CRS Leading Delivery Science and Technology

Newsletter

A publication of the Controlled Release Society Volume 31 • Number 3 • 2014

What's Inside

CRS Annual Meeting and Exposition

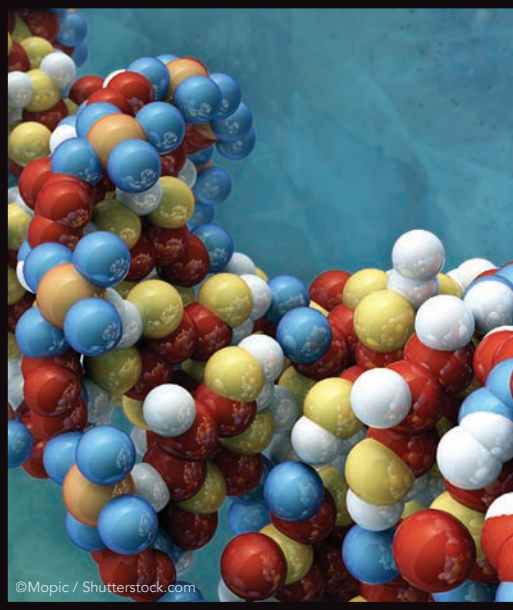
July 13–16, 2014 • Chicago, Illinois, U.S.A.

Access the Best in Delivery Science

Join us at the Hilton Chicago to connect with those in the discovery, development, and delivery continuum.

- Learn from world-renowned researchers and thought leaders.
- Be a part of the global discussion on matters that affect the future of our science.
- Visit the exposition for the newest technologies, products, and services.
- Connect with colleagues from around the world.

The entire meeting is housed in the Hilton Chicago. Book now!



Exposition Space and Sponsorships Available

TRANSLATION

of Delivery Technology:
Innovation to Commercialization

controlledreleasesociety.org

Charles Frey
Editor

Steven Giannos
Editor

Arlene McDowell
Editor

Bozena Michniak-Kohn
Editor

Yvonne Perrie
Editor

Rod Walker
Editor

CRS Newsletter
Leading Delivery Science and Technology

Vol. 31 • No. 3 • 2014

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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 controlledreleasesociety.org.

Controlled Release Society
3340 Pilot Knob Road
St. Paul, MN 55121 U.S.A.

Telephone: +1.651.454.7250
Facsimile: +1.651.454.0766

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

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

Yvonne Perrie
Aston University, School of Life and Health Sciences
Aston Triangle, Birmingham, U.K.

Controlled Release Homeopathy

Dear Reader,

I have been considering preparing some sustained release homeopathy; seems like a great idea to me. Talk about easy money. Basically I get some sugar pellets that contain the "ultra-diluted medicine," and then I give it a nice sustained release coating. I could put it into dissolution studies and measure no drug release; therefore, it must be an even more potent "remedy." I guess I could even use an ultra-dilute sustained release coating to improve the results. I could add in some DSC, mass spectrometry—indeed, a full range of analysis—and prove the drug concentration is too low for detection and therefore a good product. However, I am not sure how I would calculate the shelf-life of this system. Would any decrease in "drug concentration" increase "potency"? However a quick Google search reveals that there is already a patent application titled "Extended Release Solid Oral Dosage Form for Homeopathic Compositions," so someone has beat me to it. Perhaps I could do targeted therapy, even entrap homeopathic remedies into liposomes; a low entrapment would make the formulation work even better. This always amuses me briefly. Unfortunately, when I think about it too much I move from amusement to getting grumpy about the pharmacies that sell this rubbish to people, conning them and potentially enhancing tooth decay, given the sugar content.

Therefore, I am happy to work in a field where we offer our research up for scrutiny by our peers. What better place to do this than at the CRS Annual Meeting? It will be marvellous to catch up again with fellow CRS members and hear about their latest work. The CRS local chapters are also doing a great job of supporting research dissemination and collaboration. Within this issue of the *CRS Newsletter*, we have reports from several chapters including Taiwan, Germany, and "MyCRS" (great name), the local chapter recently set up in Malaysia. As always, we have the fantastic In the News article, the best way to keep up to speed with what is going on in the field. We also have two interesting Scientifically Speaking articles for you and a fascinating interview with Frank Szoka, which outlines how we can translate our lab science to a commercial enterprise. Hopefully, this will all whet your appetite in the runup to our annual meeting. I hope to catch up with many of you there, and in the meantime I had best go file my patent on liposomal homeopathic remedies.

Best regards,
Yvonne ■

Ian Tucker
University of Otago
Dunedin, New Zealand

Building a Robust Organisation

This year the Board of Scientific Advisors (BSA) was given the demanding challenge of identifying emerging trends in CRS science and technology and also speculating on some possible "black swans" that might be over the horizon. By definition, black swans cannot be predicted, since they do not arise from trends in our discipline. They may arise from discoveries in fundamental sciences or perhaps from responses to unanticipated problems.

So the BSA concluded that we should not attempt to predict black swan events but rather build robustness to buffer against unforeseen potentially damaging events while being able to turn positive ones to our advantage. This sound advice will influence the thinking of CRS, and we will continue to develop a nimble organisation that can adapt rapidly and creatively to disruptive events—an organisation that is "built to last."

In addressing their charge, the BSA took the approach of identifying the biological and technological barriers confronting us, particularly those barriers that, if overcome, would have a major impact. Major biological barriers include delivery of proteins to the brain and delivery of proteins by the oral route, the subject of a premeeting workshop at the CRS Annual Meeting in Chicago.

A major technological barrier is the need to address the challenges of manufacturing at a reasonable cost and to a high quality the sophisticated delivery systems we are creating in our labs. The unsolved problem of scale-up of high-quality multicomponent drug delivery systems calls for leadership from CRS scientists and technologists.

Members can learn more about some of these issues in the next *CRS Newsletter*.

The BSA members are not the only ones exercising their grey cells about the future. An article by Brambill *et al.* published in a special anniversary issue of the *Journal of Controlled Release* speculates on what a reader will find in the 2044 issue of *JCR*. What technologies will be leading the field? The writers speculate that nanoparticles will play a fundamental role in the future. Our BSA also sees this, perhaps building on our increasing understanding of some of nature's nanoparticles (e.g., exosomes).

Returning to Our Roots

While marveling at these highly sophisticated approaches that promise to address problems in human healthcare and the demand for personalized medicines, there are huge challenges in other areas where our science and technology have contributions to make. These include areas such as healthcare in developing countries (single-shot vaccines, heat-stable vaccines, and better treatments for tropical diseases); agriculture (more efficient use of pesticides and fertilisers to minimize environmental contamination); and animal health (domestic pets, wildlife, and production animals).

CRS was founded by those with interests in agriculture and animal health. I have a photo of a young Nick Peppas and a young Bob Langer at an MIT summer session "Controlled Release Technology: Polymers in Medicine, Food, and Agriculture" in 1980. It might be argued that CRS has moved on from the problems in agriculture, animals, and the environment, having addressed them many years ago. However, our science has moved substantially since then, problems caused by more intensive farming have arisen, and society's tolerance of collateral environmental damage has diminished. We need new science and technological solutions to these problems to feed the growing world population with less land (or sea for aquaculture) being used and with diminished environmental impacts.

My Recent Activities

Prof. Weisan Pan

I recently had the opportunity to visit China again and to attend the 3rd Asian Pharmaceutical Science Symposium in Shenyang. This conference was jointly organized by the CRS China Local Chapter. As your CRS president, my visit provided an opportunity to discuss the science and technology of CRS, highlight the advantages of membership, and talk with the current president of the local chapter, Prof. Weisan Pan of Shenyang Pharmaceutical University. The 2014 Annual Meeting of the CRS China Local Chapter will be held September 19–22 in Changsha. The development in CRS science in China is remarkable.

I have also contacted all local chapter presidents asking them to send me some photos and information on their chapters' activities. The response was gratifying. The materials they provided will be used, in part, at the President's Banquet in Chicago, which will include an entertaining and educational competition about CRS science and history. I hope you will be there to take part.

In some ways I feel like I am on the "home stretch" of my year as president. While it is true that the most important event in our calendar, the Chicago Annual Meeting, is still ahead, a huge amount has been done in building robustness into our organization, in strategising, and now in implementing plans. I look forward to sharing some of these developments with you in Chicago.

Ian Tucker
President ■

The Best and Brightest in Controlled Release Delivery Will Gather to Explore Breakthrough Science and Technology

Ick Chan Kwon

The 41st Annual Meeting & Exposition of the Controlled Release Society will offer delegates nearly 800 presentations covering all aspects of delivery science. Chair Ick Chan Kwon, KIST, Korea, and his fellow Annual Meeting Program Committee members have worked diligently during the past year to develop a comprehensive educational and networking opportunity for all.

The event theme, "Translation of Delivery Technology: Innovation to Commercialization," represents the CRS community's focus on facilitating critical partnerships between researchers and industry. A variety of educational formats—sessions, roundtables, workshops, mini-symposia, panel discussions, and more—will provide ample opportunity to delve deep into topics of interest.

2014 Annual Meeting Program Committee

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Register Today!

41st Annual Meeting & Exposition of the
Controlled Release Society
July 13–16, 2014
The Hilton Chicago
Chicago, Illinois, U.S.A.

controlledreleasesociety.org/meeting

Plenary Session Speakers to Discuss 3D Assays, Tissue Regeneration, and Nutrition Delivery

Join us to hear respected innovators from top academic programs chosen by the 2014 CRS Annual Meeting Program Committee. These speakers are working on the cutting edge of science, translating scientific advances into novel innovations. See complete session descriptions online under 2014 Annual Meeting/Program & Events/Invited Speakers.

David W. Grainger

Taking Shape: Transitioning 3D Assays to Improve Drug Screening and Toxicity Predictions

David W. Grainger

Attend the Monday afternoon plenary session to learn how 3D cell culture models can yield better data quality with more accurate, tissue-specific information to significantly improve the technical output, predictive value, and translation between *in vitro*, animal, and clinical human studies.

Grainger is a university distinguished professor and chair of the Department of Pharmaceutics and Pharmaceutical Chemistry and a professor of bioengineering at the University of Utah, U.S.A. His research focuses on improving implanted medical device performance using drug delivery; methods to deliver therapeutic proteins, nucleic acids, and live vaccines; nanomaterials interactions with human tissues; low-infection biomaterials; and microarray-based diagnostic devices.

Kristi Anseth

Drug Delivery to Promote Tissue Regeneration: How Simple Is Complex Enough?

Kristi Anseth

As discovery of new biological signals and targets has evolved, so has the need for improved delivery systems to facilitate improvements in wound healing, stem cell engraftment, and reversal of fibrotic diseases. This talk will highlight several examples in which advances in four-dimensional control of biomaterial scaffold properties can be used to better understand how to present and manipulate the presentation of biochemical signals, as well as to promote tissue regeneration.

Anseth's research interests lie at the interface between biology and engineering, where she designs new biomaterials for applications in drug delivery and regenerative medicine. She is a How-

ard Hughes Medical Institute investigator and distinguished professor of chemical and biological engineering at the University of Colorado at Boulder, U.S.A.

NOTE: Kristi Anseth replaces Chad Mirkin, Northwestern University, as Tuesday's plenary lecturer.

David Edwards

Redesigning Nutrition Delivery

David Edwards

The features of man-made delivery systems underlying the trillion-dollar food and beverage industry often contrast poorly with those of natural systems. Natural foods involve little or no environmental waste, encourage portion control, and efficiently deliver functional nutrition in mobile circumstances. These and other qualities, having ensured the sustainable nourishment of animals and humans for many thousands of years, can be critically absent in today's food industry. This talk highlights the current revolution in the redesign of nutrition delivery aimed at meeting the health and environmental challenges of the 21st century. It especially highlights recent breakthroughs from our labs in the fields of aerosol foods and edible and biodegradable food packaging.

Edwards is a professor of the Practice of Idea Translation at Harvard University and founding faculty member of the Wyss Institute, U.S.A.

Who's Coming?

To see a list of attendee organizations and countries, please visit **controlledreleasesociety.org** and look under 2014 Annual Meeting and then your choice of Registration or Program & Events.

Chicago—You Can Get There from Everywhere

The 41st CRS Annual Meeting & Exposition is housed entirely in the historic Hilton Chicago Hotel for ultimate comfort and convenience while you attend the meeting. Be sure to book your room immediately after you register for the meeting to guarantee accommodations. Plan to arrive in time to enjoy the Taste of Chicago festival, which runs July 9–13, 2014.

The Hilton is a 4 Diamond hotel with old-world charm and elegance along with modern sophistication and amenities. Enjoy the panoramic view from your room and then take a short elevator ride to the exhibit hall, scientific sessions, and networking events.

continued

Expand Your Knowledge with a Premeeting Workshop

July 12

Albumin: The Next Generation Protein Therapeutic

Cosponsored by Novozymes Biopharma Inc.

Chairs: Kenneth Howard, Interdisciplinary Nanoscience Center, Denmark; and Daniel Shelly, Novozymes Biopharma Inc., U.S.A.

July 12–13

Oral Delivery of Peptides and Proteins

Cosponsored by Catalent Pharma Solutions

Chairs: David Brayden, University College Dublin, Ireland; and Randall Mrsny, University of Bath, United Kingdom

Nanotechnology – Process and Formulation, Characterization and Applications

Chairs: Teresa Virgallito, Microtek Laboratories, Inc., U.S.A.; and Nicole Papen-Botterhuis, TNO, The Netherlands

July 13

Computational Pharmaceutics – The Application of Computer Modeling in Drug Delivery

Chairs: Defang Ouyang, Aston University, United Kingdom; and Alex Bunker, University of Helsinki, Finland

Locally Acting Dermal Drug Products – Global Challenges for Development and Registration

Chairs: Howard Maibach, University of California, San Francisco, U.S.A.; and Tapash Ghosh, ONDQA/CDER/FDA, U.S.A.

Sponsor a workshop. Learn how your organization can receive recognition by sponsoring one of these workshops. Contact Cindy Anderson at canderson@scisoc.org.

