be able to speak to them and network, attend the CRS Annual Meeting."

– 2012 CRS Annual Meeting Attendee

Technology Forums (*formerly Releasing Technology Workshops*)

Are you interested in learning more about a company's research and products? Interested in a new technology from the company that developed it? Open to all registered attendees, Technology Forums give you the opportunity to gain in-depth information presented by the hosting company. Presentation titles, details, and speakers are posted on the CRS Innovation Sunday webpage for these participating companies:

Capsugel
Catalent
CIMA Labs
Colorcon Inc.
Medimetrics
Mott Corporation
OctoPlus and Purac Biomaterials
Particle Sciences
SOTAX Corporation

Soapbox Sessions

Cosponsored by Catalent

What's new in delivery science? Come to the program where presenters "get up on their soapbox" to give you a quick glimpse of some of the most innovative technologies and products in development today. Linger to network with the presenters as you enjoy refreshments, with thanks to our sponsor. Soapbox applications will be received and reviewed until the session is full. Watch the CRS Innovation Sunday webpage for topics and presenters.

Soapbox Sessions were popular at the 2012 annual meeting.

Industry Roundtable: Global Perspectives on Emerging and Established Delivery Markets

A global panel of business development and R&D executives from major companies in Asia, Europe, and North America will provide insight on the latest trends, challenges, and needs they see in delivery science. CRS welcomes your audience participation in this session that is all about the international business of delivery science, offering a mix of presentations, panels, and case studies. With our meeting location in the Crossroads of the Pacific, the panel of speakers is expected to include corporate leaders from China, India, Japan, and Korea, as well as Belgium and the United States.

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Exposition Grand Opening & Welcome Reception

The logical place for a day focused on innovation to culminate is in the Exposition Hall, where you will find hundreds of new products, services, research, and innovations from CRS exhibitors and poster authors. Enjoy light hors d'oeuvres, view scientific posters, and connect one-on-one with your fellow scientists and company representatives for the official welcome to the CRS Annual Meeting & Exposition. Be sure to thank the CRS Café Sponsors (*) for providing complimentary beverages.

NEW! Stop by the Asia Pacific Pavilion to meet first-time exhibiting companies from the Asia Pacific region.

2013 CRS Exhibiting Companies

3M Drug Delivery Systems
Advanced Polymer Materials Inc.
Agilent Technologies
Asahi Kasei America
* Avanti Polar Lipids
BASF
Bend Research Inc.
Catalent
CIMA Labs
Colorcon Inc.
Corden Pharma
* Covaris, Inc.
Dissolution Technologies
Drug Delivery Partnerships
Drug Development & Delivery
DURECT Corp./Lactel Absorbable Polymers
Elsevier
EMD Millipore
Evonik Degussa Corporation Pharma Polymers
Freund-Vector Corp.
Glatt Air Techniques, Inc.
Halozyme Therapeutics
* Hovione
*Lipoid
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Medimetrics
MedinCell
The Methodist Hospital Research Institute
Michelson Prize & Grants
NanoSight
Nisso America Inc.
NOF Corp.
Northern Lipids Inc.
Novozymes Biopharma
* Octoplus NV
ONdrugDelivery Magazine
Partnership Opportunities in Drug Delivery – PODD
Patheon
Pharmaceutical Technology
PharmaCircle
Polymun Scientific Immunbiologische Forschung GmbH
PolyPeptide Group
PolySciTech Division: Akina, Inc.
Purac Biomaterials
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Sekisui Medical Co., Ltd.
Simulations Plus
Sirius Analytical
SkyePharma
SOTAX Corporation
Southwest Research Institute
Springer
Surface Measurement Systems
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Sponsors Make It Happen

Many of the annual meeting events are possible only through the generosity of sponsors. Please join CRS in thanking the following 2013 sponsors, current as of April 5, 2013.

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Diurnal Ltd.
Elsevier
Fleet Laboratories
Hovione
Lipoid LLC
Merial
Microtek Laboratories, Inc.
Mylan Technologies Inc.
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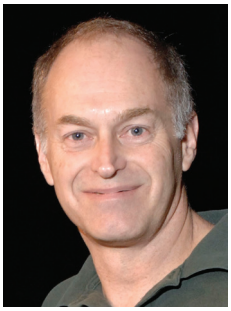
Interested in Exhibiting or Sponsorship?

Connect with the CRS international delivery science community.

Contact Debby Woodard, Business Development • +1.651.994.3817 • dwoodard@scisoc.org

An Interview with CRS Foundation Chair Randy Mrsny

CRS Foundation Chair Randall J. "Randy" Mrsny took a few minutes from his research laboratory focused on epithelial cell structure and function at the University of Bath, United Kingdom, to talk with CRS staff about one of his passions: the CRS Foundation.



Q *How did the CRS Foundation start?*

A Relative to many other scientific societies, the Controlled Release Society is fairly young. Possibly because of this youthful perspective, we acted as though the people who were active in starting CRS in 1978 and who did so much to shape it would be with us forever. I think of them as the pillars of CRS. Although we have lost several of these individuals over the years, the loss of Joe Robinson to cancer in 2006 seemed to be the watershed moment that changed how we thought about these losses. Two needs suddenly became obvious: to recognize such individuals for what they've accomplished and to develop a plan to nurture future leadership to maintain a vibrant society in the face of these losses.

These pillars of the society had identified CRS as *the* place to be for their particular science. CRS is a real multidisciplinary society that has traditionally been the interface for scientists whose backgrounds include chemistry, biology, engineering, and physics.

Q *What did the CRS Foundation do first?*

A The immediate goal was to set up fellowships for young, promising scientists who could be those next leaders. We're trying to support the brightest and best with these fellowships. Some are mainstream CRS people, but we also want to bring in people from outside whose technologies and interests could have a great impact within the field of controlled release.

That type of crossover happens often in CRS. People in one area see something in another area that is exactly the missing puzzle piece that they'd been looking for. And they learn about it at a CRS meeting. Then the leap of technologies to applications occurs. That's the whole beauty of the society, this very diverse environment that allows people to come in and look around scientifically. They may not even know what they're looking for, but when they see it, they know it.

Anyway, that's how the CRS Foundation started, taking money that was given in honor of these individuals and dispensing it as a fellowship for a postdoc—a way of ensuring that a torch is passed to maintain a vibrant society. Up until now we have been raising just enough money each year through personal donations to fund a single one-year postdoc. Everybody reaches in their pocket, and good things happen—we have an amazing, generous membership. Now, we're looking to set up a sustainable endowment to provide long-term benefit to CRS membership.

Q *What does the CRS Foundation plan to do with a sustainable endowment?*

A The first and most important activity is still postdoctoral fellowships. The foundation board has developed a plan to fund a variety of other activities, such as satellite meetings, workshops, and so on, that are focused on developing future leaders for CRS. Clearly, the extent and frequency of such programs will depend on the funding available in the future through the endowment. All of these programs will focus on bringing together people, companies, and groups that benefit from CRS technologies. And we are certainly aware of the diversity of CRS technologies and their applications—in areas such as the three big issues of drug delivery (the blood–brain barrier, cancer targeting, and oral protein delivery) but also food supply, consumer and diversified products, and green energy.

Q *Who do you think your donors will be for the endowment?*

A Starting an endowment means a shift in thinking. It's easy to donate in the name of someone you have a great affiliation with, someone in your scientific family. Getting donations from students, postdocs, and collaborators of Joe Robinson, for example, was relatively straightforward. For the endowment, we want people to recognize, in general, how much they've learned through CRS and donate as they would to their alma maters, for the same reasons. Just as an individual who went to a great school wants it to continue to be a great school, CRS is a great society, and we want it to continue as a great society. CRS members typically get their scientific training at several schools and work with several mentors, but it is their education through CRS activities throughout their entire career that defines their uniqueness as a scientist.

Q *What kind of figures are you looking at?*

A Ultimately, to get the size of endowment we need to be sustainable, we will need major donors. For example, to fund a $30,000 annual postdoctoral fellowship, we would need at least $1,000,000 in the endowment. If we had more, we could do more, without dipping into the capital.

We anticipate that major donors will be the people and corporations who have made substantial wealth from controlled release technologies—and we are looking for ways to effectively reach them. There are a number of companies in this category, and the science that comes through CRS ends up supporting and stabilizing those companies and the technologies they use. Plus, the scientists that are trained through CRS activities end up in those companies.

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Clearly, if we can inspire those individuals and companies to donate a fraction of what they've obtained through their utilization of CRS technologies, we could provide a robust program to develop that next generation of people who are going to help them capitalize on the next generation of technologies that will keep them ahead of their competitors.

Q *Why should someone donate to the CRS Foundation?*

A I have attended meetings of several other societies; my experiences have shown me that there is a special atmosphere at CRS meetings and unique bonds between CRS members. In essence, it seems that CRS, for whatever reason, has developed into what feels like a family where everyone knows each other, interacts, and looks forward to the next time they meet. I see lots of hugs at the beginning and ending of each meeting. To me, that is why someone should donate to the CRS Foundation, as a way to invest in the success of their own family. One of the ways that someone can immortalize their own work and role within this family is to make sure it continues at its optimum potential by bringing in bright young people to keep the society moving in the right direction.

Q *You mentioned three big issues in drug delivery. How does the CRS Foundation fit in with those?*

A Yes, I mentioned that there are currently three big issues in drug delivery: the blood–brain barrier, effectively targeting cancer cells, and oral protein delivery. CRS scientists are in tune—and always have been in tune—with the current needs for healthcare. *CRS is the place where complex multidisciplinary problems are solved.* No other society embraces the multidisciplinary approach required to solve such problems. More importantly, CRS members have solved many problems before and will be at the forefront of solving these current big issues. Eventually, a different top three will replace those top three. It is our goal, through the establishment of this endowment, to make sure that CRS remains the best place to solve these current problems through multidisciplinary approaches.

Q *What do you see for the future of delivery science and the CRS Foundation?*

A Big picture: multidisciplinary problems call for multidisciplinary research and solutions, and CRS provides this. The whole motivation behind the CRS Foundation is to support those things. We're looking for a sustainable future, one that's driven by the exceptional young scientists that are out there, and we need to nurture them into great CRS leaders and great accomplishments. Along the way, we can honor some of the pillars of the society that got us to where we are today. And we'd like to incorporate the people that made the technologies of controlled release successful commercially. We'd like to bring them in and have them help us achieve this goal.