41st Annual Meeting & Exposition of the Controlled Release Society
July 13–16, 2014
Chicago, Illinois, U.S.A.

controlledreleasesociety.org

"Perched on the Mag Mile—Chicago's famous boulevard for shopping and landmarks—Hilton Chicago maintains a high-profile presence and instant access to Grant Park, Lake Michigan, Museum Campus, Millennium Park and the Art Institute of Chicago. Guests simply have to walk to some of the city's best shops, restaurants and bars from the property or take advantage of ample bus and train lines nearby." –*Orbitz.com*




(Left to right) Courtesy of Choose Chicago, ©City of Chicago – Adler Planetarium Chicago; Buckingham Fountain at Grant Park; Riverboat cruise through the city and past Willis Tower; Ferris Wheel at Night, Navy Pier

Networking Events and Convenient Technology Help You Build Global Connections

CRS offers the best of both worlds: face-to-face networking opportunities and a chance to find and connect with hundreds of delegates through CRS Connect on the CRS meeting app.

Roundtable Discussions

Roundtable discussions are in-depth interactive sessions with a panel of experts who share their findings and opinions. This year's roundtables include:

Ocular Drug Delivery Roundtable
Polymers in Ocular Drug Delivery – More Than Meets the Eye?
Chairs: Ilva Rupenthal, University of Auckland, New Zealand; and Andrew Urquhart, Technical University of Denmark, Denmark

Invited Speakers
Nanocarriers That Help Overcoming the Ocular Barriers
Maria José Alonso, University of Santiago de Compostela, Spain
Sustained Release Ocular Delivery: Many Have Tried, Few Have Succeeded
David W. Grainger, University of Utah, U.S.A.
What's New in Industry – An Update on Ocular Drug Delivery Companies
Michael O'Rourke, GrayBug LLC, U.S.A.

Oral Drug Delivery
Continuous Processing of Oral Modified Release Products
Chair: Ali Rajabi-Siahboomi, Colorcon, Inc., U.S.A.

Invited Speakers
Continuous Processing of Oral Controlled Release Solid Dosage Forms: A Myth or Reality
Ali Rajabi-Siahboomi, Colorcon Inc., U.S.A.
Recent Advances in Continuous Manufacturing of Drug Products from Basic Raw Material to Finished Dosage Form
Salvatore Mascia, Contuus Pharma MIT, U.S.A.
Rapid Development Paradigm Using Continuous Process Design
Speaker to be named, Pfizer, U.S.A.

Women in Science Luncheon: "In the Middle of Difficulty Lies Opportunity"

Cosponsored by Ashland Inc.

This year's lunch will feature a fireside chat with **Danchen Gao**, Director, Intellectual Property Strategy, AbbVie. Danchen has an amazing 19-year career in the industry (complete biography online) and is an inventor or a coinventor of numerous dosage form design patent applications; among them, the Celebrex® composition patent has been granted by more than 60 countries. Danchen holds a Ph.D. in pharmaceutical chemistry from the University of Kansas School of Pharmacy.

First Timers' Meeting

If this is your first CRS Annual Meeting & Exposition, or even if you have attended for many years, learn how to get the most from the annual meeting program by attending this welcome and question-and-answer session presented by the CRS Board of Directors.

CRS Connect

Meeting attendees who opt to share their contact information are included in CRS Connect, which enables fellow attendees to easily search for one another by name, company, or specific area of interest. This networking tool also includes messaging and appointment request features. CRS Connect can be found on the CRS meeting app, which can be downloaded onto mobile devices and tablets or accessed with a laptop computer through the desktop URL. Specific instructions for using CRS Connect can be found online on the CRS Annual Meeting Program & Events page.

Preclinical Sciences & Animal Health (PSAH) Networking Get-Together

Cosponsored by Merial Ltd.

PSAH serves scientists involved in the development and regulation of drugs and biologics intended for veterinary use as well as those working in preclinical drug development. Walk to Chicago's premier blues club, Buddy Guy's Legends, for a brief division presentation and ample time for networking with members of the division and fellow meeting attendees. You do not need to be a member of the division to attend.

Consumer & Diversified Products (C&DP) Division Luncheon

Cosponsored by Coating Place Inc., The Dow Chemical Company, Microtek Labs Inc., Ronald T. Dodge Co., and Vision Processing Technologies Inc.

Join your fellow C&DP Division members for this networking buffet luncheon at the Hilton Chicago. All attendees interested in C&DP, which includes encapsulation and controlled release research for food, nutraceuticals, personal care, cosmetics, home care, agriculture, textiles, and coatings, are welcome to attend.

CRS President's Banquet

Ian Tucker

The President's Banquet is a premier opportunity to meet and dine with your colleagues from around the world. CRS President Ian Tucker is your host for a popular pub-quiz-style event that will showcase the science and history of the Controlled Release Society.

Scientific Sessions Invited Speakers

Advances in Drug Delivery to the Eye
Peter Humphries, Trinity College Dublin, Ireland

Advances in Drug Delivery to the Lung
Paul Young, University of Sydney, Australia

Advances in Process Engineering—New Methods for the Production of Particles, Capsules, and Coatings
Sateesh Sathigari, Patheon, U.S.A.

Advances in RNA and DNA Delivery
Yoshiki Katayama, Kyushu University, Japan

Breakthrough Technologies
Chris Bettinger, Carnegie-Mellon University, U.S.A.

Cells as Delivery Vehicles
Maciej Lesniak, University of Chicago, U.S.A.

Controlled Release Applications in Food, Feed, and Beverages
Erich Windhab, ETH Zürich, Switzerland

Controlled Release of Actives in Consumer Products
Nilesh Shah, Dow Chemical, U.S.A.

Evaluation and Characterization of Controlled Release Products and Production Processes
Lew Brown, Fluid Imaging Technologies, U.S.A.

Innovations in Micro- and Nano-Based Delivery
Adah Almutairi, University of California, San Diego, U.S.A.

Innovations in Oral Drug Delivery
Sponsored by Patheon Pharmaceuticals Inc.
Youngro Byun, Seoul National University, Korea

Intracellular Delivery of Nucleic Acids and Proteins
Patrick Stayton, University of Washington, U.S.A.

Overcoming Biological Barriers
Dennis Discher, University of Pennsylvania, U.S.A.

Nanoparticle-Based Delivery to the Brain
Kannan Rangaramanujam, Johns Hopkins Hospital, U.S.A.

Nanoparticles in Tumor Treatment
Youqing Shen, Zhejiang University, China

Novel Developments in Formulation, Analytical Chemistry, and Processing in Animal Health and Preclinical Sciences
Susan Cady, Merial Ltd., U.S.A.

Overcoming Barriers in the GI Tract
Laura Ensign, Johns Hopkins Hospital, U.S.A.

Predictive Animal Models for Assessing Long-Acting Formulations for Human and Animal Health and Their Challenges
James Birchall, University of Cardiff, United Kingdom

Proteins, Peptides, and Vaccines
Maria José Alonso, University of Santiago de Compostela, Spain

Transdermal Delivery
Mark Kendall, University of Queensland, Australia

Young Scientist Events

Young Scientist Workshops

Three Young Scientist workshops are complimentary for registered meeting attendees. Workshops are specifically designed with the interests of young scientists in mind (typically, students and early career scientists under the age of 40 years, or those with less than five years' experience in the field of delivery science).

The Science of Publishing
Chairs: Adam Bohr, Institute Galien Paris-Sud, France; and Jorrit Water, University of Copenhagen, Denmark

This workshop aims to educate young scientists in the different aspects of publishing and peer review in scientific journals, as well as to highlight and discuss current controversies such as open access journals, scientific integrity, impact factors, and more.

Novel Technologies in Solubility Enhancement
Chairs: Marcus Brewster, Johnson & Johnson, Belgium; and Joke Meeus, KU Leuven, Belgium

Contemporary drug pipelines contain an increasing number of poorly water-soluble candidates. To overcome this problem, solubility-enhancing technologies often focus on impacting aspects of the Noyes–Whitney relationship by increasing dissolution rate or drug solubility. The workshop aims to provide a context for deciding whether formulation enablement is necessary and which technique is most appropriate for which problem.

Communication and Networking: How to Develop and Utilize These Skills for a Successful Career
Chairs: Shahriar Absar, FDA, U.S.A.; and Kaushal Dave, South Dakota State University, U.S.A.

While scientific meetings have long served as the platform for global networking, online sites have also become critically important to widening one's professional network. Workshop speakers will outline the tools necessary to sharpen communication and networking skills.

Young Scientist Roundtable

Imaging in Drug Delivery: Current Practice, Regulatory Challenges, and Future Trends

Cosponsored by Aspect Imaging

Chaired by Patrick Lim Soo, Blend Therapeutics, U.S.A.; and Jinzi Zheng, Princess Margaret Cancer Centre, Canada

Imaging has been increasingly exploited for assessment of the *in vivo* performance of drug delivery systems. This roundtable aims to introduce young scientists to the current advances in the field and will discuss opportunities and strategies to achieve future successes in image-guided drug delivery.

Young Scientist Mentor/Protégé Meet and Greet

Protégés have already been selected for the 2014–2015 program, but CRS is still seeking mentors. Young scientists, keep this important networking event top of mind for next year and register early to be considered.

Young Scientist Networking Event

Cosponsored by Diurnal Ltd. and Upsher-Smith Labs

The Mystic Blue Yacht will launch from Navy Pier and take attendees on a two-hour boat cruise on Lake Michigan filled with networking and spectacular Chicago views.

Early career professionals at the 2013 Young Scientist Networking Event.

Mini-Symposia Invited Speakers

Advancements to Develop and Deliver Biologics

Sponsored by Catalent Pharma Solutions

Stephen Buckley, Novo Nordisk A/S, Denmark
Kang Choon Lee, Sungkyunkwan University, Korea
Rosie McLaughlin, Catalent Pharma Solutions, United Kingdom

Cancer Epigenetics, Epigenetic Drugs, and Delivery
Rojgopal Govindarajan, University of Georgia, U.S.A.
Vinod Labhasetwar, Cleveland Clinic Foundation, U.S.A.
Shujun Liu, University of Minnesota, U.S.A.

Individualized Medicine and Theranostics
Xiaoyuan Shawn Chen, NIH, U.S.A.
Yong-Min Huh, Yonsei University, Korea
Twan Lammers, Aachen University, Germany

Interspecies Clinical Pharmacology Dosing Concepts
Robert Hunter, Elanco Animal Health, U.S.A.
Mark Papich, North Carolina State University, U.S.A.
Steven Sutton, University of New England, U.S.A.

Micro- and Nano-Encapsulation: From Innovation to Commercialization
Nathan Dormer, Orbis Biosciences, U.S.A.
Tom Tice, Evonik, U.S.A.
Ron Versic, Ronald T. Dodge Company, U.S.A.

"Innovation Sunday" Kicks Off a Spectacular Annual Meeting

Cosponsored by Pfizer

CRS Innovation Sunday is all about the business of delivery science, taking innovative ideas and technologies into the commercial sector. Sunday sessions give you important new information on companies and technologies as well as great opportunities for networking face-to-face. Sunday morning opens with Technology Forums, followed by Soapbox Sessions and an afternoon Industry Roundtable led by Ronald Smith, Merck & Company. Hundreds of attendees will gather in the Exposition Hall for the Grand Opening and Welcome Reception.

Industry Roundtable

Patient Adherence and the Future of Innovative Drug Delivery

This Industry Roundtable will discuss perspectives and provide insight on the latest innovative delivery technologies, devices, packaging, patient interactive feedback systems, and other future strategies to increase patient adherence and treatment outcomes.

Panelists:
Gary Cleary, Corium International, U.S.A.
Tom Tice, Evonik Corp., U.S.A.
Julia Rashba-Step, Pfizer, U.S.A.
Ronald Smith, Merck & Company, U.S.A.
Cornell Stamoran, Catalent Pharma Solutions, U.S.A.

Soapbox Sessions

Cosponsored by Catalent Pharma Solutions

Adhesives Research
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Avanti
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TNO
University of Queensland

Technology Forum Presentations

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Lubrizol LifeScience Polymers
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Honoring CRS Leaders Past, Present, and Future

You're Invited

Alexander "Sandy" Florence

Christopher Nelson

Join us July 14 in Chicago when the CRS Foundation presents the 2014 Alexander "Sandy" Florence Postdoctoral Fellowship Award to Christopher Nelson.

The 2014 Alexander "Sandy" Florence Postdoctoral Fellowship Award honors Prof. Florence's service to CRS and his many contributions to delivery science, both in academia and industry.

Give It Forward

You can help support excellence in delivery science through your support of the CRS Foundation. Donations can be made online or at the annual meeting registration desk.

CRS FOUNDATION

In 2007 CRS established the CRS Foundation, a 501(c)(3) educational endowment, to honor individuals who have made notable contributions to the society and its technologies and to support the scientific training of its future leadership.

Exposition Grand Opening & Welcome Reception

CRS Innovation Sunday culminates in the Exposition Hall, where discovery, solutions, opportunities, and refreshments await you! Sunday evening features the Exposition Grand Opening & Welcome Reception. The Exposition/Poster Hall will also be open Monday and Tuesday as the central hub for poster viewing, program breaks, and refreshments. Be sure to thank the CRS Café Sponsors (*) for providing complimentary beverages.