Looking to the Future

Fund the 2014 Alexander T. Florence Postdoctoral Fellowship

In 2014 the CRS Foundation will give a $30,000 postdoctoral fellowship that is named to honor CRS past president Alexander "Sandy" Florence, former dean and current emeritus professor of the School of Pharmacy, University of London. He is editor-in-chief (Europe) of the *International Journal of Pharmaceutics* and was founding coeditor of the *Journal of Drug Targeting*. Author of hundreds of papers, multiple books, and recipient of numerous awards, Prof. Florence's expertise in pharmaceutical nanotechnology, drug delivery systems, physical pharmaceutical chemistry, novel dendrimers, and surface chemistry has added greatly to drug delivery research. Your contribution to the endowment will build this fellowship fund.

Build the CRS Foundation Endowment and Future of CRS

The CRS Foundation Board is focusing its time and resources to build the endowment for future sustainability. **Your contribution matters.** Please help CRS by communicating this to colleagues, by donating generously, and by expanding your donation with a request for a matching contribution from your employer. See ways to give at www.controlledreleasesociety.org/about/foundation/Pages/Donate.aspx.

Your gift will help build the endowment, future fellowships, and the future of CRS and delivery science.

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Questions? Contact Deborah Woodard, Director of Development, +1.651.994.3817, dwoodard@scisoc.org

Donations may be tax deductible. The CRS Foundation is a 501(c)(3) charitable organization qualified to accept tax-deductible contributions. The future fellowship award will honor CRS and delivery science leader Alexander T. "Sandy" Florence.

Interspecies Website: A Helpful Tool for the Interpretation of Interspecies Differences and for Choosing the Optimal Animal Model

Esther F. A. Brandon[1] *and Jos G. M. Bessems*
National Institute for Public Health and the Environment (RIVM)

Health and safety research often implies animal studies. For the purpose of reducing laboratory animal use, it is of utmost importance that scientists choose the optimal animal model to perform their studies. This is backed in the European Union by the recent Directive 2010/63/EU on the protection of animals used for scientific purposes, which states: "It is also essential, both on moral and scientific grounds, to ensure that each use of an animal is carefully evaluated as to the scientific or educational validity, usefulness and relevance of the expected result of that use."[1] Numerous studies in which a variety of compounds were tested have demonstrated that inter- and even intraspecies differences can be substantial. This may hamper reliable extrapolation of the results of animal kinetics or effect studies to the human situation. Interspecies and intraspecies differences include differences in intestinal anatomy and physiology, metabolic enzymes, extent of biliary excretion, metabolic rates, and so on. Furthermore, during aging, various anatomic and physiological changes occur, for example, development of metabolising enzymes after birth. On the other hand, there are also various similarities between most laboratory animals and humans, for example, liver as important metabolizing organ, liver and kidneys as important excretory organs, comparable circulatory systems, and specialised mechanisms for elimination of xenobiotics.

Performing a study with an animal model that is not the most relevant one poses several risks: 1) the outcome of the study provides an incorrect answer in terms of human health hazard, and so subsequent decision-making based on this outcome will also be incorrect, and 2) if noted, the study will have to be performed again, now with a more relevant animal model. This means that the relevance of animal study results can be increased and at the same time the number of laboratory animals can be reduced when study protocols are set up taking into account differences between and within species. Important in this respect are anatomical and physiological differences (including biotransformation enzymes) between species and within species.

[1] P.O. Box 1, 3720 BA Bilthoven, The Netherlands. E-mail: esther.brandon@rivm.nl

Performing high-quality health research and at the same time using fewer animals is one of the main challenges nowadays. In 2006, the National Institute for Public Health and the Environment (RIVM) of the Netherlands launched the website www.interspeciesinfo.com by order and for the account of the Dutch Ministry of Health, Welfare and Sports with the purpose to assist researchers in their attempts to reduce the use of laboratory animals. Of the three Rs of Russell and Burch—meaning replacement, reduction, and refinement of the use of animals for research and regulatory purposes—the R of reduction is the basis of the RIVM interspecies website.[2] The interspecies website provides access to a database containing freely available information on physiology and on anatomical and biochemical parameters of different species (including human) of different strains (ethnic background), gender, and age. Originally, the focus was on parameters in organs and tissues relevant for kinetics of chemicals and drugs after oral exposure and oral first-pass elimination. Meanwhile, parameters for lung and kidneys were added. The information on the website is based on a meta-analysis of peer-reviewed scientific literature and is updated yearly. Regulatory scientists ensure the quality of data before incorporation into the interspecies database.

The information on the interspecies website can be used to reduce the number of laboratory animals. Several examples:

- Bioequivalence studies are warranted for marketing authorization of a new drug formulation. The similarity in kinetics between the drug already on the market and the new drug has to be shown by the applicant. To this end, *in vivo* studies in nonclinical species are requested. It is important to study the bioequivalence in a nonclinical species that is most comparable to humans. For example, if the pH in the stomach is most crucial for the release of the drug from the formulation, the stomach pH in the nonclinical species should be as similar as possible to that of humans.
- The information available via the interspecies website can also be used for studies on the metabolism of a chemical or drug. Exogenous compounds are often metabolized by specific enzymes to ensure a better excretion. Because the presence and activity of enzymes may differ between species, it is important to choose the nonclinical species that most closely

resembles the human with respect to expression of the enzymes involved in the metabolism of the drug or chemical of interest. The interspecies website can help in this.

- Since 2007, drugs that are intended for children have to be investigated in children. However, before testing in children, relevant *in vivo* animal studies need to be performed in nonclinical animals. The information on the website can be used to choose the most relevant species for the relevant age category.

Furthermore, the information on the interspecies website can also help risk assessors in determining which toxicity study in different species is most relevant for assessing the risks in humans.

It is the intention of the RIVM to increase the use of the interspecies website to foster the further reduction of laboratory animal use. A website user survey showed that information provided by the interspecies website led to a reduction in laboratory animal use. It can therefore be concluded that the website effectively contributes to the reduction in the use of laboratory animals.

To foster an expanded use and relevance of the available information on our website, the RIVM is investigating collaboration with CRS through the Preclinical Sciences & Animal Health Division. In keeping with our objective of reducing unnecessary animal use, the intention is to expand the database to include species of interest to animal health. In doing so, we can partner with animal health experts throughout the world for the purpose of developing a broad library of information that will be invaluable both to human and veterinary scientists to support optimization of animal model selection and the interspecies extrapolations of available pharmacological and product development data.

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Amy Hope Is Newly Appointed Executive Vice President of CRS's Operational Headquarters

Amy Hope has officially assumed the role of executive vice president of Scientific Societies, the operational headquarters for CRS and several additional scientific associations.

Hope joined Scientific Societies in 1986 and worked in sales until 1991, when she became a senior staff administrator. As a result of her ability to effectively manage staff and resources, she was given progressively more responsible positions focusing on operations and administration. She was appointed director of administration in 1995 and vice president of operations in 2000.

Hope succeeds former executive vice president Steve Nelson, who retired on April 1. Nelson said Hope's appointment helps ensure a seamless transition. "Amy's extensive experience with Scientific Societies and her talent will serve the organization well," said Nelson. "It will mean a continued pursuit of increased membership value for our associations."

Hope has a B.A. in business administration and an M.A. in organizational leadership from St. Catherine University, St. Paul, Minnesota, U.S.A., and is a Certified Association Executive. She is a member of the American Society of Association Executives and the Council of Engineering and Scientific Society Executives. ■

Controlled and Scalable Synthesis of Liposomes Using Microfluidic Mixing

Elisabeth Kastner,[1] Euan Ramsay,[2] Randip Kaur,[1] Andrew J. Ingham,[1] and Yvonne Perrie[1]

Introduction

The majority of current vaccines in development are composed of subunit vaccines, among which liposomes represent a popular method for entrapment and delivery of compounds such as DNA, RNA, or proteins. When considering the delivery of such compounds, the biodistribution of liposomes (and thus their loaded moiety) is significantly affected by the size of liposomes, which is tailored to their application and varies because of constraints governing the penetration of the target tissue.[1] Hence, liposome size is regarded as a critical quality attribute and should be precisely monitored throughout the synthesis process and manufactured in a desired size-uniform range. However, traditional liposome synthesis methods raise several difficulties; mechanical stresses like sonication, high-shear homogenisation, or high pressures are difficult to upscale, and methods rarely lead to size-uniform liposomes.[2]

Microfluidics

The area of microfluidics, and its associated development of novel lab-on-a-chip based devices, has gained increasing attention over the past decades. Besides saving time and money, usage of microfluidics methods reduces space and sample volume. Characterisation of the fluid flow in micromixing is essential for understanding its impact on mixing performance.[3] The significance of the channel diameter for mixing performance in a microchannel[4] has been the basis for engineering of novel micromixers with enhanced mixing capabilities.[5]

The Featured Technology and Method

The staggered herringbone micromixer (SHM) is a micromixer that has been designed for effective mixing in microchannels by grooves in the channel floor. Characterisation includes the measure of asymmetry and angle of grooves, as well as the "centre of rotation," which applies to the changing groove orientation after a half-cycle[5] (Figure 1). Accumulative mixing cycles lead to the exponential increase in surface area of two inlet streams, followed by fluid layers being folded on top of each other, aiding the overall mixing process.[5]

The featured technology presented here uses the automated NanoAssemblr™ (Precision NanoSystems, Inc.), equipped with an SHM, for liposome synthesis. Lipids in solvent are mixed with an aqueous buffer system by passing through the series of herringbone structures with the aid of syringe pumps (Figure 2).