2014 CRS Exhibiting Companies

3M Drug Delivery Systems
Adhesives Research, Inc./ARx, LLC
Advanced Polymer Materials Inc.
Agilent Technologies
Akina, Inc.: PolySciTech Division
Anton Paar USA
Avanti Polar Lipids, Inc.*
Bend Research, Inc.
BioPharm Solutions, Inc.
BUCHI Corporation
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Celanese EVA Polymers
Colorcon*
CordenPharma
Croda Inc.*
Delta Industrial Services Inc.
Destination Edinburgh
Dissolution Technologies
Distek, Inc.
Drug Delivery Partnerships (IIR)
Drug Development & Delivery
DURECT Corp./LACTEL® Absorbable Polymers*
EMD Millipore
Erbo Spraytec AG
Evonik Corporation, U.S.A.
Fluid Imaging Technologies, Inc.
Formex LLC
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Medimetrics Personalized Drug Delivery B.V.
Nanocopoeia, Inc.
NanoImaging Services, Inc.
Nisso America Inc.
NOF Corporation
Northern Lipids Incorporated, Inc.
Novozymes Biopharma
OctoPlus, a subsidiary of Dr. Reddy's Laboratories Ltd.*
ONdrugDelivery Magazine
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Patheon Pharmaceuticals Inc.
Pharmaceutical Technology
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Polymun Scientific Immunbiologische Forschung GmbH
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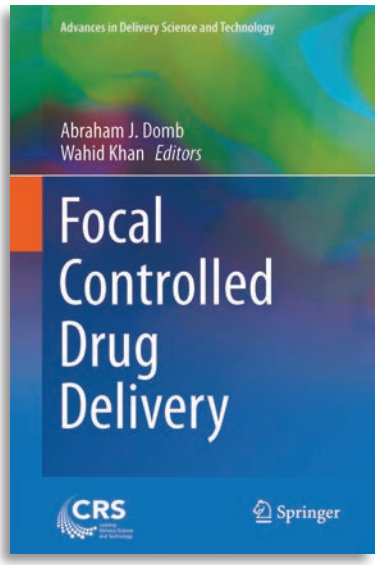
NEW TITLE

Focal Controlled Drug Delivery

Edited by A.J. Domb, School of Pharmacy-Faculty of Medicine, Jerusalem, Israel; W. Khan, School of Pharmacy-Faculty of Medicine, Jerusalem, Israel



- Includes fundamental introductory chapters for focal drug delivery
- Describes drug delivery to body sites/system
- Provides an authoritative account of the essential pharmaceutical, technological, physiological, and biological sciences

The concept of focal drug delivery has been applied for treating illnesses that are localized to a certain tissue or organ. These delivery systems are applied directly to the diseased site and deliver a desired dose for an extended time period while minimizing systemic distribution of toxic drug. Despite the upsurge of interest in focal targeted drug delivery, there is currently no single reference text on this subject. Thus, the aim of *Focal Controlled Drug Delivery* is to bring together leading experts and researchers in this field to provide an authoritative account of the essential pharmaceutical, technological, physiological, and biological sciences underpinning the topic. This book contains two sections. The first includes fundamental introductory chapters for focal drug delivery, whereas the second section includes chapters describing drug delivery to body sites/system. The book allows clinical, pharmaceutical, and biological scientists to offer their own perspectives on the subject, making it of potential interest to a wider audience than just drug delivery scientists.

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Understanding the Transition of Laboratory Science to Commercial Biotech Companies with Dr. Frank Szoka, Professor at UCSF

Vishwas Rai[1] and Bozena B. Michniak-Kohn[2]

Dr. Francis (Frank) Szoka is a professor in the Department of Bioengineering and Therapeutic Sciences and the Department of Pharmaceutical Chemistry at the University of California, San Francisco (UCSF), U.S.A. Frank is a well-recognized figure in the field of liposomal drug delivery. During the course of his career, he has been both an academician and an entrepreneur.

He obtained his A.B. in liberal arts from John Hopkins University in Baltimore. Then he served as a captain in the U.S. Army and director of clinical chemistry at Walson Army Hospital for two years (1969–1971). During this time, he also earned an M.S. degree in microbiology from University of Maryland, College Park (1971). He obtained his Ph.D. in biochemistry from SUNY Buffalo in 1976. He then joined the lab of Dr. Demitri Papahadjopoulos at Roswell Park Memorial Institute in Buffalo, NY, as a National Institutes of Health postdoctoral fellow for two years. He moved to Roswell Park Cancer Institute as a research scientist for a year (1978–1979) before joining academia. He took the position of assistant professor of physiology at Tufts Medical School and later moved to UCSF, joining the Departments of Pharmacy and Pharmaceutical Chemistry as an assistant professor in 1980. In 1991, he became a full professor.

During the 1980s, Dr. Szoka was at the forefront of commercializing the delivery of drug molecules using lipid vesicle technology. He was a cofounder of Liposome Technology Inc. (LTI), where he and his colleagues found a way to scale up liposomal manufacturing operations. In a short span of 5–6 years, LTI went public and introduced a successful FDA-approved liposomal amphotericin antifungal product, Amphotec®, which was based upon research from Dr. Szoka's group. LTI also developed a doxorubicin liposome that is now known as Doxil® in the United States and Caelyx® in Europe. The company changed its name to Sequus Pharmaceuticals and obtained FDA approval for Doxil for the treatment of cancer. The company was acquired by Alza, which in turn was acquired by Johnson & Johnson. In early 1994, Dr. Szoka cofounded GeneMedicine, Inc. (Houston, TX), and he took a leave from the university to serve as the chief scientific officer for nine months. GeneMedicine went public in 1994, and the company was later acquired and incorporated into a new company, Valentis. He recently cofounded ZoneOne Pharma, Inc., which is housed at start-up space in the QB3 building at UCSF. ZoneOne is developing chelation therapies to treat iron overload resulting from thalassemia, a blood disorder caused by a mutated form of hemoglobin.

For more details, please visit the Szoka laboratory website at http://bts.ucsf.edu/szoka/index.html.

Q *Site-specific delivery of gene therapy products is challenging. What are some of the challenges you have come across for delivering gene therapies? How did you solve some of these important issues?*

A We have always focused on nonviral DNA-based gene delivery. Biological barriers to success in this field are better understood, but the technology for efficient DNA delivery has not reached the level required for a successful therapeutic product. The barriers have been amply described in many reviews, for instance, in a recent one from our group: Nguyen, J, Szoka, FC. Nucleic acid delivery: The missing pieces of the puzzle? Acc. Chem. Res. 45: 1153-1162 (2012).

Our group has not solved the problems. What we have done is to better characterize certain polymer- and lipid-based DNA delivery systems and identified critical biological intracellular barriers, such as DNA escape from endosomes and entry into the nucleus. We also provided testable mechanistic hypotheses for how these systems deliver the DNA cargo. High-efficiency transfer of DNA into the cytoplasm and its entry into the nucleus of nondividing cells remain two critical barriers that nonviral DNA delivery systems need to become much better at before we will have robust DNA delivery success.

Q *Looking at the business aspects, what is the estimated market size for thalassemia therapies?*

A The combined chelation market in the United States and Europe is about US$1.2 billion. In the United States, the market is $800M and consists of approximately 20,000 patients, most of whom suffer from sickle cell anemia. The thalassemia patients in the United States number between 1,000 and 2,000. This disorder currently requires chronic therapy with the administration of about 60–75 g of a chelator per month. My cofounders Mark Hope, Charles Noble, Peter Working, and I hope to greatly reduce the

1 Chrono Therapeutics Inc., Waltham, MA, U.S.A.
2 Ernest Mario School of Pharmacy, Rutgers–The State University of New Jersey, U.S.A.

amount of chelator needed and substantially improve the removal of iron from the liver, bone marrow, and spleen by using a drug carrier to increase delivery of the chelator into the reticuloendothelial system.

Q *Because the product is also intended for the Asian and African subcontinent, could you find investors for such products in the United States or is the investment coming from abroad?*

A You are absolutely correct that the patient population is largest across the "Malaria Belt" that stretches from Italy to Indonesia and includes approximately 400,000 patients in southern China. The estimate is that there are about 900,000 annual births per year with some form of thalassemia. The total patient population, the chronic nature of the disease, and the dollar amount currently spent in the United States and Europe has fueled intense interest in early stage companies such as FerroKin (acquired by Shire in early 2013 for about $325 million) and Sideris (series A funding of $32 million in late 2013). These investments have raised the attention of investors in this treatment space.

Q *Any advice for young entrepreneurs trying to raise capital for small biotech companies in the United States?*

A This is a difficult question for me to answer. The quality of the idea and the reputation of the founders are important; probably more important than anything is the mental state of the investors. The investment space was quiescent in 2011, 2012, and early 2013, but by the end of the 2013 successful IPOs of biotech companies made investors more optimistic about having an exit from their investments. So it is not enough to be clever, thorough, hardworking, and persistent—you have to be lucky.

One ring to rule the research: Frank Szoka with members of his lab.

Q *As an academician, what are some of the lessons you learned trying to get into the world of business? What is your advice to young professionals and graduate students in pharmaceutical science and related fields in this regard?*

A The people are the most important part of the venture. You have to like and respect your cofounders, investors, and those with whom you do business. The science part of the business is the minority part. Implementing a new idea requires good organization, outstanding quality control, and careful management of the company's resources. Without the right people, it is hard to pull it all together.

Q *What are some of the ideal characteristics for small chemicals/biomolecules (gene products) for successful liposomal drug delivery?*

A This is a lecture in itself. In short: potency, selectivity, and stability of the molecule are key determinants of success.

Q *In addition to liposomal delivery of chemicals and biomolecules, what are some of the other current research projects in your lab?*

A We've spent the last 14 years in a productive collaboration with the Jean Fréchet group formerly at the University of California, Berkeley, campus investigating factors that impact the therapeutic activity of polymer drugs. We are currently exploring cell-based approaches to cancer and gene therapy.

Q *Please highlight some journal articles that you have published that you feel have had a high impact in science in the last 10–15 years.*

A These articles received good attention from the research community or explored interesting underexplored aspects of the carriers our group has investigated.

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Q *You started working with siRNA delivery almost a decade ago. How has your understanding of siRNA-targeted delivery changed over the past few years? Do you feel we will have commercial successes in this area soon?*

A The entry of biotech and big pharma changed the landscape of this field from a cottage research based industry to big science approach. Modified siRNA are incredibly potent, and companies working in this space have discovered very efficient carriers. The carriers are well tolerated at therapeutic doses in patients. I think siRNA products will reach the market in the next five years.

Q *From your past experience, are there any areas in the pharmaceutical sciences that have significant business potential but have not been followed up on as yet?*

A The effective use of drug transporters is an underutilized mechanism for improving drug uptake and distribution. There are startups in this space. The success of Captisol® as a carrier for poorly soluble drugs is notable and identifies an area where the pharmaceutical sciences could bring improvements to the delivery of new drugs. Improved oral delivery mechanisms, pathways, and systems are also areas that require a better understanding of how drug transporters function in animals and humans as well as how drug carriers might interface with transporters. Success here could make oral formulations an effective route for the delivery of peptides and peptide-like drugs, such as exenatide.

Q *Other than your own, are you familiar with any biotech startups that you feel may have the potential of becoming successful soon?*

A I don't pay too much attention beyond my own doorstep, but more to the point, I am not a good handicapper of horses or startups.

Q *What is your advice to academic professionals who intend to enter the world of business?*

A Understand the science you bring to the table, find partners who understand the business equation of drug development and with whom you enjoy working, and don't fall too deeply in love with your own ideas. Many startups refocus after they learn their lead compound will not make it to the market, so you have to be able to identify new opportunities for your team.

Q *With such a busy career, do you have time to enjoy any hobbies? Any favorite travel destinations?*

A If you love what you do, it doesn't seem busy. I enjoy traveling, especially to Hawaii: the people are friendly, the climate is ideal, and the sound of the ocean is relaxing.

Q *Would you like to share any information about your family and how they have helped in your career?*

A My wife, Paula, is a Ph.D. geneticist who cloned a bovine growth hormone and then moved into the business side of science. Her passion is music. Paula's support through the years enabled me to enjoy research, as well as to try to translate research findings into medicines. My daughter, Nova, is now ending her surgery residency program and is finally starting to understand why her dad was having so much fun all these years.

The scientists who mentored me, such as Demitri Papahadjopoulos, provided role models of how to do science. I have tried to pass these lessons on. In a broader sense, the students, fellows, and technicians who have worked in our group, graduate students who I have advised over the decades, or colleagues who I have collaborated and competed with are an extended family. I have many fond memories of watching them solve problems, raise new questions, lead the way up hills, and launch successful careers. ■

DDTR Special Issue: Proceedings of the Drug Delivery Australia Symposium

Vinod Labhasetwar, Editor-in-Chief

The upcoming *Drug Delivery and Translational Research* special issue is based on the presentations at the 2012 Drug Delivery Australia conference, which is the major annual meeting of the CRS Australian Local Chapter, and provides an important forum for the interaction between "geographically challenged" Australian scientists in the drug delivery field. It has grown significantly since its inception in 2007 and now attracts over 150 delegates, many from abroad, and has held its new position as the premier independent drug delivery conference in the Australasian region for several years. The 2012 meeting was of particular significance, with many international visitors to Melbourne for the conference, including Val Stella (University of Kansas, U.S.A.) and Peter Swaan (University of Maryland, U.S.A.) as invited international lecturers. The special issue arising from the 2012 meeting is thus an important milestone for the conference and the community, and it offers a great opportunity to showcase some of the outstanding research and contributors on the Australian drug delivery scene.

About the Guest Editors

Ben Boyd

Ben Boyd is a colloid and physical chemist with a Ph.D. from the University of Melbourne, Australia. After industry experience in the explosives and pharmaceutical industries, he commenced an academic position at Monash Institute of Pharmaceutical Sciences (MIPS) and is currently group coordinator for drug delivery sciences at MIPS. His group is focused on colloidal and structural aspects of lipids, lipid self-assembly and pharmaceutical systems, and controlling materials at the colloidal scale for delivery in pharma and other fields. His group is also active in developing new synchrotron-based characterization approaches for lipid and solid-state systems. He is president of the CRS Australian Local Chapter and chair of the CRS Board of Scientific Advisors. He serves on several editorial boards, including *Journal of Pharmaceutical Sciences* and *Journal of Colloid and Interface Science*. He is currently on an Australian Research Council (ARC) Future Fellowship for the discovery of light-activated drug delivery systems.

Paul Young

Paul M. Young is head of respiratory technology at the Woolcock Institute of Medical Research, associate professor at the Sydney Medical School (University of Sydney), and an ARC Future Fellow. He has made a significant contribution in the field of advanced drug delivery and inhalation science. Paul has published over 120 peer-reviewed international journal articles (more than 1,900 citations), 5 patents, 13 book chapters, and in excess of 100 conference proceedings. In addition, Paul has given invited conference seminars on multiple occasions and has been on the organizing committees for international science conferences. Paul has been appointed onto the ARC College, the external Therapeutic Goods Administration medical advisory committee, and the editorial boards of a range of journals, including *Pharmaceutical Research*, *Journal of Pharmacy and Pharmacology*, *Drug Development and Industrial Pharmacy*, *Inhalation* magazine, and *Respiratory Drug Delivery*. Paul collaborates with both academia and industry on an international level and has attracted around AUD 10 million in funding within the area of inhalation medicine.

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Formulating Amorphous Drug Delivery System Using Low-Molecular-Weight Components as Stabilizers

Korbinian Löbmann,[1] Riikka Laitinen,[2] Holger Grohganz,[1] and Thomas Rades[1]

One of the most challenging problems pharmaceutical formulation scientists face today is finding a proper formulation strategy for the increasing number of poorly water soluble drugs in the pipelines of the pharmaceutical industry. Several different strategies are available to address this problem, with nanosizing, lipid-based drug delivery systems, and amorphous formulations being probably the most studied ones. Each of these approaches has its benefits and drawbacks.

Amorphous formulations in particular proved to be a promising approach for so-called brick dust molecules, that is, drugs with poor solubility in both lipophilic and hydrophilic solvents. However, the thermodynamically unfavorable high energy state of the amorphous form, which is the reason for the higher dissolution rate and solubility compared with their crystalline counterparts, is also the reason for its poor physical stability, leading to a relatively fast transformation back into the thermodynamically stable but poorly soluble crystalline state. Therefore, amorphous multicomponent systems were introduced to stabilize the drug in its amorphous form. Within these systems the formation of solid dispersion using polymeric excipients and the use of mesoporous silica have proven to be promising approaches.

One main disadvantage of these systems is the often low drug-loading capacity, that is, large amounts of excipients are sometimes required to ensure a (practically) stable amorphous system. To deal with these shortcomings, co-amorphous drug delivery systems, were recently introduced using low-molecular-weight partner molecules that can stabilize the amorphous form of the drug through strong intermolecular interactions, usually at a similar weight ratio (Figure 1), thus keeping the amount of amorphous stabilizer relatively low.[1]

The term "co-amorphous" in this context can be defined as homogenous amorphous multicomponent systems comprising only low-molecular-weight components, to separate them from the terms "solid dispersion" and "glass solution," which are strongly connected to the use of polymers as amorphous stabilizers. However, the existence of binary amorphous blends containing only low-molecular-weight excipients such as urea, citric acid, sugars, and nicotinamide has been reported in literature previously.[2–4]

Two different types of co-amorphous formulations have been described in literature, namely, drug–drug mixtures intended for use in combination therapy and drug–excipient mixtures intended for single drug administration. In the former approach, two drug molecules whose combination is pharmacologically useful were chosen for the preparation of co-amorphous drug–drug mixtures.[5–7]

Several case studies have shown that these systems result in physically more stable systems with an increased dissolution rate of the drugs compared with the individual crystalline or amorphous drugs. It was shown that intermolecular interactions between the components in the co-amorphous systems are the reason for the improved characteristics, and usually they are most pronounced at a molar ratio of 1:1. In a particular study using the two nonsteroidal anti-inflammatory drugs indomethacin and naproxen, it was shown that both molecules form a heterodimer in the co-amorphous formulation, leading to not only an increased *in vitro* drug release but also a synchronized release, suggesting that the molecular interactions are responsible for a pairwise dissolution.[8] Furthermore, such an interaction pattern suggested an intrinsic resistance against recrystallization (Figure 2). For the two drugs to recrystallize, the interactions between the molecules in the heterodimer need to be broken before the molecules can rearrange into homodimers, which are the basis for nuclei formation and thus recrystallization.[9]

It could be argued that co-amorphous drug–drug mixtures are a particularly promising approach, because both drugs act as

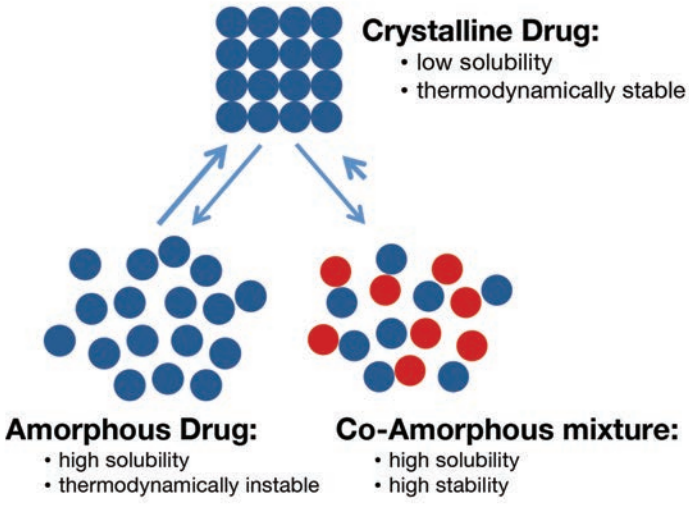

Figure 1. *Schematic depiction of the thermodynamically stable ordered crystalline state, the thermodynamically instable disordered amorphous form of a drug with a high tendency to recrystallize, and a co-amorphous system of the drug with another low-molecular-weight molecule stabilized through strong intermolecular interactions and, thus, lower tendency to recrystallize.*

[1] Department of Pharmacy, University of Copenhagen, Denmark.
[2] School of Pharmacy, University of Eastern Finland.

amorphous stabilizers for each other, thus excluding the use of any excipient at all. The drawback of this approach, however, is that the two active components need to form a pharmacologically useful pair and need to be present in similar doses.

To extend the concept of co-amorphous drug formulations, amino acids were introduced as low-molecular-weight excipients in these formulations.[10] Because of the relatively low molecular weight of amino acids compared with those of the drugs, the weight ratio of drug to amino acid is usually in favor of the drug when using 1:1 molar ratios. This can be seen as a particular advantage of these systems compared with other amorphous stabilization approaches that usually have large amounts of excipients present in the formulations.

In a recent study, the drugs carbamazepine and indomethacin were combined with the amino acids arginine, phenylalanine, and tryptophan. The co-amorphous systems in general had very high glass transition temperatures compared with the pure amorphous drugs and showed a high degree of molecular interactions.[10,11] Both factors could be related to the high increase in physical stability from below seven days for the pure amorphous drugs to at least one year at 40°C under dry conditions when prepared as co-amorphous drug–amino acid mixtures.[12] In addition, the dissolution rate was increased significantly compared with the pure amorphous drugs.

Overall, the use of low-molecular-components is a promising new way to stabilize the amorphous form of a drug and overcome limitations connected to the existing technologies. In co-amorphous multidrug systems, the drugs in the mixture act as stabilizing excipients for each other, whereas the use of low-molecular-weight amino acids presents an attractive option for preparing single drug–excipient systems. In both cases, the co-amorphous formulations showed increasing dissolution properties as well as physical stability properties. This improvement could mainly be attributed to strong intermolecular interactions between the components in the mixture. Future studies now have to show if this new approach can realize its potential as a competitive technique to already-established amorphous stabilization approaches.

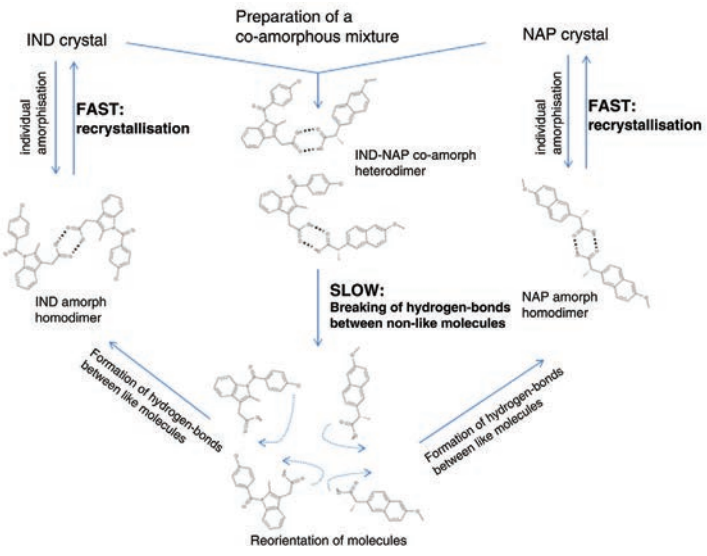

Figure 2. *Schematic mechanism of the fast recrystallization of the pure amorphous drugs indomethacin (left) and naproxen (right), and the slow recrystallization path of the co-amorphous indomethacin naproxen mixture (middle).*

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Application of Büchi Microencapsulation Technology: An Example of an Industrial Scalable Process

Rossella Dorati, Ida Genta, Tiziana Modena, and Bice Conti
Department of Drug Sciences, University of Pavia, Italy

Introduction

Microencapsulation is widely employed in areas such as agriculture, cosmetics, and pharmaceutics. In the last field it has been exploited for different purposes such as taste masking, protection of labile drugs, and control of drug release. Moreover, it is an important tool for improving the efficacy and safety of protein drugs of biotech origin, and one of the most recent and attractive applications is cell microencapsulation for advanced cell therapies and regenerative medicine.[1,2] High-efficiency vibration nozzle microencapsulation (HEVM) technology commercialized by Büchi (Flawil, Switzerland) in the Encapsulator B-395 seems to be versatile and promising for achieving good process reproducibility and yields of production. It is based on the principle that a laminar liquid jet breaks up into equally sized droplets by a superimposed vibration. Thus, the selected vibration frequency determines the amount of droplets produced; for example, a vibration frequency of 7,000 Hz generates 7,000 droplets per second. The parameters involved in the HEVM technique used are nozzle size, jet flow rate, vibration frequency, and electrode tension.

Several publications investigating atomization processes[3–5] can be found in the literature, and some of them[2–10] refer the applicative potentialities of HEVM technology. All the papers highlight the advantages of the technique to solve, in an effective and valid way, the obstacles and difficulties in the design and optimization of microencapsulation processes by developing protocols that are easy to scale for the microencapsulation of drugs and biologic material (e.g., cells and probiotics).

The goal of the present work was to evaluate the performance of the Büchi Encapsulator B-395 in the microencapsulation of a hydrophilic model molecule in a hydrophilic polymer.

Table 1. Tested process parameters.

Parameter	Setting
Type of system	Automatic
Polymer solution concentrations (w/v %)	0.5–2
Type of dispersed phase	Aqueous
Type of dispersing phase	Aqueous
Alginate solution volumes (mL)	10–60
Polymer solution/gelifying solution ratio	~1:10
Polymer/fluorescein w/w ratio	10:1
Additional solvents	–
Vibration frequency (Hz)	1,600–1,900
Electrode tension (V)	1,100–1,900
Process curing time (h)	2

Table 2. Vibration frequencies (Hz) and electrode voltages tested.

Batch	Vibration Frequency (Hz)	Electrode Tension (V)
1	1,900	1,100
2	1,900	1,600
3	2,500	1,900
4	2,500	1,900
5	2,500	1,900
6	1,600	1,700

Experimental Methods

Microparticles made of alginate and loaded with fluorescein, a model hydrophilic molecule, were prepared by HEVM.

A Büchi Encapsulator B-395 equipped with an 80 µm nozzle was used. A variable volume (see Table 1) of aqueous solution of Protanal LF 120M was loaded into the instrument syringe and injected, at a flow rate of 1.21 mL/min, in 500 mL of 1.1% w/v $CaCl_2$ aqueous solution (gelifying solution). Different values of vibration frequencies (Hz) and electrode voltages (V) were tested and set up, as reported in Table 2. Fluorescein was loaded into the polymer solution in a polymer/fluorescein 10:1 w/w ratio. Microparticle curing time was 2 h under continuous magnetic stirring in the gelifying solution at 450 rpm. After this time, the microparticles were filtered through a 40 µm paper filter (VWR International, Fontenay-sous-Bois, France). Microsphere batches were prepared in triplicate for each process condition tested. The microparticles were characterized for their morphology, particle size distribution, yield of production, drug loading, and *in vitro* drug release.

Results and Discussion

The advantages of the HEVM technique are automation, rapidity, and the ability to avoid the use of oil and organic solvents. The limit of this microencapsulation technique was that the concentration of the alginate solution could not be higher

Table 3. Microparticle characteristics.

Batch	Production Yield (%)	d_{50}	Span	Fluorescein Content (mg)	Encapsulation Efficiency (%)
3	93.3	138.10	3.677	6.90	76.6
4	90.1	260.00	4.067	4.50	50.0
5	88.6	254.90	4.410	3.30	36.6
6	100.0	158.00	3.198	5.59	61.6

than 1.2%: higher polymer concentrations correspond to higher viscosity values and require higher liquid jet flow rates that are not suitable to obtain regular and well-formed microparticles. The polymer concentration selected was particularly suitable in the case of cell encapsulation because it allowed obtaining the appropriate cell environment, avoiding stressing conditions. The most suitable alginate and gelifying/dispersing solution volume ratios were 1:14 and 1:20 v/v for the encapsulation of fluorescein to avoid coalescence phenomena during the gelification step.

The results in terms of microsphere yield of production, particle size distribution (d_{50}), fluorescein content, and encapsulation efficiencies are reported in Table 3. Batches 1 and 2 were discarded because microspheres did not form, probably because of the low electrode tension (1,100–1,600 V) and vibration frequency (1,900 Hz) in relation to polymer solution viscosity. Electrode tension at 1,900 V and vibration frequency at 2,500 Hz led to well-formed microspheres. Fluorescein addition to the alginate solution led to a change in polymer solution viscosity; hence, process conditions needed to be set up again. Batches 4 and 5 showed irregular shape resulting in larger size. The suitable process conditions leading to well-formed fluorescein-loaded microspheres were those reported for batches 3 and 6, as confirmed by Figure 1, which shows the light microscope images of the microparticle batches. Thanks to the one-step well-calibrated technique, the yields of production of microspheres were always high (93.3–100%) with narrow particle-size distributions.