The driving force behind liposome formation is the increase in polarity, which drives a nanoprecipitation reaction once a certain polarity is reached.[1] The increase in polarity is controlled by alterations of the rate of mixing and the ratio of aqueous buffer to solvent stream. Hence, the increase in flow rate, as well as increased aqueous-to-solvent ratios, contribute to the synthesis of smaller and size-controlled liposomes. Additionally, increase in flow rate ratio leads to decreased solvent concentration in the

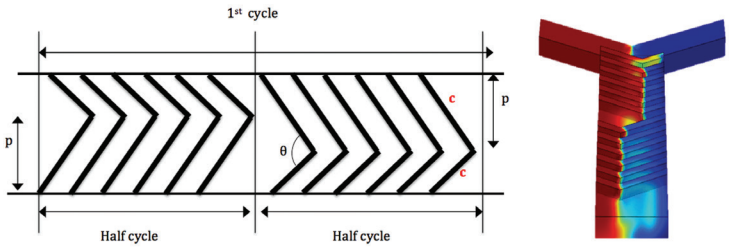

Figure 1. *Schematic of six grooves per half-cycle with c = centre of rotation, θ = angle of grooves, and p = measure of asymmetry of the herringbones (left). Increase in mixing rate by herringbone structures of two inlet streams (right).*

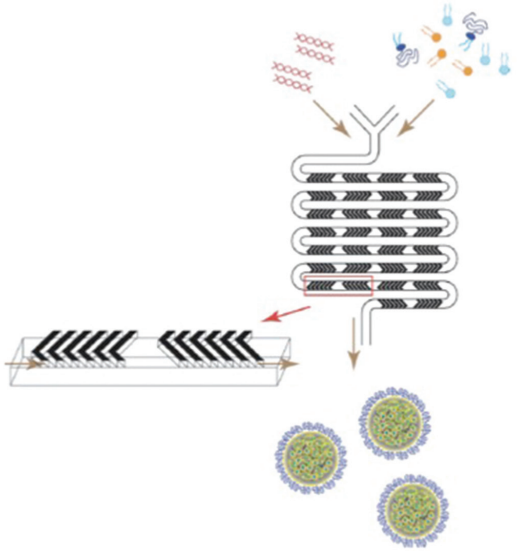

Figure 2. *Overview of the SHM device for liposome synthesis. Synthesis process involves lipid-in-solvent injection in one inlet and an aqueous buffer (including the molecule of interest, here DNA) into the second inlet using a syringe pump.[1]*

1 Aston Pharmacy School, Aston University, Aston Triangle, Birmingham, B4 7ET, United Kingdom.
2 Precision NanoSystems, 6138 Sub Boulevard, P.O. Box 78543, Vancouver, BC, V6T 2E7, Canada.

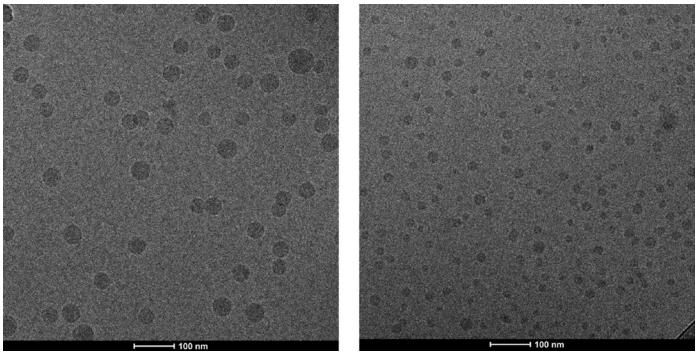

Figure 3. *Cryo-transmission electron microscopy images of siRNA liposomes synthesized by the automated NanoAssemblr™ comprising 1 mol% and 5 mol% PEG-lipid. Mean particle diameters are 50 nm at 1 mol% PEG-lipid (left) and <30 nm at 5 mol% PEG-lipid (right).*

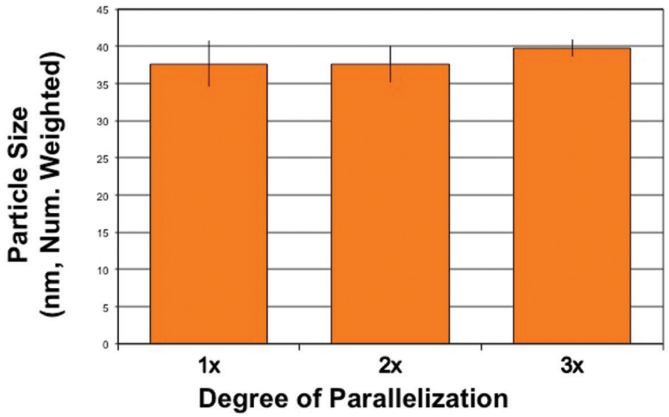

Figure 5. *Scalability demonstrated by increasing degree of parallelization of POPC/cholesterol formulation (55:45 mole ratio), with 15, 30, and 45 mL/min total flow rates for 1×, 2×, and 3×, respectively, and remaining particle sizes.*

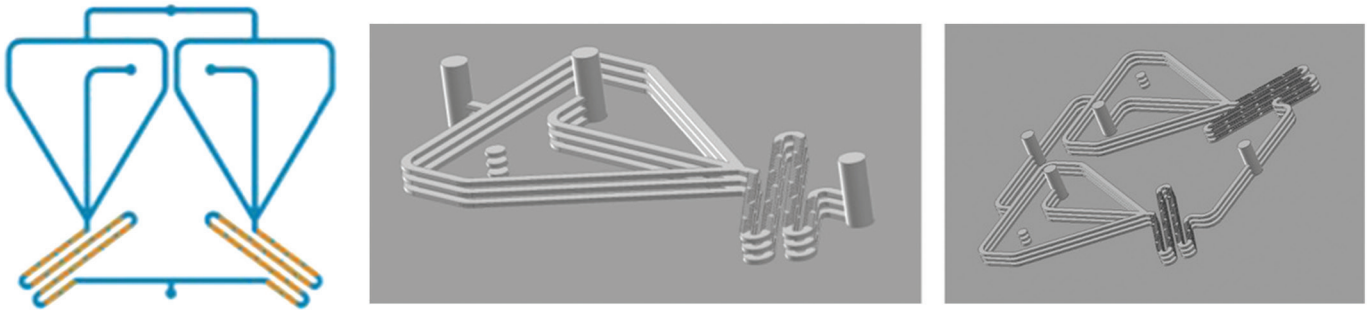

Figure 4. *Parallelization of the micromixer to increase the throughput. 2× parallelization in plane direction (left), 3× parallelization in vertical direction by stacking (middle), or 6× parallelization by a combination of both (right).*

final formulation, reducing liposome fusion and leading to smaller vesicles.[1]

Featured Advantages

The system is software controlled; the size of liposomes is engineered as a function of micromixing. Alterations of flow rates as well as the flow rate ratios (solvent to aqueous buffer stream) can be process controlled and affect the synthesized liposome size. Additionally, molecule addition (RNA, DNA, protein) can be incorporated into the synthesis process. Based on the content of PEG-lipids incorporated into the liposome synthesis process, the size of liposomes could be decreased to <30 nm (Figure 3).

The scalability of the mixing process has been demonstrated by parallelization of the micromixers (Figure 4), which leads to an increase in throughput by maintaining the mixing conditions and remaining particle sizes (Figure 5).

Method and results presented here indicate the advantages of process robustness and diminished severity compared with traditional liposome synthesis methods. Process conditions are robust, aiding process validation, and are hence favorable for the applicability in large-scale GMP production. Additionally, the microfluidic cartridges are disposable and therefore circumvent the necessity of cleaning validation.

Conclusion

Process robustness and scalability are major requirements for manufacturing and are restricting current liposome synthesis methods from market introduction. The technology featured here emphasizes the advantage of the automated NanoAssemblr™ for controlled, scalable, and robust synthesis of size-uniform liposomes of desired dimensions, with the possibility of combining liposome synthesis and drug loading. Work presented emphasizes the potential of biomicrofluidics and process control by novel lab-on-a-chip based applications as the potential method of choice for reproducible and controlled bottom-up liposome synthesis in the future.

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Found in Translation at the Joint FDB/NZCRS Conference, 2013

By James R. Falconer[1] and Arlene McDowell[2]

This conference was the 15th annual meeting of the Formulation and Delivery of Bioactives (FDB) research theme at the University of Otago and the New Zealand Chapter of the Controlled Release Society (NZCRS). The meeting was held at the Hutton Theatre, Otago Museum, Dunedin, New Zealand, and included invited and contributed speakers and posters from an interesting range of fields, with excellent academic and industrial representation. This year's theme, "Found in Translation," focused on scientific research and its translational challenges (the Valley of Death where the chance of failure is 98%!).

With a friendly welcome from Prof. Ian Tucker, convenor of the FDB research theme, day one of the conference began. The first presentation was from invited speaker Dr. Richard Furneaux from Callaghan Innovation (formerly Industrial Research Ltd.) of Wellington, New Zealand, who presented a talk titled "The Challenges of Translational Research in New Zealand." This talk highlighted some of the issues associated with discovering treatments for unmet medical needs and seeing these through to advanced human clinical trials. The first session concluded with a presentation from invited speaker Prof. Thomas Rades (University of Copenhagen, Denmark), who described the translational experience in Denmark, a country of similar size to New Zealand. Prof. Rades outlined in his talk the model for completing doctorates at Danish universities, which included industry involvement.

NZCRS invited speaker Prof. Hamid Ghandehari at the FDB Conference in Dunedin, New Zealand, 2013. Photo by Jo Preston.

Continuing with the conference theme, the second session was opened by Prof. David Jones (Queen's University, Northern Ireland), and he spoke about past experiences in a number of government and industrial partnerships and how research in the United Kingdom will be (in 2014) undergoing a shift in focus involving an assessment of research quality and impact. The next speaker was Prof. Parry Guilford (Pacific Edge Ltd., New Zealand), who gave insight into the development of a multiplex qRT-PCR assay for early diagnosis of bladder cancer. This was followed by the final presentation of the morning, by Dr. Steve Moratti (University of Otago, New Zealand), on the commercialisation of a medical gel for use in surgery and the general processes and pitfalls that accompanied that journey.

The third session opened with Dr. Julian Clark (Walter and Eliza Hall Institute of Medical Research, Australia) talking about the division between academia and industry and how this needs to change. He spoke about how important intra-, inter-, and beyond-disciplinary approaches are to help successfully bridge the gap, linking researchers with industry. Further, Dr. Andrew McLeod (Douglas Pharmaceuticals, New Zealand) gave an excellent talk about New Zealand's pharmaceutical industry and his collaborations with academia. Dr. Greg Walker (University of Otago, New Zealand) closed the session with a talk about the use of a new haemostat (PeproStat) to control surgical bleeding. Dr. Walker described that when applied to blood, the haemostat polymerises fibrinogen to form a fibrinlike clot, not requiring thrombin *in vivo*. There is considerable application for such technology in military and surgical settings.

The fourth and final session of the day was a rapid-fire oral presentation of posters from Ph.D. students, summer students, postdoctoral fellows, and one experienced researcher (Prof.

Prof. Ian Tucker awards Avis Kao with her prize certificate for winning the FDB poster prize. Photo by Laura McNeil.

1 School of Pharmacy, University of Auckland, Auckland, New Zealand
2 School of Pharmacy, University of Otago, Otago, New Zealand

Delegates at the 15th annual FDB Conference in Dunedin, New Zealand. Photo by Jo Preston.

Tucker). The session gave participants the opportunity to introduce their research and tempt people to come and view their posters. We were delighted that the Honourable Peter Hodgson, a Member of Parliament (MP) for North Dunedin and former Minister of Research, Science and Technology, attended throughout the day. This stimulating first day ended with the conference dinner at The Savoy Conference Centre in Dunedin, giving participants the further opportunity to build on past networks and build new ones.

The second day of the conference was opened by the NZCRS invited speaker, Prof. Hamid Ghandehari (University of Utah, U.S.A.). Prof. Ghandehari gave a comprehensive overview on polymer–peptide conjugates for targeted delivery to solid tumours. He also elaborated on the challenges ahead for translation of these conjugates, in preparation for human use. Then Dr. Khaled Greish (University of Otago, New Zealand) introduced the audience to self-assembled amphiphilic copolymers that form micellar structures and that can be customised to various biological factors of certain tumours. Dr. Zimei Wu (University of Auckland, New Zealand) talked about the potential of hypoxia-activated prodrugs (HAPs) and codelivery of an efflux transporter inhibitor to multidrug resistance. Prof. Sarah Hook (University of Otago, New Zealand) gave an interesting presentation on a novel strategy for inducing an immune response via transcutaneous delivery of vaccines. Dr. Ian Hermans (Malaghan Institute of Medical Research, New Zealand) talked about his ongoing research into the use of vaccines and immuno-modular combinations to reach "the effective response level" and "cure" cancer(s). The final speaker of the conference was Assoc. Prof. David Morton (Monash University, Australia). In this presentation, he pointed out interesting aspects of the collaboration between the Monash Institute of Pharmaceutical Sciences and GSK Australia.

The afternoon session, the final one of the second day, consisted of oral presentations covering a wide range of topics given by

Joint winners of the NZCRS prize for best oral presentation Farah Al Barwani (left) and Silke Neumann (right). Photos by Laura McNeil.

postgraduate students from New Zealand and one postdoctoral fellow from China. At the very end of the 15th FDB conference, the awarding of prizes and final formalities were initiated. The FDB poster prize was announced by Prof. Ian Tucker as Avis Kao (School of Pharmacy, University of Otago, New Zealand). The NZCRS student prizes were then announced by NZCRS President Dr. Arlene McDowell. This year the first prize was jointly awarded to two outstanding presentations by Farah Al Barwani (Department of Microbiology and Immunology, University of Otago, New Zealand) and Silke Neumann (School of Pharmacy, University of Otago, New Zealand).

This conference had a friendly environment, allowing for young scientists to rub shoulders with invited speakers during the breaks, and it constantly involved and engaged the audience. Any way you look at it, this was a successful FDB and NZCRS conference hosted in Dunedin. ■

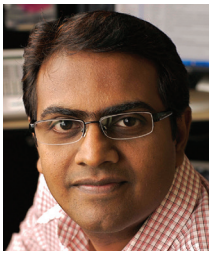
Drug Delivery and Translational Research

Vinod Labhasetwar, Ph.D., Editor-in-Chief

Special Issue on Cancer Stem Cells
DDTR Volume 3, Issue 2, April 2013

Cancer stem cells (CSCs) represent a small subset of stemlike cells, with the capacity for asymmetric cell division; that is, they can generate one daughter stem cell and another that is committed toward a certain differentiation pattern. The latter undergoes a series of divisions and differentiation steps that result in the generation of terminally differentiated cell populations. CSCs may play a critical role in cancer treatment outcomes, because they are resistant to conventional chemotherapy and can initiate tumor recurrence following treatment. The goal of this theme issue is to review the role that CSCs may play in tumor response to therapy and the strategies to inhibit CSCs. The articles in this theme issue highlight the recent advances in our understanding of the biology of CSCs and how this mechanistic information can be exploited to overcome challenges posed by the presence of CSCs. Members can view the issue at www.controlledreleasesociety.org/publications/Pages/DDTRAccess.aspx.

About the Guest Editor



Dr. Jayanth Panyam is an associate professor of pharmaceutics at the University of Minnesota, U.S.A. He received his bachelor's degree in pharmacy from the Tamil Nadu Dr. M.G.R. Medical University, India, and his master's in pharmaceutics from Banaras Hindu University, Varanasi, India. He earned his doctorate in pharmaceutical sciences from the University of Nebraska Medical Center, Omaha. He joined the Department of Pharmaceutical Sciences at Wayne State University, Detroit, as an assistant professor in December 2003. In August 2007, he joined the Department of Pharmaceutics at the University of Minnesota. Dr. Panyam's current research focuses on the use of nanotechnology-based drug delivery systems for the treatment of breast cancer. He has authored or coauthored more than 45 peer-reviewed publications and three pending patent applications. He has won several honors, including fellowships from the American Heart Association, the Thomas Jefferson Ingenuity Award presented by the University of Nebraska, and the Ralph Wilson Award presented by the Ralph C. Wilson Foundation.

New Upcoming DDTR Special Issue:

RNA Interference–Based Therapeutics and Diagnostics
Prof. Ken Howard, Aarhus University, Denmark, and Prof. Dan Peer, Tel Aviv University, Israel

The capability to control and study cellular gene expression by the process of RNA interference (RNAi) has provided researchers with an unprecedented tool for investigating functional genomics and the potential to harness the RNAi mechanism as a potent therapeutic. The special issue will cover the processes, molecules, and delivery solutions relevant for the clinical translation of RNAi.

Drug Delivery and Translational Research (DDTR) is an official journal of CRS. Visit the DDTR webpage to glance through research articles, reviews, editorials, and special issues. CRS members get free access to the journal content as a membership benefit. Members must login to the CRS website first and then click the Publications tab to get to the member access link. Join the leading scientists who are publishing their work in DDTR and also compete for the 2013 DDTR Outstanding Research Paper Award. The award will be selected from research articles published in DDTR during 2013. It will be presented during the 2014 CRS annual meeting, to be held July 13–16, 2014, at The Hilton Chicago, U.S.A. Visit the CRS website for award criteria (www.controlledreleasesociety.org/about/Awards/Pages/DDTROustandingPaper.aspx).

DDTR has published six well-received special issues. Please contact me (labhasv@ccf.org) if you are interested in developing a special issue on current topics in drug delivery. ■

Welcome New Members

Rohan Bhavane
Shiran Ferber
Christina L. Hofmann
Lisheng Kang
Muhnho La
Thomas Ottoboni
Alessandra Rossi
Adnan Salameh
Roxane Schulten
Sabeel Shamsudeen
Stephen Zhou

CRS
Leading Delivery Science and Technology

2013 CRS Elections: Cast Your Ballot

The 2013 CRS Elections will open May 16, and all members are encouraged to vote. Following the call for nominations that was sent to the membership in December, the CRS Nominating Committee formalized the ballot based on the needs of the organization for both the CRS Board and the Board of Scientific Advisors (BSA). The ballot was then sent to the membership for the petition period. Because no members were added to the ballot through the petition process, Art Tipton will take the position of President Elect, and Ruth Schmid will be the Treasurer Elect. Electronic ballots will be sent to all eligible voting members of CRS in May along with biographies and vision statements from all candidates. Be sure to cast your ballot by June 6, when the election period will close. The newly elected Board and BSA members will take their positions in July at the conclusion of the 2013 CRS Annual Meeting.

CRS Board

President Elect

Art Tipton, Evonik Birmingham Labs, U.S.A.

Treasurer Elect

Ruth Schmid SINTEF, Norway

Secretary

Debra Bingham Valeo Partners, U.S.A.

Padma Devarajan, Institute of Chemical Technology, India

Director-at-Large (Two Open Positions)

Maria Jose Alonso, University Santiago de Compostela, Spain

Andrew Lewis, Ipsen, France

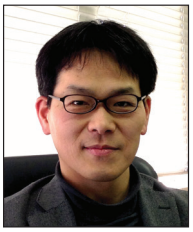
Christopher McDaniel, Fleet Laboratories, U.S.A.

Rod Walker, Rhodes University, South Africa

Board of Scientific Advisors

In addition to the CRS Board positions, the membership will also vote on the six open BSA positions. The BSA is charged with providing advice to CRS on all aspects of the science and technology of delivery so that CRS will fulfill its mission. The candidates for BSA are:

Jake Barralet McGill University, Canada



Akihiko Kikuchi, Tokyo University of Science, Japan

Richard Korsmeyer, Pfizer Inc., U.S.A.

Glen Kwon, University of Wisconsin, U.S.A.

Claus-Michael Lehr, Saarland University, Germany

Barbara Lueckel, F. Hoffmann-La Roche Ltd., Switzerland

Jean-Antoine Meiners, Laboratoire Meiners Sàrl, Switzerland

James Oxley, Southwest Research Institute, U.S.A.