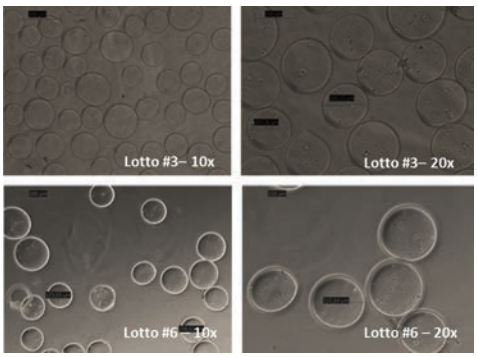

Figure 1. *Light microscope images of the alginate microspheres (batches 3 and 6).*

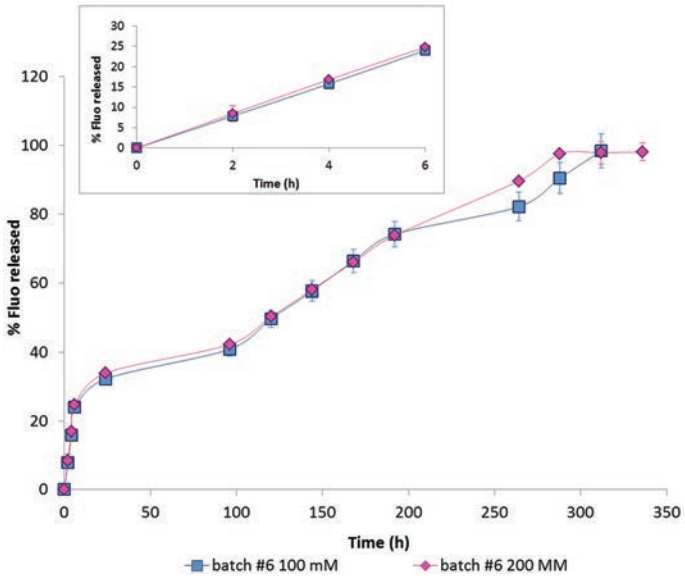

Figure 2. In vitro *release profiles of fluorescein (Fluo) from the alginate microspheres.*

The *in vitro* release test showed triphasic release profiles (Figure 2) with initial burst release in the first 24 h accounting for 34% of fluorescein released, a plateau phase up to 96 h followed by a second phase of fast release up to 200 h and reaching 80% of fluorescein released, and a third phase of fast release between 264 and 336 h that led to release of 100% of the fluorescein.

Conclusions

The HEVM technique applied, with the Büchi Encapsulator B-395 Pro, to the microencapsulation of a hydrophilic molecule in a hydrophilic polymer resulted in several advantages and good potentialities because it permitted 1) working in mild conditions avoiding organic solvents, 2) obtaining reproducible batches in short times, 3) achieving good encapsulation efficiencies, and 4) permitting a one-step single-implant procedure.

Acknowledgements

The authors thank Dr. Simone Giordano and Dr. Michael Whelehan from Büchi Labortechnik AG for technical assistance.

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Introducing the Volunteer Experience

The growth and success of CRS can be ascribed to the enthusiasm, energy, and vision of numerous member volunteers. Because CRS is a member-driven and member-led society, a constant need exists for new volunteers possessing varying skills and interests who are at various career points in academia, industry, or regulatory fields. Ways to get involved within our society include but are not limited to the following:

- joining CRS committees
- planning a workshop
- influencing the content of the annual meeting
- participating in editing a CRS book series

During the past year, a Volunteer Recruitment Committee was established to implement a program for the sustainable recruitment of volunteers for a variety of CRS committees and activities.

To provide an insider's look into the volunteers' "life" within CRS, we are launching a series of short interviews in the *CRS Newsletter*, with the overarching theme of featuring CRS volunteers. Each Volunteer Spotlight article will highlight two volunteers: an experienced one who has been involved in CRS committees and activities for a considerable time (usually more than 5 years) and a "newcomer" in terms of volunteering for the society (one year or less in terms of serving CRS). We anticipate that these interviews will clarify several aspects of volunteering for the society, including benefits to the volunteer and CRS, possibilities, and prerequisites for being assigned to various positions in the society. Our hope is that we will see many new faces among our group of volunteers.

In this Volunteer Spotlight, we are happy to feature **Louise Rosenmayr-Templeton** and **Jinzi Zheng**.

Louise Rosenmayr-Templeton

Louise Rosenmayr-Templeton is a pharmacist with over 15 years' experience in pharmaceutical product development and project management. In 2002 she set up her consultancy business, Tower Pharma Consulting. Based in Vienna, Austria, it provides a variety of scientific and project management services to pharmaceutical and biotech companies in the fields of product development and drug delivery research. Before setting up her consultancy, Louise worked in various capacities for major pharmaceutical companies such as Abbott Laboratories (United Kingdom), the Élan Corporation (Ireland), and Boehringer Ingelheim (Austria). Louise graduated from the University of Strathclyde with first-class honors and obtained her Ph.D. in the field of novel drug delivery from Nottingham University. Many CRS members know Louise from her longstanding leadership and dedication to the Young Scientist Committee and contributions to other CRS activities.

Jinzi Zheng

Jinzi Zheng received her bachelor's degree in applied science and engineering from the University of Toronto and holds a Ph.D. from the department of Medical Biophysics, University of Toronto, Canada. She completed her postdoctoral training at the French Atomic Energy Commission and the French National Institute of Health and Medical Research. She is currently a staff scientific associate at Princess Margaret Cancer Centre in Toronto. Jinzi's research interests are in the area of nanotechnology-based agents for imaging and image-guided interventions. She has been the recipient of over 20 awards and is currently leading the commercialization and clinical translation of a nano agent for image-guided surgery. Jinzi recently joined the Young Scientist Committee and is excited to work together with the rest of the committee members in continuing the existing programs and events, as well as pushing forward new initiatives.

Volunteer Recruitment Committee member Biana Godin interviewed Louise and Jinzi recently.

Q *Louise, how did you get involved in CRS?*

A I had attended annual meetings in the past, but at the Long Beach meeting in 2007 I chaired a session and introduced myself to the CRS Headquarters staff member who had sent me the invitation. We talked about the society, how it was organized, and the role of volunteers. A few months later, I was asked if I was interested in becoming a member of the Education Initiatives Subcommittee, a former subcommittee of the Young Scientist Committee.

Q *Jinzi, what shaped your decision to volunteer for CRS?*

A I have been attending CRS meetings since 2012. I found that the society members were very personable, and the annual meetings created a great environment for the drug delivery community to connect and start very fruitful discussions and collaborations. My great experience with CRS events and members motivated me to join the Young Scientist Committee and to do my little bit to give back to the society.

Q *Louise, tell us about your current and past volunteering experiences and leadership roles within the society.*

A I loved being on the Education Initiatives Subcommittee, whose role was to develop new educational and training initiatives for young scientists. I have always had an interest in the education and training of young people, but I had not actively pursued it for a number of years. The subcommittee later merged with the Young Scientist Committee, and I was asked to be cochair. I had this position until 2012. The Young

Scientist Committee is responsible for organizing the Young Scientist events at the annual meeting plus other initiatives such as the Mentor/Protégé Program. It is a very lively committee, full of ideas and composed of a mixture of experienced and early career scientists. I am currently deputy chair of the Volunteer Recruitment Committee. CRS is committed to offering more opportunities for its members to participate actively in the society. Volunteers are critical for CRS, and without them the society would not exist. The goals of the Volunteer Recruitment Committee are to improve the way that the society recruits volunteers, matches their skills and experience to the needs of individual committees, and trains new committee members and those taking up leadership positions within the society.

Q *Jinzi, what do you enjoy the most so far about volunteering for CRS?*

A I really enjoy my interactions with the members of the Young Scientist Committee, particularly when it comes to brainstorming new ideas and topics for the Young Scientist events at the upcoming annual meeting. It is great that CRS gives young scientists such a great opportunity to contribute and carry out our ideas and interests. The monthly conference calls are also a great way to learn more and interact with members from all around the world.

Q *Louise, what in your opinion are the main benefits and rewards in volunteering for the society?*

A First, you get an inside view of the challenges of running a global organization such as CRS and have the chance to influence its future. For example, I have taken part in CRS leadership forums that dealt with topics such as improvements in the volunteer recruitment and placement system. This subject is one I feel strongly about, and it may be for this reason that I was asked to be deputy chair of the Volunteer Recruitment Committee last year. Second, you work in teams of colleagues, many of whom you would not otherwise meet, and the camaraderie built up through this teamwork makes for a stronger network of contacts than just attending meetings or workshops. Third, you have a chance to develop new skills or develop specific interests. For example, working on the Young Scientist Committee allowed me to satisfy my long-held but until then latent interest in education and training. Last but not least, volunteering is fun and is a chance to give back.

Q *Jinzi, what kind of rewards do you need to stay motivated?*

A The most rewarding aspect so far with respect to my participation at CRS is the opportunity to co-organize this year's Sunday roundtable on image-guided drug delivery with Patrick Lim Soo. I found that all of the speakers and the CRS staff were more than supportive in our initiative and found the entire experience very rewarding so far. We hope that the roundtable will attract a good attendance and that stimulating discussions will take place.

Q *Louise, what skills or qualities are required for your volunteering role?*

A In my present role, I need to have previous experience as a volunteer, because I require knowledge of the current systems in place for volunteer recruitment, the CRS Board's expectations for change, and an idea of what is likely to work and what is not. I also require the ability to lead and motivate teams of volunteers. Volunteering takes up time and involves work in the evenings and on weekends. It has to be an enjoyable experience for everyone. Good listening skills are also vital. Almost all of our meetings take place via teleconference, so I can't pick up on body language.

Q *Jinzi, how do you expect volunteering for CRS to contribute to your overall personal and career development?*

A I hope to continue supporting CRS, and I am sure that the interactions and opportunities generated from this will positively impact my personal and professional development.

Q *Finally, Louise, what advice would you give to someone who is considering volunteering for CRS?*

A First, I would look in detail at the website and at the volunteer opportunities available. Then, if you are attending the annual meeting or belong to a local chapter, I would talk to people who are already volunteers about what is involved. If you apply, depending on the timing of your application, there may be no open positions available, but don't give up, because open positions arise every year (typically in May), and your details are held in a database. With the Volunteer Recruitment Committee now established, the recruitment and committee appointment process is becoming more organized and centralized, so you can contact Megan Pagel from CRS Headquarters with questions or requests for further information on volunteering. Her email is mpagel@scisoc.org.

There are numerous ways to shape the present and future of CRS and contribute to your personal growth through volunteering. Your involvement with CRS will help to advance the field of delivery science and technology as well as enable you to build a substantial network of professional contacts and friends. We encourage you to get involved! ■

Volunteer Recruitment Committee Members

Chair: Arlene McDowell, University of Otago, New Zealand
Deputy Chair: Louise Rosenmayr-Templeton, Tower Pharma Consulting, Austria
David Chen, Pfizer, U.S.A.
Prajakta Dandekar-Jain, Institute of Chemical Technology, India
Biana Godin Vilentchouk, Houston Methodist Research Institute, U.S.A.
Hideyoshi Harashima, Hokkaido University, Japan
Board Liaison: Maria Jose Alonso, University of Santiago de Compostela, Spain

Articles and Websites of Interest in Animal Models of Diseases, Cross-Species Comparisons, and "One Health"

Compiled and Edited by David Brayden[1] and Terry Bowersock[2]

It is not often that companion animal research gets air time in major journals, but a very interesting paper on gene therapy for lysosomal storage diseases using a feline model appeared in *Science Translational Medicine*.[1] It is important because of potential interesting comparisons of disease types with the human conditions. Feline GM1 gangliosidosis is a progressive lysosomal storage disease caused by deficiency of lysosomal β-galactosidase and is caused by a neurological deficit. A similar condition occurs in children; there is no effective treatment, and the majority tend to die very young. In the study, an adeno-associated viral vector (AAV) carrying the therapeutic gene for wild-type lysosomal β-galactosidase was injected bilaterally into the thalamus and deep cerebellar nuclei of a cat with GM1 gangliosidosis. The abstract stated that "the procedure normalized β-galactosidase activity and storage throughout the brain and spinal cord. The mean survival of 12 treated GM1 animals was >38 months, compared with 8 months for untreated animals. Seven of the eight treated animals remaining alive demonstrated normalization of disease, with abrogation of many symptoms including gait deficits and postural imbalance." The authors went on to conclude that correction of the phenotype was therefore sustained after gene therapy in a companion animal model and suggest that using AAV as a vector for the gene may have potential for treating GM1 gangliosidosis in children. To put this in context, the first AAV gene therapy (Glybera®) was approved by the European Medicines Agency in 2012 for another orphan disease.

Nature Biotechnology recently provided a fascinating insight into the rationale for the increasing interest in startup companies working in canine and feline animal health. In an article by Gunjan Sinha, the adventures of Aratana Therapeutics (U.S.A.) and Kindred Biosciences (U.S.A.) were especially highlighted.[2] These companies are focusing on the pet market and are leveraging human drugs that have reached clinical trials into animal health as reformulations. The business model is that these drugs have already been tested in animals and that the subsequent companion animal trials are cheaper and quicker than human clinical progression. Examples of drug classes and disease areas being focused on in pets by Aratana included alternatives to NSAIDS for chronic arthritis, ghrelin-mimetics to stimulate appetite, nonopioid anesthetics for postoperative pain, and animal-specific antibodies for cancers leveraged from human medicine. Academics suggest to their vet students that they will not see many biologics coming onto the companion animal market, because they are so expensive and the market is so small, but the counterargument is that the regulatory pathway for biologics seems to have lower hurdles at the U.S. Department of Agriculture. Perhaps a trend was set by approval of a canine melanoma vaccine in 2010? So the key question on the biologics argument is whether owners will pay for expensive medication for pets in a recession. Kindred Biosciences, on the other hand, focuses on reformulating human small-molecule generics in palatable chewable formulations for pets, so their niche is in delivery and ensuring appropriate pharmacokinetics in the target species. A figure of $10 million was quoted as being adequate to get a new chemical entity onto the pet market in a time of about six years, compared with $1–2 billion and 10 years for the human equivalent. Many other startups were mentioned in the United States and European Union, so apologies to any we have omitted to mention.

Animal models for predicting vaccine responses in humans to microneedle vaccines are a source of debate, because mouse stratum corneum composition and permeation properties are not the same as those in humans. In the December 2013 issue of *Nature Biotechnology*, DeMuth *et al.* used rhesus macaques as a large animal model to test a solid microneedle system based on a poly(L-lactide) construct for transcutaneous penetration and generation of an immune response against luciferase-coding adenovirus (Ad5), which was coated on the surface.[3] Following two doses 12 weeks apart, significant cellular and humoral immunity was achieved, and the data were on a par with intramuscular immunization of adenovirus. Importantly, assessment of skin luminescence revealed that the microneedles deposited formulation in the same areas as an intradermal injection, close to Langerhans cells and the draining lymph nodes in the dermis. The authors see potential for the system in mass vaccination for the developing world because of the ease of application, capacity for multiple vaccines, and possibility of addressing cold chain issues. The rhesus macaque model also has particular relevance as an animal model used in HIV vaccine studies.