Abhay Pandit, National University of Ireland

Thomas Rades, University of Copenhagen, Denmark

Ming-Thau Sheu, Taipei Medical University, Taiwan (Republic of China)

People in the News

Compiled by Steven Giannos, University of Maryland, Baltimore, MD, U.S.A.
Industrial Editor

Catalent Applied Drug Delivery Institute Welcomes Accomplished Life Sciences Leader Dr. Ralph Lipp to Advisory Board and Terry Robinson as Executive Director

Business Wire: March 7, 2013 – SOMERSET, NJ, U.S.A. – The Catalent Applied Drug Delivery Institute announced today that Dr. Ralph Lipp, a well-known pharmaceutical industry executive and inventor, will become the founding member of the institute's advisory board. Dr. Lipp brings over 20 years of industry and academic experience to the institute, having previously served as vice president of pharmaceutical sciences R&D at Eli Lilly and Company and in R&D leadership roles at Schering AG. He has brought dozens of new medical entities into clinical studies and contributed to the launch of 10 new treatments. Dr. Lipp's accomplishments include more than 20 patents, including 5 marketed medicines, and more than 120 scientific publications. His broad research experience includes oncology, cardiovascular disease, central nervous system disorders, women's health, *in vivo* diagnostics, and dermatology.

"I believe enhanced adaption of applied drug delivery technologies and increased collaboration across the industry and with academia will help innovator companies develop better products, resulting in improved outcomes for patients."

"I look forward to leveraging my experience and knowledge to help the institute accomplish its important mission of delivering better treatments to patients," Dr. Lipp commented. "I believe enhanced adaption of applied drug delivery technologies and increased collaboration across the industry and with academia will help innovator companies develop better products, resulting in improved outcomes for patients." Dr. Lipp is currently president and CEO of Lipp Life Sciences, LLC.

The institute also has appointed Ms. Terry Robinson as executive director. Since joining Catalent Pharma Solutions five years ago, Ms. Robinson has fostered countless collaborations with top pharmaceutical innovators, bringing business and scientific leaders together to help develop better treatments. Ms. Robinson brings over 25 years of health care experience at Eli Lilly and Company and Amgen, Inc., to her new role leading the institute. Ms. Robinson will work closely with the institute's advisory board to advance the use of drug delivery technologies to bring more and better treatments to patients via new technology development, increased cross-industry and academic collaborations, advanced industry education, research, and publications.

"The welcome additions of Dr. Lipp and Ms. Robinson are a significant step in building a strong foundation for the institute," noted Dr. Kurt Nielsen, a director of the institute and Catalent's SVP of R&D. "Terry's ability to build collaborative partnerships, combined with the well-known drug development and delivery expertise of Dr. Lipp and other future advisory board members, will enable the institute to advance the future of drug delivery to improve patient treatments."

The mission of the Catalent Applied Drug Delivery Institute is to promote collaboration between industry and academia, provide applied drug delivery education and training, and accelerate adoption of innovative drug delivery technologies to help develop better treatments, as well as encourage industry engagement on major issues pertaining to drug development, formulation, and delivery. The institute welcomes additional collaborations and technology partnerships.

To learn more about the Catalent Applied Drug Delivery Institute, visit the new website: www.drugdeliveryinstitute.com

Contact Holly Rackett (holly.rackett@drugdeliveryinstitute.com) for more information on upcoming institute programs and initiatives.

Aptalis Pharmaceutical Technologies Expands Licensing Team

Aptalis Pharma: February 13, 2013 – Bridgewater, NJ, U.S.A. – Aptalis Pharmaceutical Technologies, a business unit of Aptalis Pharma that develops differentiated products utilizing its oral delivery technologies, today announced that Nigel Ray has been named as the company's vice president of global licensing. Reporting to John Fraher, president of Aptalis Pharma, Mr. Ray will lead the unit's global licensing efforts as well as the identification and evaluation of strategic opportunities within the pharmaceutical industry that maximize the value of Aptalis's technologies. Prior to joining Aptalis, during his 25 years in specialty pharmaceuticals, Mr. Ray held executive-level positions with companies including AcelRx Pharmaceuticals, DURECT Corporation, and Alza Corporation. Mr. Ray holds a bachelor of arts in human biology from Stanford University and a master of business administration, finance, and strategy from the UCLA Anderson School of Management.

"Nigel's rich experience in identifying, structuring, and negotiating complex, worldwide product licensing transactions, as well as his business leadership skills, will serve Aptalis well," said Mr. Fraher. "His leadership and experience in business development and marketing will enable the expansion of our technology partnerships while providing pharmaceutical companies with the drug delivery solutions they need to advance and protect product portfolios," added Mr. Fraher. ■

In the News

Compiled by Steven Giannos, University of Maryland, Baltimore, MD, U.S.A.
Industrial Editor

March

Sorrento Therapeutics Signs Exclusive Option to Acquire IGDRASOL

PRNewswire: March 7, 2013 – SAN DIEGO, CA, and FOUNTAIN VALLEY, CA, U.S.A. – Sorrento Therapeutics, Inc. ("STI"; SRNE: OB) today announced that it has signed an exclusive option to acquire IGDRASOL, a private company focused on the development of oncologic agents for the treatment of metastatic breast cancer (MBC), non-small cell lung cancer (NSCLC), and other cancers. If the transaction is consummated, the combined company will form an oncology franchise of potential products with phase 2 data for multiple solid tumor indications as well as two synergistic drug discovery and development platforms.

IGDRASOL's lead compound, Cynviloq™, is a next-generation micellar diblock copolymeric paclitaxel formulation creating a stable, easy-to-administer injectable for effective delivery of drug into tumor tissues. Cynviloq™ is currently approved and marketed in several countries, including South Korea for MBC and NSCLC under the trade name Genexol-PM®, and has completed phase 2 testing for potential advancement into registration trials in the United States. IGDRASOL has the exclusive U.S. distribution rights to Genexol-PM® from Samyang Biopharmaceuticals, a South Korean corporation.

IGDRASOL is preparing for an "end of phase 2" meeting with the U.S. Food and Drug Administration (FDA) regarding Cynviloq™ targeted for the first half of 2013. As a formulation of paclitaxel, Cynviloq™ is potentially eligible for approval via FDA's 505(b)(2) bioequivalence regulatory pathway versus albumin-bound paclitaxel (Abraxane®) in its currently approved MBC and NSCLC indications. Abraxane® recently demonstrated overall survival benefit in a pivotal phase 3 study as a first line combination therapy with gemcitabine in advanced pancreatic cancer.

In the transaction, STI also acquires a tocopherol polyethelyene glycol succinate (TPGS)-based drug formulation technology, which could serve as a foundation for novel, next-generation, targeted therapeutics competitive against current antibody drug conjugates (ADC). Effective immediately, STI will assume responsibility for operating expenses related to development of these next-generation antibody-formulated drug conjugates (AfDC). The transaction will enable the combined team to leverage STI's extensive human antibody G-MAB® libraries and preclinical antibody programs, including those targeting metabolic, autoimmune, and infectious diseases, together with IGDRASOL's expertise in drug formulation and drug development, to deliver a strong pipeline of targeted tumor therapies.

"This transaction is transformational for STI, as early- and late-stage product candidates, technologies, and development expertise combine to create an oncology franchise and pipeline with tremendous value potential. This transaction also reflects our commitment to improving the lives of cancer patients worldwide through innovative medicines discovered and developed both in-house and via external opportunities," said Henry Ji, Ph.D., president and chief executive officer of STI. "In particular, Cynviloq™ provides us with a high-value asset that has near-term revenue potential in MBC and NSCLC and longer-term revenue potential in pancreatic, ovarian, bladder and gastric cancers. These combined addressable markets represent more than 50% of cancer cases in the United States. Importantly, STI's overall business model recognizes the importance of collaboration and partnering with pharmaceutical and biotechnology companies to achieve its corporate objectives."

Dr. Ji added: "We look forward to the opportunity to collaborate with key members of the team responsible for the creation, development, and commercialization of the most successful branded paclitaxel formulation to date, Abraxane®. This includes Abraxis Biosciences veterans Dr. Vuong Trieu, Dr. Kouros Motamed, Dr. Larn Hwang, and George Uy, who will give STI an outstanding core competence for the development and commercialization of its in-house lead therapeutic programs."

"We look forward to completing this transaction and becoming part of the STI family," said Vuong Trieu, Ph.D., chief executive of IGDRASOL. "Our experienced development and commercial team is excited to combine efforts with STI to develop and introduce a new franchise oncology product in Cynviloq™ as well as a next-generation of targeted drug delivery technology for unmet medical needs in cancer. Through our patented formulation technology and STI's G-MAB® fully human antibodies, the combined entity will be well positioned for long-term growth as a targeted therapeutics company."

Cynviloq™ (or IG-001; a paclitaxel-loaded micellar diblock copolymers) is a next-generation branded paclitaxel formulation currently approved and on the market in several countries as Genexol-PM®. Sorrento Therapeutics, Inc. (STI) is a publicly traded, development-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel and proprietary biotherapeutics for the treatment of a variety of disease conditions, including cancer, inflammation, metabolic and infectious diseases. STI's objective is to identify drug development candidates derived from its proprietary human antibody libraries and, either independently or through partnerships, advance selected targets into preclinical or clinical

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development. In 2012, STI identified and further developed a number of potential drug product candidates across various therapeutic areas, and STI intends to select several lead product candidates to progress into preclinical development activities in 2013. More information is available at www.sorrentotherapeutics.com.

IGDRASOL's lead therapeutic platform is Cynviloq™, a branded micellar paclitaxel formulation that is free of cremophor and human serum albumin (HSA), the excipients for Taxol® (cremophor-based paclitaxel) and albumin-bound paclitaxel (Abraxane®), respectively. Cynviloq™ combines the simplicity of manufacturing and preparation of Taxol® and potentially the albumin-mediated transport of paclitaxel. IGDRASOL intends to conduct registration trials for multiple cancer indications.

Pharma Tech Industries Selected to Manufacture Innovative Nasal Delivery System for NDA

Business Wire: March 4, 2013 – ROYSTON, GA, U.S.A. – Pharma Tech Industries (PTI), the largest pharmaceutical contract manufacturer and packager of powder products in the world, has been selected to handle filling, assembly, and packaging services for a migraine relief medication administered through an innovative new method: a breath-powered nasal delivery system. The drug itself is powder-based, and PTI was chosen for this initiative—which will start as developmental, supporting FDA submission for approval, and will continue into commercial—due to the company's experience handling a broad range of powders and its ability to vertically integrate the entire production process.

The OptiNose delivery system employs a novel means of easily administering drugs deep into the nasal cavity, enabling the treatment of both local and systemic diseases. The new technology offers a much-needed alternative to existing poor-performing nasal sprays, as well as to tablets and injections. OptiNose has completed phase III development for a sumatriptan succinate medicine that, when taken using its patented device, is expected to shorten the timeframe for relief from migraines when compared to widely used oral migraine medications.

Pharma Tech Industries will play a critical turnkey role in preparing OptiNose's NDA batches over the coming months. Utilizing a Planeta capsule filler from leading equipment manufacturer MG2, PTI will fill low-dose capsules with dry powder medication, achieving tight weight tolerances at high commercial speeds. From there, the capsules will be loaded into special unit-dose cartridges. PTI will then pack each cartridge—along with the primary nosepiece and an instruction insert for the end-user—into individual cartons, where they are mechanically packed into cases and palletized for shipping.

"We chose Pharma Tech Industries as our CMO through a rigorous selection process that evaluated more than half a dozen potential candidates," said Peter Miller, CEO of OptiNose. "We are working to bring a groundbreaking delivery system to market, and its commercial development depends upon a partner that can execute with excellence. We believe that Pharma Tech Industries is such a partner."

"It is exciting to work so closely with the team at OptiNose, who have spearheaded the creation of a very promising new drug delivery system, and we are thankful for this opportunity," said Tee Noland, chairman of Pharma Tech Industries. "This project allows PTI to showcase the broad spectrum of capabilities that make us such an attractive option for our customers."

Aphios Granted U.S. Patent for Zindol

Business Wire: March 4, 2013 – WOBURN, MA, U.S.A. – Aphios Corporation today announced that it received notification of allowance for a U.S. patent entitled "Use of Gingerols for Cancer Patients Suffering from Nausea and Emesis Induced by Chemotherapy."

Despite the widespread use of 5-HT3 receptor antagonist antiemetics such as palonosetron (Aloxi; Eisai), chemotherapy-induced nausea continues to be reported by 70% of adult patients and 58% of children receiving highly emetogenic chemotherapy. Furthermore, these antiemetics are associated with significant adverse effects such as sedation, extra-pyramidal side effects, and hypotension as well as headache, diarrhea, and constipation. A desirable attribute in any substitute or additional antiemetic medication is the absence of clinically significant adverse effects.

Zindol is a highly purified and standardized ginger product. According to Dr. Trevor P. Castor, president and CEO, "Our scientists and engineers utilized proprietary polarity-guided SuperFluids CXF fractionation technology to establish conditions for the isolation of the active pharmaceutical ingredients and then scaled-up production of gingerols using proprietary SuperFluids CXP manufacturing technology."

Dr. Castor continued, "We recently completed a successful phase II/III clinical trial on Zindol as an adjuvant to conventional 5-HT3 antiemetics. This randomized, placebo-controlled, double-blind clinical trial assessed the efficacy of Zindol in treating chemotherapy-induced nausea in 576 cancer patients. All doses of Zindol significantly reduced acute nausea severity compared to the placebo. No significant adverse events were reported."

Aphios plans to conduct a pivotal phase III clinical trial on Zindol for the adjunctive treatment of nausea in adults undergoing chemotherapy, file an NDA, and then initiate a clinical program in a pediatric population. In the interim, the product will be made available as a dietary supplement under the brand name Zindol DS. Zindol will also be developed for nausea caused by surgery, pregnancy, motion sickness, and drugs.

Aphios (www.aphios.com) is a clinical-stage biotechnology company developing green, enabling technology platforms for improved drug discovery and manufacturing, nanotechnology drug delivery and pathogenic drug safety. Based on these

platforms, Aphios is developing enhanced therapeutic products for health maintenance, disease prevention, and the treatment of certain cancers, infectious diseases, and neurological disorders such as Alzheimer's disease.

February

Kala Pharmaceuticals Secures $11.5 Million in Series A Financing

Business Wire: February 28, 2013 – WALTHAM, MA, U.S.A. – Kala Pharmaceuticals, Inc., a leading developer of innovative products that rapidly and effectively penetrate the mucosal barrier to treat a wide range of debilitating diseases, announced today that it has secured $11.5 million in Series A equity financing through new and existing investors. New and lead investor, Crown Venture Fund, LLC, the venture capital arm of the Crown family of Chicago, joined Kala's existing investors, including Lux Capital Management, Polaris Venture Partners, and Third Rock Ventures. Proceeds from the financing will be used to advance a portfolio of innovative ophthalmic programs based on Kala's mucosal-penetrating product (MPP) platform through clinical proof of concept.

"Kala's front of the eye drug delivery advantages and ability to topically deliver a wide variety of drugs to the back of the eye will transform the ophthalmology sector," said Richard Robb, a CVF representative. "Crown Venture Fund is pleased to join Kala's existing investors and support this team of ophthalmology industry leaders."

"With Crown Venture Fund we are pleased to expand our circle of committed, long-term investors who recognize the significant potential of this breakthrough technology," said Guillaume Pfefer, Ph.D., Kala's CEO. "This financing provides Kala with the resources to further deploy our technology as we focus our internal drug development efforts on innovative ophthalmic treatments while leveraging our platform to pursue collaborations for a range of other diseases where mucosal barriers have previously limited therapeutic efficacy. The potential breadth of this opportunity is evidenced by our recently announced collaboration with the Cystic Fibrosis Foundation."

The financing will enable Kala to continue to progress on two of its most advanced programs, which focus on topical treatment of ocular inflammation and wet age-related macular degeneration (AMD). Beyond ocular diseases, Kala is pursuing collaborations with partners in other disease areas where its proprietary MPP platform can be applied to serious diseases that involve mucosal tissues such as the lung, the gastrointestinal tract, and the female reproductive system.

Kala Pharmaceuticals, Inc., is developing innovative products that are capable of penetrating mucosal barriers for the treatment of major diseases that affect the eyes, lungs, gastrointestinal tract, and female reproductive system. Mucosal barriers have been largely overlooked as a limitation for drug efficacy. Using the company's proprietary technology platform, Kala's MPPs have the unique ability to rapidly and uniformly coat and permeate mucosal tissues, leading to highly effective treatments with improved side effect profiles. The company is leveraging its platform as an internal product engine for a wide spectrum of potential applications, including treatments for respiratory, ophthalmic, female reproductive tract, and gastrointestinal diseases. Kala is also pursuing collaborations with partners to transform the therapeutic properties of marketed drugs and compounds in development. Kala was founded by leaders in the fields of nanomedicine and biopharmaceutical engineering: Dr. Justin Hanes of The Johns Hopkins University School of Medicine, Dr. Robert Langer of the Massachusetts Institute of Technology, and Dr. Colin Gardner formerly of TransForm Pharmaceuticals/Johnson & Johnson and Merck. Leading investors including Lux Capital, Polaris Venture Partners, Third Rock Ventures, and Crown Venture Fund, LLC, now back the company. For more information, please visit www.kalarx.com.

InVivo Therapeutics Submits Updated IDE to FDA to Begin Spinal Cord Injury Human Study

Business Wire: February 28, 2013 – CAMBRIDGE, MA, U.S.A. – InVivo Therapeutics Holdings Corp. (NVIV), a developer of groundbreaking technologies for the treatment of spinal cord injuries (SCI) and other neurotrauma conditions, today announced the company has submitted an updated investigational device exemption (IDE) to the U.S. Food and Drug Administration (FDA) requesting permission to begin human studies in order to test its biopolymer scaffolding for the treatment of acute SCI.

The updated IDE submission is in response to exchanges since InVivo's April 12, 2012, meeting with the FDA. The filing contains additional information regarding the manufacturing and preclinical testing of the scaffolding device. Once approved, the IDE will allow InVivo to conduct an open-label human study to collect safety and efficacy data to support FDA approval of the first in-cord treatment for SCI. The company is also working with the FDA in order to have the scaffolding device designated as a humanitarian use device (HUD), a designation that InVivo expects will create a faster path to market.

"We are prepared to safely treat acute SCI patients, and in the coming months we hope to have the first opportunity to translate to humans the positive effect from the scaffold that we observed in our 2008, 2009, and 2011 nonhuman primate studies," said Frank Reynolds, InVivo chief executive officer. "Our technology remains the only treatment to have demonstrated functional recovery when applied to nonhuman primates with SCI, and this first study has the potential to change the treatment options for neurotrauma patients forever.

"We've all heard that 'an ounce of prevention is worth a pound of cure,' and over a hundred people on the InVivo team have

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worked tirelessly since 2008 to bring this 'ounce of prevention' to patients. We intend to intervene shortly after injury to minimize the advancement of scarring and to provide functional recovery within weeks of treatment." Continued Reynolds, "I want to thank our chief medical officer, Dr. Eric Woodard, and our chief technology officer, Brian Hess, along with their teams, for their deep and never-ending commitment to SCI patients. We look forward to receiving feedback from the FDA and to getting started on this historical first-in-man clinical trial."

Said Brian Hess, InVivo chief technology officer, "We appreciate the collaborative dialogue we have had with the FDA. Since our April 2012 meeting, we've established regulatory processes to treat neurotrauma with biomaterials, and we've completed knowledge transfer with the FDA that we believe will benefit all of our additional products in development. We expect to bring a wide range of neurotrauma treatments to patients as quickly as possible with the potential for two new 510(k) products to hit the market in late 2014. In addition to the scaffolding device for SCI, we are developing products for conditions such as pain, fibrosis, and drug delivery, and we continue to make excellent progress in these applications as well."

Antares Pharma Announces FDA Acceptance of New Drug Application for OTREXUP™

Business Wire: February 27, 2013 – EWING, NJ, U.S.A. – Antares Pharma, Inc. (NASDAQ: ATRS) today announced that the New Drug Application (NDA) for OTREXUP™, a potential new product for the subcutaneous delivery of methotrexate (MTX) using Medi-Jet™ technology, has been accepted by the U.S. Food and Drug Administration (FDA), indicating that the application is sufficiently complete to permit a substantive review. OTREXUP is being developed for self-administration of MTX to enhance the treatment of rheumatoid arthritis (RA), poly-articular-course juvenile RA, and psoriasis.