Obsessive compulsive disorder (OCD) in dogs was the subject of a recent article in this *CRS Newsletter* slot. OCD in dogs can manifest as repetitive biting, tail chasing and chewing, and

1 University College Dublin, Ireland.
2 Zoetis, LLC, U.S.A.

behaviors associated with separation anxiety. The genomes of Dobermans were recently studied by Tang *et al.*, and up to four genes emerged as being associated with the canine version of the disorder.[4,5] The authors examined 90 genomes of Dobermans suffering from canine OCD with those of 60 healthy Dobermans, and key differences emerged at the genome level. They then analyzed genomes of other canine breeds with high OCD rates and came up with four genes in common across breeds that had high rates of mutations in animals expressing OCD behaviors. These may turn out to have some relationship to genes aberrantly expressed on the human genome. This study is important because tracking down genes associated with psychiatric disease has proved a challenge even when a genetic component is well established via twin studies of early-onset OCD. The authors proposed that if the genes identified in OCD dogs can be associated with similar genes involved in human OCD (but not yet discovered), then dogs may serve as a good model for the human disorder, a highly prevalent condition estimated as occurring in 1–3% of the population that is only partially alleviated in a cohort of patients by serotonin-selective uptake inhibitors and cognitive behavioral therapy. Studies of this type can lead to discovery of neurological pathways and may lead to more specific druggable targets for OCD. This is yet another example in which spontaneously occurring diseases in small animals (e.g., some cancers) appear to model the human condition better than rodents.

Abby Olena in the February 2014 edition of *The Scientist* described how researchers from Eötvös Loránd University in Budapest and the Hungarian Academy of Sciences studied both humans and dogs to compare areas of the brain that respond to sounds by using functional magnetic resonance imaging (fMRI).[6,7] There is a lack of data on comparing anatomy and auditory processing between dogs and humans. Olena described how Andics *et al.* used both positive reinforcement techniques and social learning to train collies and golden retrievers stay still for up to 8 minutes in an fMRI scanner. The 11 dogs and 22 humans were scanned as they listened to nearly 300 sounds (dog vocalizations, nonverbal human vocalizations, and nonvocal sounds) and silent controls. Andics *et al.* identified the sound-sensitive areas in human and canine cortices and in subcortical regions. In both dogs and people, vocal-processing areas were located in similar places. In humans, the majority (87%) of auditory regions were most responsive to human vocalizations, whereas in dogs, the sound-sensitive brain areas were most responsive to either dog vocalizations (39%) or nonvocal sounds (48%). The researchers also found evidence suggesting that "sounds associated with positive or negative vocal emotions are processed similarly in human and canine brains." One of the most interesting aspects is how they overcame the issue of restraining a dog in such a scanner through training, which has obvious potential for examining a range of brain disorders across species.

Returning to the theme of large animal models for important diseases, a new paper from Dean *et al.* reaffirmed the relevance of the knock-out pig model of human cystic fibrosis (CF).[8] Transgenic murine models have lack of expression of the cystic fibrosis transmembrane regulator (CFTR), but they do not express the CF-like pathological aspects of lung and nasal disease. The transgenic CF pig does have lung and sinus problems similar to humans with CF, and this study highlighted the creation of wild-type CFTR +/+ and homozygous CFTR –/– porcine nasal epithelial primary cultures from either the septum or turbinates on filters using air-interface feeding, following by mounting in Ussing chambers. They found that cAMP-stimulated chloride transport across septum cells was greater than that of turbinates in wild-type cells. However, this transport system was absent in the CFTR –/– cells compared with wild-type cells. The authors conclude that this is a good *in vitro* model derived from a relevant transgenic animal for studying ion transport aspects of CF-induced sinus disease.

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Formation of the CRS Malaysia Local Chapter (MyCRS)

Mohd Cairul Iqbal Mohd Amin, Universiti Kebangsaan Malaysia

The recent establishment of the CRS Malaysia Local Chapter (MyCRS), approved by the CRS Board on March 19, 2014, marked an important milestone in the history of controlled release and drug delivery in Malaysia. MyCRS will serve as a platform for sharing ideas and technical expertise with those interested in this area of research. To successfully achieve this ultimate goal, a series of lectures, discussion groups, and conferences will be organized at regular intervals.

The idea of establishing MyCRS was suggested by none other than CRS president Ian Tucker during his appointment as an adjunct professor in the Faculty of Pharmacy, Universiti Kebangsaan Malaysia (UKM), in October 2013. His suggestion was warmly accepted by the faculty members, and a series of discussions took place to ensure that the formation of MyCRS benefits every member in the society.

CRS president Ian Tucker congratulates the president of the MyCRS pro-tem committee, Mohd Cairul Iqbal Mohd Amin.

The first meeting regarding the formation of MyCRS was held on January 8, 2014, at the Faculty of Pharmacy, UKM, Kuala Lumpur. The meeting was well attended and was supported by people with various backgrounds and expertise.

A short meeting between CRS president Ian Tucker and the MyCRS pro-tem committee members at the Faculty of Pharmacy, UKM.

At this historic meeting, the following pro-tem committee members were appointed: president, Mohd Cairul Iqbal Mohd Amin (Faculty of Pharmacy, UKM); vice president, Allan Coombes (School of Pharmacy, International Medical University); secretary, Tuan Mazlelaa Tuan Mahmood (Faculty of Pharmacy, UKM); treasurer, Ng Shiow Fern (Faculty of Pharmacy, UKM); and postgraduate representative, Haliza Katas (Faculty of Pharmacy, UKM). The following people will serve on the nonexecutive council: Mohd Hanif Zulfakar (Faculty of Pharmacy, UKM), Wong Tin Wui (Faculty of Pharmacy, Universiti Teknologi MARA), Ahmad Fuad Shamsuddin (Faculty of Pharmacy, UKM), Farahidah Mohamed (Kulliyyah of Pharmacy, International Islamic University of Malaysia), Peh Kok Khiang (School of Pharmaceutical Sciences, Universiti Sains Malaysia), Kartini Noorsal (SIRIM Berhad), Ida Idayu Muhamad (Bioprocess Engineering Department, Faculty of Chemical Engineering, Universiti Teknologi Malaysia), and Azmy A. Hamid (Xorix Sdn Bhd, Xorix Business Centre).

The MyCRS website is under construction and will be available soon. Anyone interested in joining MyCRS should contact CRS program manager Megan Pagel (mpagel@scisoc.org) for further information. ■

CRS Taiwan Local Chapter

Tsuimin Tsai, Managing Director and Secretary

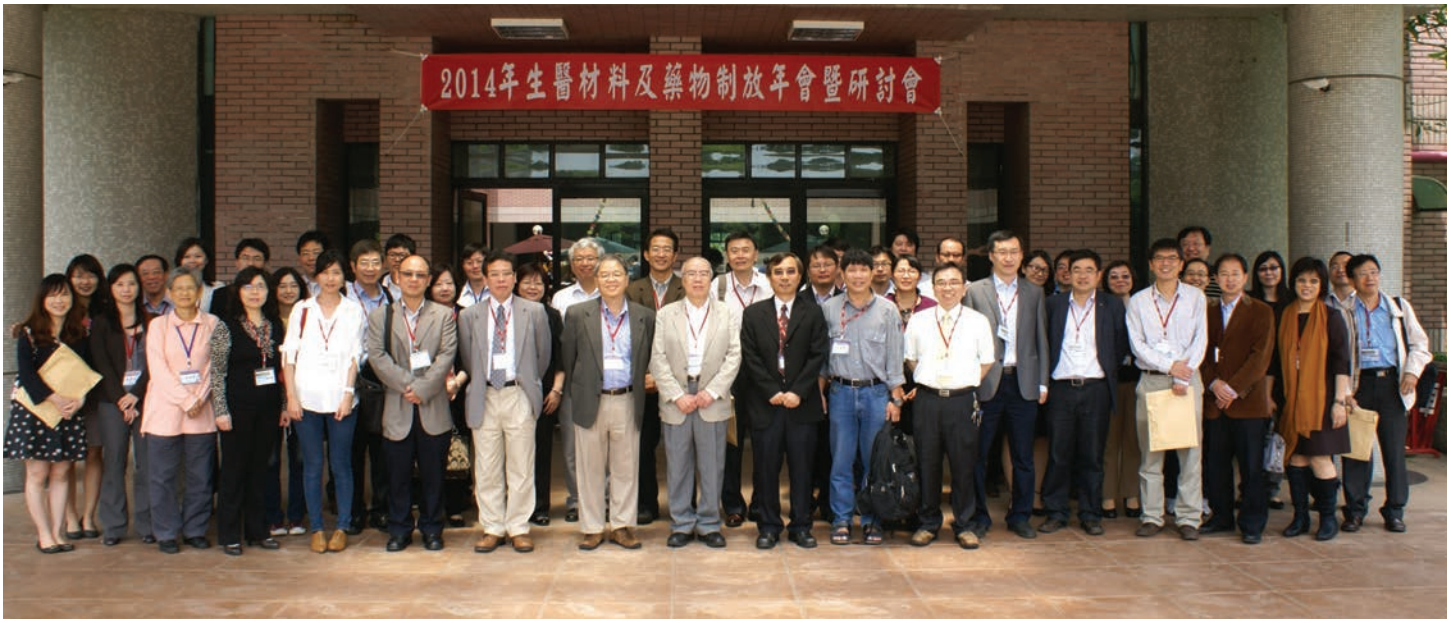
The CRS Taiwan Local Chapter cosponsored the 2014 Cross-Strait Symposium on Biomaterials and Drug Delivery Systems with the Biomaterials & Controlled Release Society on May 2 at the campus of National Tsing Hua University in Hsinchu, Taiwan. About 150 attendees were at the meeting.

Prof. Ming-Thau Sheu, immediate past president of the Taiwan Local Chaper, served as the chair of this symposium. Prof. Hsing-Wen Sung, chair of the organizing committee of this symposium, was elected as the new president of the society.

Keynote speaker Leaf Huang (University of North Carolina, U.S.A.) shared his recent research about tumor microenvironment and nanodrug delivery systems. The role of tumor-associated fibroblasts (TAF) in cancer resistance, metastasis, and design of effective treatment was vigorously discussed in the meeting. Additional invited speakers included 10 experts from both Taiwan and China. Combination therapy to enhance cancer treatment outcome was another focus in this meeting.

In addition to research discussion, future collaboration between China and Taiwan in CRS was also discussed. There is a possibility of having next year's Cross-Strait Symposium on Biomaterials and Drug Delivery Systems in China. The CRS Taiwan Local Chapter sincerely welcomes everyone to visit us here in Taiwan. For more information about this symposium and CRSTLC, please contact us at crstlc2010@gmail.com. ■

An energetic scientific session.



Delegates to the CRS Taiwan Local Chapter meeting.

Chapter News continued on page 26

CRS Germany Local Chapter 2014 Annual Meeting: Site-Specific and Controlled Delivery

Regina Scherließ, Chapter President

This year's annual meeting took place at Kiel University on February 27 and 28 and was excellently organized by a team from the Department of Pharmaceutics and Biopharmaceutics at Kiel University. Around 80 participants from all over Germany, Austria, and Switzerland came to Kiel to present their scientific work and to interact with colleagues from academia and industry. Most of the participants were Ph.D. students working on different topics of controlled release.

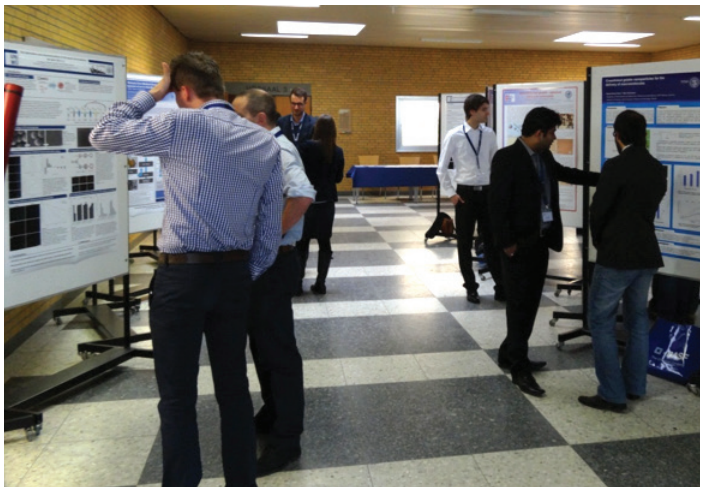
On the first morning, two well-received workshops took place. In a practical workshop on hot-melt extrusion led by Evonik, participants learned about the use of polymers for controlled delivery in hot-melt extrusion and had the opportunity to get hands-on experience working with a laboratory-scale extruder. Concomitantly, another workshop elucidated the relationship between academia and industry, and workshop leader Martin Bultmann gave helpful advice for young scientists who want to start their career in industry.

The meeting venue was an auditorium and foyer, so that lecture room, poster presentation, exhibitors, and refreshments could be located at the same place, intensifying interaction between the delegates and allowing time for poster discussion. Several pharmaceutical companies were present as exhibitors, presenting themselves as employers for young scientists and showing their areas of expertise.

After registration and a lunch break, which was used to discuss the 25 posters presented by scientists attending the meeting, the symposium was opened by Regina Scherließ, the chapter vice president and head of the organizing committee in Kiel. Following the meeting topic, invited speaker Ben Forbes (King's College, London, U.K.) gave an introduction to "Controlled Delivery to the Lungs." It was followed up, after a coffee break and poster session, with a session of short lectures on pulmonary delivery. All the short lectures were recruited from the abstracts submitted for the meeting and were given by Ph.D. students and young scientists.

Regina Scherließ and the award winners. Left to right: Sebastian Puhl, Gereon Rau, and Alexandra Braun.

Delegates at the CRS Germany Local Chapter 2014 annual meeting.



Delegates discuss research during a poster session.

Among others, Sebastian Puhl, who was later selected by the jury as giving the best oral presentation, talked about "Controlled Release of Proteins: Electrospinning of Protein Crystals in Biodegradable Polymer Nonwovens." The scientific program of the day ended with another poster session, and the annual chapter member assembly and board elections took place. All delegates were invited to participate in the evening event at a restaurant beautifully located by Kiel's fjord in the center of the city. Enjoying food and wine, the participants experienced networking with colleagues in a relaxed and friendly atmosphere.

The next day started with another invited lecture from Werner Weitschies (Greifswald University, Germany), who talked about "Oral Controlled Release Systems: Who Is in the Driving Seat, Physiology or the Controlled Release System?" After a coffee break and poster session, during which the jury made their final round for selecting the two best posters, another set of short lectures on parenteral and oral delivery followed.

Networking at the evening event.

The meeting ended with the presentation of awards. Alexandra Braun (Würzburg University) won for her poster "Synthesis and Characterization of 'Clickable' Myostatin Inhibitors." Gereon Rau (Kiel University) won for his poster "Application of a Novel *In-Vitro* Bone Model—Drug Release from Medical Devices." Sebastian Puhl was the best oral presentation award winner, and this award is coupled to a travel grant to attend the 2015 CRS Annual Meeting in Edinburgh. After concluding remarks and a special thanks to Martin Bultmann, the former local chapter president, newly elected chapter vice president Oliver Germershaus announced the next local chapter meeting to take place in Switzerland in the spring of 2015. Before leaving the venue, all participants were invited to get a grab-and-go lunch snack, and we hope to see them all again in Switzerland in 2015. ■

Patent Watch

Charles Frey, Coating Place, Inc., U.S.A.

This article briefly summarizes novel aspects of selected U.S. patents involving controlled release or delivery that were issued from July 1 to December 31, 2013. A generic search in the U.S. patent website on the terms "controlled release" or "controlled delivery" in the title or abstract fields yielded over 150 hits. Most were within the spirit of this article, and a subset of those is mentioned here. They have been generally categorized to focus on various interest areas. Greater detail on each can be found on the U.S. patent website (http://patft.uspto.gov/).

Consumer and Diversified Products

Germicidal Wipe (U.S. Patent 8,486,427)

A system of a polycationic additive to a wipe provides masking to anionic sites on the wipe structure to prevent antimicrobial binding to those sites for more efficacious delivery.

Methods and Articles for Identifying Objects Using Encapsulated Perfluorocarbon Tracers (U.S. Patent 8,501,481)

Encapsulated perfluorocarbon vapors and vapor sensors are employed as a means of identification.

Hygiene Articles Containing Nanofibers (U.S. Patent 8,487,156)

Polymeric nanofibers are used to form fabrics that can be used to control release of active components in personal care products.

Oral Care and Delivery Device (U.S. Patent 8,501,222)

Surface features are built into an edible device to hold medicaments or mouthwash for controlled delivery to the mouth.

Method of Controlled Delivery for Use in Electrochemical Power Sources (U.S. Patent 8,501,338)

Energy production from a galvanic electrochemical power source is controlled by incorporating a solid reaction initiator into a hydrogel matrix or the like.

Microreservoir with End Plugs for Controlled Release of Corrosion Inhibitor (U.S. Patent 8,507,056)

Mineral-based microtubules for controlled release of corrosion inhibitors in paints and the like are described.

Method, Material, and System for Controlled Release of Antimicrobial Agents (U.S. Patent 8,512,725)

This invention involves controlled release of silver, copper, or zinc antimicrobials from a solid delivery device into a fluid. A physical abrasion process is used to overcome inert film formation common to these materials.

Molecular Gel-Based Controlled Release Devices for Pheromones (U.S. Patent 8,512,726)

Aryl glycolipid gels such as mannitol dioctanoate are employed as controlled release agents for pheromones in pest control.

Controlled Release Remediation System and Composition (U.S. Patent 8,519,061)

Sustained delivery of oxidants from matrix or encapsulated systems for environmental remediation are disclosed.

Protein-Stabilized Antimicrobial Composition Formed by Melt Processing (U.S. Patent 8,524,264)

Antimicrobial plant oils are melt blended with proteins to provide a stable form of the oil.

Insect-Repelling Resin Composition and Extended-Release Insect-Repelling Resin Molded Product Obtained Therefrom (U.S. Patent 8,535,699)

A nonvaporizable insect control agent is incorporated into a molded polyvinyl chloride resin product for sustained delivery.

Delivery System for Biological Component (U.S. Patent 8,540,980)

Systems for controlled delivery of probiotics via oral, anal, or vaginal routes in humans or animals are described.

Inhalation Device Including Substance Usage Controls (U.S. Patent 8,550,069)

This invention discloses a cartridge and sensor system for controlling substance release in items commonly referred to as e-cigarettes or e-cigars.

Apparatus and Method for a Solid Catalyst and Fluid Dynamic Eruption Reaction (U.S. Patent 8,550,379)

An apparatus to enable controlled fast release of a catalytic solid into a beverage bottle to initiate a fluid eruption for acceleration of toys is described.

Article with Health-Benefit Agent Delivery System (U.S. Patent 8,552,251)

A system of laminate films/tissues or the like are used for localized controlled release of health benefit agents in products such as diapers, feminine pads, and bandages.

Slowly Digesting Starch and Fermentable Fiber (U.S. Patent 8,557,274)

Microparticles of digestible starch and fermentable dietary fiber are proposed for controlled starch digestion to deliver glucose to the small intestine and fiber to the colon.

Dispenser for the Controlled Release of Volatile Substances (U.S. Patent 8,567,693)

This invention involves controlled dispensing of volatile components such as perfumes, crop protection agents, pheromones, and repellents from a reservoir arrangement.

Organopolysiloxane Compositions Containing an Active Material (U.S. Patent 8,580,729)

Admixtures of silicone and wax are used to control release of materials such as perfume, sunscreen, vitamin, drug, biocide, pest repellent, catalyst, or cooling agents.

Inhibiting Crystallization of Steroidal Hormones in Transdermal Delivery Systems (U.S. Patent 8,586,080)

Polyoxazoline polymer is incorporated into steroid/polymer compositions to inhibit crystal formation and stabilize controlled release properties in transdermal applications.

Devices and Methods for Controlled Release of Additive Compositions (U.S. Patent 8,591,747)

A reservoir system with a controlled release membrane for delivery of corrosion inhibitors, microbicides, scale inhibitors, dispersants, buffering agents, surfactants, anti-fouling agents, and the like is disclosed.

Inclusion Complexes

Cyclodextrin-Based Polymer for Therapeutics Delivery (U.S. Patents 8,475,781; 8,580,242; 8,580,243; 8,580,244; 8,603,454; 8,609,081; 8,497,365; and 8,518,388)

This series of related patents involves use of cyclodextrins within polymer chains to carry drug molecules in a manner that reduces overall toxicity. Linker group and targeting ligand selection provide a means of controlled release.

Mesoporous Metal Oxide Materials for Phosphoproteomics (U.S. Patent 8,507,287)

Nanostructured metal oxide mesoporous materials offering controlled release of phosphorylated proteins and peptides for isolation, purification, and/or enrichment are disclosed.

Method of Using a Metal Organic Framework Based on Aluminum Fumarate (U.S. Patent 8,518,264)

A porous metal organic framework is described for incorporation and controlled release of substances.

Devices/Implants

Room-Temperature Curable Polymers (U.S. Patent 8,475,822)

This patent discloses a room-temperature curable phosphorylcholine polymer for controlled release of bioactives from medical devices such as stents.

Coating Systems for the Controlled Delivery of Hydrophilic Bioactive Agents (U.S. Patent 8,496,954)

A two-coat system for medical devices is described for delivery control. The vinyl acetate content of the outer poly(ethylene-*co*-vinyl acetate) coating layer controls release of hydrophilic material from the inner coating.

Long-Term Drug Delivery Devices with Polyurethane-Based Polymers and Their Manufacture (U.S. Patent 8,529,936)

This invention uses a polyurethane polymer to sustain release of bioactives from implant devices.

Medical Devices Having Porous Polymeric Regions for Controlled Drug Delivery and Regulated Biocompatibility (U.S. Patent 8,535,702)

Implantable medical devices containing phase-separated polymeric regions for controlled drug delivery are described. One of the phases consists of bio-unstable copolymer blocks that degrade to nanoporous regions for drug incorporation and delivery.

Process for Producing Poly(vinyl alcohol)-Bacterial Cellulose Nanocomposite (U.S. Patent 8,551,502)

Nanocomposites of poly(vinyl alcohol) and cellulose fibers are disclosed as soft tissue replacement with controlled bioactive release capabilities.

Medical Devices Having Nanoporous Coatings for Controlled Therapeutic Agent Delivery (U.S. Patent 8,574,615)

An implant consisting of drug-loaded surface depressions and an overlaying nanoporous coating are used for control of drug release or mechanical, thermal, magnetic, or electrical processes in the body.

Implant Pellets and Method Using Same (U.S. Patent 8,574,617)

Pain relief agents in the form of injectable implants are described for treatment of animals/livestock.

Nonpolymeric Compositions for Controlled Drug Delivery (U.S. Patent 8,586,103)

Ion complexes of a drug and an amphiphilic molecule are incorporated into a nonpolymeric hydrophobic carrier and water-miscible biocompatible organic solvent to create an injectable depot drug delivery system.

Therapeutic Agent Delivery Systems and Devices (U.S. Patent 8,617,143)

An implant consisting of a chamber loaded with both drug and an expansion agent. Permeation into the expansion agent through a porous membrane controls drug release through an aperture at the opposite end of the chamber.

Patent Watch continued on page 30

Patent Watch continued from page 29

Method for Delivering a Therapeutic Agent Comprising Injection of Microspheres (U.S. Patent 8,481,064)

Barbed devices for localized controlled bioactive delivery and disclosed.

Eye Care

Controlled-Release Ophthalmic Vehicles (U.S. Patent 8,501,800)

A combination of anionic and cationic polymers is employed to impart increased viscosity at the higher pH of tear fluid for extended therapeutic drug delivery to the eye.

Ear Delivery

Controlled Release Corticosteroid Compositions and Methods for the Treatment of Otic Disorders (U.S. Patent 8,546,363)

Controlled release corticosteroid thermo-reversible gel formulations enable new treatment options for ear diseases.

Mouth Delivery

Buccal Drug Delivery (U.S. Patents 8,603,516 and 8,603,517)

These patents disclose lozenges for controlled buccal delivery.

Bone Care

Controlled Release Micro-capsule for Osteogenic Action (U.S. Patent 8,496,964)

Controlled release of a flavonoid is achieved with multiple layers of oppositely charged polyelectrolytes.

Controlled Substances

Compositions Comprising Enzyme-Cleavable Oxycodone Prodrug (U.S. Patent 8,497,237)

An enzyme-activated oxycodone prodrug and enzyme inhibitor are formulated for a controlled release oxycodone.

Pharmaceutical Formulation (U.S. Patent 8,506,998)

A matrix tablet designed for sustained release of morphine or other water-soluble controlled substances is disclosed.

Sustained Release Micro-pellets and Process for Producing the Same (U.S. Patent 8,512,744)

A sustained release system for water-soluble opioids and the like is described. The system includes drug layering on a solid core, followed by application of a water-soluble interlayer, followed by application of a water-insoluble layer.

Extended Release Dosage Form (U.S. Patent 8,524,277)

An osmotic tablet for sustained release of hydrocodone is disclosed.

Pharmaceutical Formulation Containing Gelling Agent (U.S. Patent 8,529,948)

A sustained release hydrocodone formulation is formulated with a gelling agent as an abuse deterrent.

Controlled Release Hydrocodone (U.S. Patent 8,551,520)

A hydrocodone sustained release matrix tablet is disclosed.

Formulations and Methods for the Controlled Release of Active Drug Substances (U.S. Patent 8,563,038)

An abuse-deterring oxycodone cylindrical matrix tablet within a cylindrical body for sustained release is disclosed.

Compositions Comprising Enzyme-Cleavable Oxycodone Prodrug (U.S. Patent 8,569,228)

This disclosure provides oxycodone in a prodrug form whereby drug release is controlled by trypsin.

Controlled Release Formulations Having Rapid Onset and Rapid Decline of Effective Plasma Drug Concentrations (U.S. Patent 8,580,310)

A coated multiparticulate form of methylphenidate that provides immediate release from an outer drug layer and sustained enteric release from an inner layer that is controlled by separate enteric and sustained release layers.

Morphine Polymer Release System (U.S. Patents 8,609,143 and 8,617,605)

A partially coated matrix tablet is described for sustained morphine release and the like.

Pharmaceutical Formulation Containing Gelling Agent (U.S. Patent 8,609,683)

A sustained release oral dosage of morphine is provided with an associated abuse-deterring gelling agent.

Misuse Preventative, Controlled Release Formulation (U.S. Patents 8,486,448 and 8,486,449)

A superabsorbent material is incorporated into oral controlled-substance sustained release formulations to inhibit release when crushed and exposed to aqueous media.

Miscellaneous Pharmaceutical

Controlled Release System and Method for Manufacturing the Same (U.S. Patent 8,512,748)

A multilayer coated multiparticulate oral delivery formulation strategy is described for pH-independent release of actives with pH-dependent solubility. The strategy includes a pH control agent layer, a drug layer, a protective interlayer, and an outer controlled release layer.

Electronically and Remotely Controlled Pill and System for Delivering at Least One Medicament (U.S. Patent 8,518,022)

A remotely controlled gastrointestinal delivery system is described.

Biocompatible Polymers and Hydrogels and Methods of Use (U.S. Patent 8,535,705)

Cross-linked biocompatible hydrogels with controllable biodegradation for controlled delivery and other uses are disclosed.

Controlled Release Oral Dosage Form (U.S. Patent 8,545,880)

This patent involves a controlled release delivery platform involving bupropion hydrochloride in immediate release and enteric coated pellets for once per day delivery.

Modular Systems for the Controlled Release of a Substance with Space and Time Control (U.S. Patent 8,545,883)

A system of "stackable" drug release modules provides structural flexibility for tailoring drug release profiles.

Controlled Release of Biologically Active Compounds (U.S. Patent 8,552,139)

This invention involves use of biodegradable polyesters and polyester amides derived from functionalized bioactives for controlled biodegradation and bioactive compound delivery.