The FDA has assigned a Prescription Drug User Fee Act (PDUFA) date of October 14, 2013, ten months from the official NDA filing. The PDUFA date is the target date for the FDA to complete its review of the NDA.

"The FDA's acceptance of the OTREXUP NDA is an important start to the review process and a significant milestone for our shareholders," said Paul K. Wotton, Ph.D., president and chief executive officer. "We look forward to working closely with the FDA during their review of the application."

RBCC Opens Talks to Help Develop Revolutionary Breakthrough in $60 Billion Drug Delivery Market

Business Wire: February 27, 2013 – NOKOMIS, FL, U.S.A. – Rainbow Coral Corp. (OTCBB: RBCC) biotech division Rainbow BioSciences is currently in talks to help develop and market a revolutionary sustained-release drug delivery platform that could soon make local delivery of biologic agents and small molecules safer, more effective, and more convenient than ever before. The company is currently working on a potential joint venture agreement with a privately held drug delivery company developing the novel technology. The delivery platform is being engineered to solve the problems posed by systemic drug delivery, including oral and IV delivery. In many cases, systemically delivered drugs can't reach sufficient concentrations in target organs to be effective without damaging the liver, kidneys, or heart. Often, systemic delivery also requires frequent, expensive injections.

The technology RBCC is currently reviewing has the potential to enable selective, site-specific delivery, allowing for lower drug concentrations and greatly reducing the risk of drug toxicity.

"Because it's a sustained-release delivery system, patients could potentially only need one injection every six months," said RBCC CEO Patrick Brown. "In addition to helping millions of patients struggling with chronic conditions, the technology also has the benefit of extending the patent life cycles of drugs, giving potential pharmaceutical partners a tremendous market advantage."

"RBCC hopes to conclude its due diligence work on the drug delivery company and sign a joint venture agreement to begin getting the new technology into doctors' hands in the next few weeks," Brown added.

For more information on Rainbow Biosciences' current projects, please visit www.rainbowbiosciences.com/investors.html.

Crystal Pharmatech and Particle Sciences Form a U.S.-China Pharmaceutical CRO Partnership

Business Wire: February 26, 2013 – PRINCETON, NJ, U.S.A., and SUZHOU, China – Crystal Pharmatech, a technology-driven solid-state research contract research organization (CRO) based in Suzhou, China, announced a partnership with Particle Sciences, one of the world's leading contract drug development companies focused on the formulation and support of advanced drug delivery solutions. The partnership, one of many that Crystal Pharmatech is forging with research driven organizations, combines a level of expertise previously not available to CROs that will increase the success rate for the development of insoluble pharmaceutical compounds. Both will now offer clients an optimal solution for developing low solubility pharmaceutical compounds.

Over the past five years, approximately 65% of pharmaceutical compounds under development have been sparingly soluble to practically insoluble in water. This has led to the need for more innovative formulation and solubilization techniques. As scientific complexity of drug development increases, finding the appropriate CRO to bring about the optimal development path for both drug substance (API) and drug product (formulation) is of utmost importance. Crystal Pharmatech, a preferred provider among innovator pharmaceutical companies, has extensive experience selecting the appropriate solid phase of a wide range of compounds. The company has a proven track record among its

customers to provide fundamental material property evaluation, in addition to screening, evaluating, and selecting the optimal form for pharmaceutical development. Particle Sciences brings over two decades of experience in formulating active pharmaceutical ingredients (APIs) and multiple delivery/formulation formats. In addition, the company is able to identify common obstacles in drug product development and provide a resource of delivery technologies to address these obstacles.

"Whether the best way to develop your product is a co-crystal or nano-suspension depends on the material properties of your drug and the delicate interplay between API and formulation development," explains Alex Chen, CEO of Crystal Pharmatech. Robert Lee, vice president of pharmaceutical development at Particle Sciences, adds, "Oftentimes, a client will work with a CRO to find a path forward for API development, only to realize that the chosen path is unacceptable for formulation development and, as a result, the project goes over the allocated time and budget." Both Crystal Pharmatech and Particle Sciences vetted a number of potential partners prior to aligning with each other, and each company will utilize the other's core expertise to seamlessly offer clients the optimal program for their drug candidates.

Crystal Pharmatech, headquartered in Suzhou, China, with an office in Princeton, NJ, is a technology-driven CRO that offers materials research service for active pharmaceutical ingredients and formulations used in drug discovery. It provides its customers with data derived from experiments and also partners with clients to ensure comprehensive solutions for their research needs based on sound scientific understanding.
www.crystalpharmatech.com

Particle Sciences is an integrated provider of drug development services. Through a full range of formulation, analytic, and manufacturing services, it provides pharmaceutical companies with a complete and seamless development solution that minimizes the time and risk between discovery and the clinic.
www.particlesciences.com

Orexo: Agreement with Novartis on OX17 for GERD Terminated

Business Wire: February 25, 2013 – UPPSALA, Sweden – Orexo AB (STO:ORX) today announced that Novartis AG has sent a notice of termination of the license agreement dated August 27, 2009. The OX17 program was aimed for the treatment of gastroesophageal reflux disease (GERD) and is still in early clinical phase.

Under the license agreement, Novartis was responsible for all development, production, and marketing of future products.

The OX17 program has not developed according to plans, and given the strategic direction that Orexo has taken, the program will be discontinued. The termination of OX17 will have no impact on the financial position of Orexo from both a cost and revenue perspective.

PolyActiva Raises AUD$9.2M in Series B Venture Funding

Business Wire: February 19, 2013 – MELBOURNE, Australia – PolyActiva announced today that it has raised AUD$9.2 million in a Series B financing round from a consortium of investors including the Medical Research Commercialisation Fund (MRCF) and Brandon Biosciences Fund 1 (BBF1) (both managed by Brandon Capital), Yuuwa Capital, and additional participation from angel investors.

PolyActiva said the funds would be used to further the preclinical and clinical development programs of its products under development, including an intraocular implant to treat glaucoma, an intraocular implant to treat severe infections of the eye, and an intra-articular product to treat osteoarthritis.

Dr Russell Tait, CEO of PolyActiva, commented: "The funding significantly transforms our business by providing sufficient funds to take each of our planned development programmes to clinical proof of concept. The investment reflects the confidence our investors have in our capacity to deliver. Once we have demonstrated significant clinical outcomes, we will seek commercial partners for these products. We are also open to any companies looking to adopt our technology for the delivery of their own drugs."

Dr Chris Nave, managing director of Brandon Capital and chairman of the company, said: "It is a significant achievement in the current financial environment for an early stage company to have attracted this level of funding from new investors, and it reflects the confidence the investors have in the quality of PolyActiva's technology and the commercial potential of its products."

PolyActiva's proprietary drug-polymer conjugate technology enables sustained-release, site-specific drug delivery from products with different physical forms, including rods, films, fibers, and gels, substantially broadening its potential applications. The drug-polymer conjugates are able to carry high drug loads, which allows therapeutic quantities of drug to be delivered over extended periods of time from a very small implant. At the end of therapy, the polymer is designed to erode completely leaving no residue, which facilitates its chronic use and repeat administration and obviates the need for removal of the implant at the end of therapy. PolyActiva has proven the technology in validated animal models for delivery of drugs to the posterior region of the eye.

PolyActiva's development portfolio includes both low-risk products that deliver established drugs to a proven site of action, which abbreviates the product registration process, and also high-value products that deliver novel drugs to treat clinically unmet needs.

PolyActiva is a pioneering biotechnology company developing drug-polymer conjugates that allow for site-specific drug delivery from medical device components such as ocular implants, intra-

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articular gel implants, and drug-eluting fibers. The company has developed a novel and scalable manufacturing process that can easily be adapted to existing device component production processes, providing greater flexibility over the composition of the final material. Using this process, PolyActiva has built drug-polymer conjugates from a number of drug candidates with different chemical structures and linkage points and has also developed a number of functional co-monomers and polymer segments. The company has completed proof of concept studies on these and is working towards developing first products. PolyActiva is interested in hearing from medical technology companies interested in incorporating PolyActiva's drug eluting components in their devices. PolyActiva was founded in 2011 as a joint venture between CSIRO and the Bionic Ear Institute and is located in Melbourne, Australia. For more information, please visit www.polyactiva.com.

Ferring to Highlight Phase 3 Data for Cervical Ripening Candidate at Society for Maternal-Fetal Medicine Annual Meeting

PRNewswire: February 12, 2013 – SAN FRANCISCO, CA, U.S.A. – Ferring Pharmaceuticals will present pivotal phase 3 efficacy and safety data from its EXPEDITE study for its investigational controlled release misoprostol vaginal insert (MVI) at the 33rd annual meeting of the Society for Maternal-Fetal Medicine (SMFM) in San Francisco, February 11–16. These and other research findings formed the basis for Ferring's New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) supporting the use of the controlled release MVI as a treatment option for cervical ripening as part of the labor induction process.

Studies accepted for presentation include

- An oral presentation on Saturday, February 16 (9 a.m. – 9:15 a.m. PST), titled "Efficacy and safety of misoprostol vaginal insert compared with dinoprostone vaginal insert for labor induction" (lead author: Deborah A. Wing, M.D., University of California, Irvine); and

- A poster presentation on Thursday, February 14 (3:30 p.m. – 5:30 p.m. PST), titled "Comparison of misoprostol vaginal insert and dinoprostone vaginal insert: Incidence of treatment-emergent adverse events" (lead author: Stacey Ehrenberg-Buchner, M.D., University of Michigan Health System).

The EXPEDITE study is a phase 3, double-blind, randomized, multicenter study of exogenous prostaglandin comparing the efficacy and safety of the misoprostol vaginal insert (MVI) 200 mcg to the dinoprostone vaginal insert for reducing time to vaginal delivery in pregnant women at term.

Impax and Shire Settle Litigation Concerning Supply of Authorized Generic Adderall XR®

Business Wire: February 8, 2013 – HAYWARD, CA, U.S.A. – Impax Laboratories, Inc. (NASDAQ: IPXL) today announced that it has settled all pending litigation with Shire LLC and Shire Laboratories, Inc. (collectively Shire) relating to supply of its authorized generic Adderall XR® under the parties' license and distribution agreement that was signed in January 2006. As part of the settlement, the parties will submit a stipulation of dismissal for entry by the court. Shire has agreed to make a one-time cash payment to Impax of $48 million upon the court's order of dismissal.

Impax commenced sales of authorized generic Adderall XR in October 2009. On November 1, 2010, Impax filed suit against Shire for breach of contract and other related claims alleging that Shire failed to fill Impax's orders for the authorized generic Adderall XR. Shire filed a counterclaim against Impax relating to its ordering practices under the agreement. Under the terms of the settlement, Impax's claims and Shire's counterclaims will be dismissed.

The parties have entered into an amended license and distribution agreement, which will govern the future supply of authorized generic Adderall XR from Shire to Impax. Following the end of the supply term on September 30, 2014, Impax will continue to have the right to sell its products on hand or owed to it under the agreement until depleted and will continue to pay a profit share to Shire on sales of such products.

Impax will continue to pursue approval of its pending Abbreviated New Drug Application for generic Adderall XR, which was filed with the U.S. Food and Drug Administration in September 2003.

NEONC Technologies Scientific and Clinical Advisory Board Plans Development and Clinical Testing of NEO100 in Treatment of Gliomas and Other Cancers

Business Wire: February 7, 2013 – LOS ANGELES, CA, U.S.A. – NEONC Technologies, Inc. (NTI), an early-stage biotechnology company developing new drugs using intranasal brain delivery, today announced that the company's NEO100 compound will undergo extensive clinical testing for treatment of gliomas and other cancers of the central nervous system. The clinical testing program was developed at meetings in Los Angeles on January 25–26 of the company's Scientific and Clinical Advisory Board, consisting of internationally prominent researchers and clinicians in the field of neuro-oncology.

NEONC has conducted *in vitro* and *in vivo* testing and built extensive intellectual property around NEO100, a novel, highly purified form of the monoterpene perillyl alcohol (POH). The clinical program will be led by Dr. Thomas Chen, founder, chairman, and CEO of NEONC, codirector, USC/Norris Neuro-Oncology Program, and professor of neurological surgery and pathology, USC Keck School of Medicine. "Clinical research using intranasal delivery of POH in patients with recurrent malignant gliomas has resulted in a statistically significant increase in survival for patients with primary or secondary brain cancers. Our vision is to become the pharmaceutical leader in the promising technique of nasal brain delivery, which bypasses the blood-brain barrier and can greatly decrease the side effects of anticancer medication," said Dr. Chen.

Malignant gliomas currently have no cure and are nearly always fatal to patients within 12–15 months of diagnosis. Research in Brazil published in April 2010 by Dr. Clovis da Fonseca and his team, who are also founders of NEONC, in glioma patients using intranasal delivery of POH, demonstrated unparalleled success treating this disease. The study included 89 adult patients with recurrent malignant glioblastoma multiforme (GBM) and 52 matched GBM patients in a historical untreated control group. Patients with recurrent primary GBM survived significantly longer than the untreated group. Patients with primary GBM treated with inhaled POH showed a survival advantage (5.9 months) compared with the control group (2.3 months). In addition, the side effects of treatment were almost nonexistent, even in patients treated for more than four years.

"The power of Dr. Fonseca's pioneering work on intranasal POH, and NEONC's development, testing, and intellectual property protection of even more effective inhaled compounds, have laid the groundwork to attract a highly experienced Scientific and Clinical Advisory Board to support the company's upcoming clinical testing program," said Dr. Vincent Simmon, chief regulatory officer of NEONC. "The advisory board has helped create a roadmap for clinical testing that we believe can ultimately lead to pivotal trials to determine the effectiveness of inhaled NEO100 in treating GBM."

January

NanoSmart® Pharmaceuticals and UCLA Enter Collaboration Agreement for Pediatric Cancer Drug Development

PRNewswire: January 16, 2013 – LAGUNA HILLS, CA, U.S.A. – NanoSmart Pharmaceuticals, a private biotechnology company, has entered into a research collaboration agreement with University of California Los Angeles (UCLA) to continue the development of NanoSmart's novel drug delivery platform for the treatment of cancer and other life-threatening diseases.

"We are very excited to work closely with Dr. Noah Federman and his colleagues at UCLA, as they will provide access to an extraordinary level of research, development, and clinical resources," said Dr. James Smith, president of NanoSmart Pharmaceuticals. "Their expertise in the development of nanotechnology-based drugs will enable us to continue making efficient progress towards commercializing these products."

NanoSmart's patented platform drug delivery system utilizes human autoimmune antibodies that target many different types of tumors. When combined with already FDA-approved cancer drugs, this patented technology allows for the creation of a broad range of next-generation, safer, and more effective cancer drug products.

"Despite the extensive research into new drug formulations, the pace of advancing benefit to this patient population is unfortunately slowing," said Dr. Noah Federman, director of the Pediatric Bone and Soft Tissue Sarcoma Program at UCLA, a part of the UCLA Sarcoma Program and UCLA's Jonsson Comprehensive Cancer Center; and assistant professor of pediatrics, hematology/oncology, at Mattel Children's Hospital at UCLA. "We are pleased to collaborate with NanoSmart to help drive the development of these much-needed products."

UCLA's Jonsson Comprehensive Cancer Center (www.cancer.ucla.edu) is among the nation's largest and top-ranked comprehensive cancer research centers. With more than 240 researchers and clinicians, the Jonsson center is dedicated to promoting research and translating basic science into leading-edge clinical studies.

Mattel Children's Hospital UCLA, one of the highest-rated children's hospitals in California and a vital component of Ronald Reagan UCLA Medical Center, offers a full spectrum of primary and specialized medical care for infants, children, and adolescents. The hospital's mission is to provide state-of-the-art treatment for children in a compassionate atmosphere and to improve the understanding and treatment of pediatric diseases.

NanoSmart Pharmaceuticals, Inc. (www.nanosmartpharma.com) is developing novel proprietary drug delivery products to treat cancer and other serious life threatening diseases. NanoSmart's patented platform drug delivery system utilizes human autoimmune antibodies that target many different types of tumors and other diseases. NanoSmart has completed development of its preliminary immunoliposomal formulations and is currently engaged in preclinical testing of its lead candidate drug products.

Genoa Pharmaceuticals and McMaster University to Collaborate on Idiopathic Pulmonary Fibrosis Research

PRNewswire: January 16, 2013 – SAN DIEGO, CA, U.S.A. – Genoa Pharmaceuticals, a leader in the field of pulmonary fibrosis, today announced it is collaborating with Dr. Martin Kolb and researchers at McMaster University to characterize the *in vivo* advantages and potential clinical impact of Genoa's lead program, inhaled GP-101 (aerosol pirfenidone) for the treatment of IPF. The research will combine Genoa's expertise in aerosol drug delivery with McMaster's expertise in exploring mechanisms of pulmonary fibrosis and managing patients with IPF.

"Genoa is very excited about the opportunity to collaborate with Dr. Kolb and McMaster University to better understand how inhaled GP-101 may benefit IPF patients," said Mark Surber, Ph.D., Genoa's founder, president, and chief scientific officer. "Genoa is committed to establishing academic relationships with leading institutions to further advance its efforts to develop novel treatments for IPF."

"We are very interested to evaluate novel therapies such as GP-101 to better understand the molecular effects and *in vivo* relationship to the human disease," said Dr. Martin Kolb, M.D., Ph.D., and associate professor in the Division of Respirology,

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within the Department of Medicine Pathology and Molecular Medicine at McMaster University. "We are pleased to collaborate with Genoa, as we believe GP-101 has the potential to be a key treatment for IPF."

Genoa Pharmaceuticals, Inc., is committed to developing improved therapies for the treatment of IPF. Based in San Diego, Genoa's lead program, GP-101 (aerosol pirfenidone), is advancing towards the clinic for the treatment of IPF. Learn more at www.genoapharma.com.

Dr. Kolb is associate professor of medicine at McMaster University and research director of the Firestone Institute for Respiratory Health. Dr. Kolb is a recognized expert in the field of lung fibrosis whose research activities focus on the biology of lung injury, repair, and fibrosis, particularly in idiopathic pulmonary fibrosis (IPF). He has a strong interest in growth factor biology (e.g., TGFβ and IL-1), extracellular matrix, and mesenchymal cell progenitors (mesenchymal stem cells and fibrocytes). In his lab he uses a variety of disease models to study biological mechanisms and also the efficacy of novel drugs in the preclinical setting. Small animal imaging with CT and PET is one of the exciting new research areas that Dr. Kolb pursues at McMaster in collaboration with other faculty members (Dr. Renee Labiris). Further, Dr. Kolb leads activities in biomarker development for lung fibrosis, and he participates as principal investigator and steering committee member in numerous clinical trials on interstitial lung disease. He is elected chair of the 18th International Colloquium on Lung Fibrosis in September 2014 (Tremblant, Quebec). ■

Controlled Release Society
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United States of America

Calendar of Events

2013

European Molecular Imaging Meeting (EMIM 2013)
May 26–28
Torino, Italy
www.emim.eu

15th International Workshop on Physical Characterization of Pharmaceutical Solids (IWPCPS-15)
June 24–27
Philadelphia, PA, U.S.A.
www.assainternational.com

Controlled Release Technology: Polymeric Delivery Systems for Pharmaceuticals, Proteins, and Other Agents
July 8–12
Cambridge, MA, U.S.A.
http://shortprograms.mit.edu/crt

40th Annual Meeting & Exposition of the Controlled Release Society
July 21–24
Hawaii Convention Center
Honolulu, Hawaii, U.S.A.
www.controlledreleasesociety.org

Advances in Tissue Engineering Short Course
Sponsored by CRS
August 14–17
Houston, TX, U.S.A.
http://tissue.rice.edu/

11th International Nanomedicine and Drug Delivery Symposium (NanoDDS'13)
October 25–27
La Jolla, CA, U.S.A.
http://nanomedicine.ucsd.edu/nanodds13