Water-Swellable Polymers (U.S. Patent 8,557,281)

A linear polymer composed polyethylene oxide, a diol, and a diisocyanate with enhanced swell properties is disclosed for incorporation and controlled release of larger pharmaceutically active water-soluble agents.

Nanoparticles (U.S. Patent 8,580,311)

Silica shell-based core shell nanoparticles built by silica deposition onto cationic polymeric micelles that can be adapted for controlled delivery of active agents are described.

Method for Producing a Water-Insoluble Amorphous or Partially Amorphous Controlled Release Matrix (U.S. Patent 8,557,286)

A coextrusion of starch and drug is used to create a controlled release matrix for oral delivery.

Chimeric Viral Envelopes (U.S. Patent 8,557,971)

This invention involves chimeric polytropic viral envelope polypeptides for directed and targeted fusion of virus particles with cellular membranes.

Localized Delivery of Drug Agents (U.S. Patents 8,574,191 and 8,574,225)

Shrink or swell associated with a coating on a balloon catheter is used to control pores in the coating that mediate drug passage.

Ultrathin Multilayered Films for Controlled Release of Anionic Reagents (U.S. Patent 8,574,420)

Multilayer cationic polymer films are used for controlled release of anionic peptides, proteins, nucleic acids, or other anionic biological agents.

Dual Controlled Release Dosage Form (U.S. Patent 8,591,947)

This invention involves controlled release of two drugs from an osmotic device comprised of a bilayer core.

Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions (U.S. Patent 8,603,514)

An oral delivery system comprised of a rapid-dissolve thin film and taste-masked or controlled release coated drug particles is described.

Methods and Compositions for Controlled Release of Drugs (U.S. Patent 8,609,080)

Drug molecules with amine, alcohol, or thiol functions are covalently bound to a polymer and released in a controlled manner by a two-stage reaction mechanism.

Controlled Release Compositions with Reduced Food Effect (U.S. Patent 8,486,453)

A combination of immediate and sustained release properties are employed in an oral dose of metformin to reduce food effects on bioavailability. ■

Welcome New CRS Members

Fran Adar
Oluwatoyin A. Adeleke
Mohammed Alqahtani
Abhay Asthana
Arrandeep S. Basra
Miroslav Baudys
Oshra Betzer
Michiel Bolkestein
Susanne Bredenberg
Yeongseon Byeon
Shuang Cai
Mary Cano
Daniel Carson
Linda J. Chan
Jun Chen
Yan Chen
Yufei Chen
Yung-Chu Chen
Kiran Kumar Chereddy
Yanggyu Choi
Katherine A. Chu
Allan G. A. Coombes
Patrick P. Dayal
Raquel De Souza
Sergio del Rio-Sancho
Yusuke Doi
Nathan H. Dormer
Hitesh A. Doshi
Yutaka Ebisawa
Ahmed A. El-Ashmawy
George Feast
Qiang Fu
Birgit Lundskov Fuhlendorff
Wei Gao
Arong Gaowa
Yuhui Gong
Laura Gonzalez
Jijin Gu
Vipul Gujrati
Emily Gullotti
Hee Dong Han
Atsuhiro Hasegawa
Koji Hattori
Yuki Hiruta
Zhaohua Huang
Kyu-Mok Hwang
Md Saiful Islam
Jayanthy Jayanth
Hee Jeong Jeong
Jessica Joyce
Samir Julka
Elisabeth Kastner
Yuji Kawashima
Joakim Kennedy
Sang-Joon Kim
Tae Jung Kim
Nanna Ny Kristensen
Rui Kuai
Joshua L. Kulakofsky
Daeyong Lee
Seung-Hoon Lee
Soyoung Lee
Yonghyun Lee
Laura Lerner
Cheuk Yui Leung
Yiwei Liu
Adolfo Lopez-Noriega
Jianqin Lu
Laibin Luo
Katharina Maisel
Nancy Marchant
Ela Markovsky
Hidehito Matsuoka
Pierre Maudens
Mark G. Mazzie
Oren Mizrahi
Lee Moir
Hidefumi Mukai
Yusuke Murakawa
Ja Hye Myung
Yukihiro Nomura
Lukasz Ochyl
Donna Omiatek
Jaehyung Park
Jinho Park
Seho Park
Sohyun Park
Jinliang Peng
Quynh Pham
Phouthone Phravorachith
Jose Portilla Arias
Eswara Vara Prasadarao K.
Yangsheng Qiu
Sima Rahimian
Tannaz Ramezanli
Oljora Rezhdo
Ronak Savla
Steve Schuehle
Jae Hak Seol
Meng-Han Shen
Kai Shi
Kathryn Skilling
Svenja Sladek
Donghui Song
Jose Antonio Suarez del Pino
Wai-Leung Suen
Jing Sun
Taku Takami
Francesco Tres
Takahiro Uchida
Ambrogio Usuelli
Merel van Elk
Aiping Wang
Jian Wang
Lianyan Wang
Linda Wang
Qi Wang
Rubin Wang
Xin Wei
Rhys Williams
Jennifer Wong
Jie Wu
Li Xu
Tomoya Yamazaki
Sidi Yang
Yang Yang
Yanzhu Yang
HoJun Yoo
Bin Zhang
Clark Zhang
Peng Zhang
Pengcheng Zhang
Wujie Zhang
Xiaolan Zhang
Xuemei Zhang
Yifei Zhang
Yu Zhang
Jiani Zheng
Yi Zhuang

CRS
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Delivery Science
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People in the News

Compiled by Steven Giannos, Independent Consultant

Icon Bioscience Announces David S. Tierney, M.D., Joined the Company as President and Chief Executive Officer

Business Wire: April 7, 2014 – SUNNYVALE, CA, U.S.A. – Icon Bioscience, Inc., a specialty biopharmaceutical company focused on utilizing its Verisome® drug delivery platform to develop unique intraocular eye-care therapeutics, today announced that David S. Tierney, M.D., joined the company as president and chief executive officer.

Icon Bioscience noted that Dr. Tierney is an accomplished healthcare executive with a proven record of achievements leading the growth of both pharmaceutical and medical device companies. Additionally, Dr. Tierney possesses significant experience in successfully developing and commercializing drug delivery platforms, a particularly valuable asset with regard to Icon's Verisome technology.

"We are delighted to have David join our team," said Vernon G. Wong, M.D., chairman and founder of Icon Bioscience and inventor of Verisome. "David possesses a wealth of expertise in medical science, clinical and regulatory affairs, and in overseeing the advancement of healthcare companies through the product development phase to commercial operations, key elements in support of Icon's exciting growth outlook."

David Tierney commented, "Icon is on the threshold of an important new growth phase, as is evident from the company's robust product pipeline with its lead product candidate in late-stage development." He further noted, "I expect Icon's Verisome technology to drive a transformational change in ophthalmic pharmaceuticals and am thrilled to have the opportunity to participate and contribute to that prospect."

Previously, Dr. Tierney served as president and COO of Oceana Therapeutics, Inc., a specialty therapeutic company he cofounded in mid-2008. Oceana quickly established a global commercial network and by December 2011 was acquired by Salix Pharmaceuticals (NASDAQ: SLXP). In 2000, David was appointed president and CEO of Hydro Med Sciences (HMS), a research firm with a promising drug delivery platform. Under his leadership, HMS emerged as Valera Pharmaceuticals, a fully integrated, commercial, specialty pharma company that successfully completed an initial public offering in 2005. Valera has since been merged into Endo Pharmaceuticals (NASDAQ: ENDP). Prior to Valera, Dr. Tierney was president of Biovail Technologies, a drug delivery division of Biovail Corporation—a predecessor to Valeant Pharmaceuticals International (NYSE: VRX). Earlier in his career, he served as senior VP, drug development, at Roberts Pharmaceutical and in a variety of management positions at Elan Corporation. Dr. Tierney received his medical degree from the Royal College of Surgeons in Dublin, Ireland.

David Tierney is the recipient of two Ernst & Young Entrepreneur of the Year® awards, first in 2005 and again in 2011, respectively, reflecting his accomplishments at Valera and Oceana. He was also featured in the inaugural 2010 Irish Life Science 50, an honor presented by the president of Ireland in conjunction the *Irish Voice* and *Irish America* magazine. Additionally, in 2005, 2006, and 2011, David was named one of the most inspiring people in the health sciences by PharmaVOICE 100.

Icon Bioscience, Inc., is a privately held specialty biopharmaceutical company focused on the development and commercialization of unique ophthalmic pharmaceuticals based on its patented and proprietary Verisome® drug delivery technology. The technology encompasses a broad number of related but distinct drug delivery systems capable of incorporating an extensive range of active agents, including small molecules, proteins, and monoclonal antibodies. Moreover, this drug delivery platform is a highly advanced yet elegantly formulated system for controlling the release of medication within the eye for up to a year through the administration of a single injection. The technology's exceptional versatility can support products individually formulated to meet the particular clinical requirements of a given active agent targeting a specific ophthalmic disease. Icon is actively developing a broad portfolio of specialty pharmaceuticals targeting several ophthalmic indications, including macular edema, glaucoma, age-related macular degeneration, and cataract surgery. For additional information visit the Icon website at www.iconbioscience.com.

Mystic Pharmaceuticals Appoints Gerald D. Cagle, Ph.D., and Grady Rylander, M.D., to Scientific Advisory Board

Business Wire: March 19, 2014 – AUSTIN, TX, U.S.A. – Mystic Pharmaceuticals, Inc., a privately held integrated specialty pharmaceutical company, announced today that Gerald D. Cagle, Ph.D., and Grady Rylander, M.D., have joined Mystic's Scientific Advisory Board. Dr. Cagle is the former chief scientific officer and senior vice president of research and development of Alcon Laboratories, Inc. Dr. Rylander is a board-certified ophthalmologist with the Eye Institute of Austin and a professor in biomedical engineering at the University of Texas–Austin.

"We are delighted to have Dr. Cagle and Dr. Rylander join our Scientific Advisory Board," said Timothy Sullivan, Mystic's president and CEO. "Dr. Cagle's significant experience in ophthalmic product development, regulatory, and drug delivery, along with his deep global industry pharmaceutical experience will be invaluable to Mystic as we commercialize our novel ophthalmic drug delivery technologies. Dr. Rylander's experience as a board-certified ophthalmologist and clinical practice, combined with his biomedical engineering expertise provides

People in the News continued on page 34

People in the News continued from page 33

Mystic's team with a tremendous knowledge base in the development of patient-centric ophthalmic drug delivery systems."

Dr. Cagle is currently chief operating officer at Cognoptix, Inc., focused on the diagnosis of Alzheimer's disease. He currently serves on the board of directors of Aerie Pharmaceuticals and Clearside Biomedical. Previously, Dr. Cagle served as senior vice president of research and development at Alcon Laboratories Inc. from 1997 to 2008, assuming the responsibility of chief scientific officer in 2006. Dr. Cagle began his 32-year career at Alcon in 1976 as a senior scientist in microbiology, rapidly advancing to lead the product development organization and being named vice president, product development, in 1985. He also served a two-year assignment as the vice president of regulatory affairs. Under Dr. Cagle's leadership, Alcon's research and development group grew to 1,300 employees in 18 countries. Dr. Cagle has served on the Wilmer Eye Institute Advisory Council and is a member of the ARVO Foundation Board of Governors. Dr. Cagle received his B.S. degree from Wayland College in Plainview, Texas, and earned both his M.S. and Ph.D. degrees from the University of North Texas in Denton, Texas.

Dr. Rylander is a board-certified general ophthalmologist with a special interest in retina, glaucoma, and cataract. He has been in practice for 34 years and is on the staff of seven Texas hospitals. He has performed thousands of cataract surgeries and hundreds of laser procedures through his ophthalmic practice at the Eye Institute of Austin. He has three issued patents and has authored or coauthored more than 125 scholarly articles within the field of ophthalmology and biomedical engineering. Dr. Rylander attended the University of Texas at Austin, where he earned BSEE and MSEE degrees. He received his M.D. from the University of Texas Health Science Center, San Antonio, in 1980. Dr. Rylander is a professor in biomedical engineering at the University of Texas at Austin and has been the William J. Murray and Harry H. Power Professor since 2002.

Mystic Pharmaceuticals™ is an integrated specialty pharmaceutical company based in Austin, Texas. Mystic provides patient-centric delivery solutions for pharmaceuticals, biopharmaceuticals, and biologics for intranasal, ophthalmic, sublingual, and otic applications. Mystic combines its novel delivery systems with pharmaceuticals and biologics under development by Mystic and its partners to meet the expanding global market demand for healthcare products that are safer, simpler to use, and cost effective. For more information, please visit the Mystic website: www.mysticpharmaceuticals.com.

CytRx Establishes Research and Development Team and Opens New Laboratory to Develop Albumin-Binding Anticancer Drug Platform

Business Wire: March 17, 2014 – LOS ANGELES, CA, U.S.A. – CytRx Corporation (Nasdaq: CYTR), a biopharmaceutical research and development company specializing in oncology, today announced the appointment of Felix Kratz, Ph.D., as vice president of drug discovery and André Warnecke, Ph.D., as senior director of drug discovery. Drs. Kratz and Warnecke and their scientific team will expand the corporation's novel albumin-binding anticancer drug pipeline.

Dr. Kratz, one of the most highly regarded conjugation chemists in oncology, joins CytRx with 25 years of experience in drug discovery and research. Dr. Kratz's research includes the development of novel, targeted molecules for cancer therapies, with a special emphasis on the use of albumin as a targeting agent. His research in preclinical and early clinical development of these therapies has led to the creation of a number of new cancer-fighting agents that use albumin to concentrate chemotherapeutics inside cancers, including the invention of CytRx's lead compound, aldoxorubicin. Dr. Kratz has been at the forefront of designing novel agents, using various linker chemistries to create a variety of protein-drug conjugates.

Dr. Warnecke comes to CytRx with 16 years of experience in chemistry research, including the development of chemical architectures for innovative drug release mechanisms and albumin conjugates of anticancer agents.

The new laboratory, located in Freiburg, Germany, will conduct discovery and translational research to create drug candidates that utilize novel linker technologies that couple chemotherapeutic agents and proteins either inside the body or externally and then concentrate drug in tumors. The work done at the laboratory will generate new pipeline product candidates and thereby enable expansion of the company's existing patent portfolio, adding to intellectual property that was originally developed by the KTB Tumor Biology Center in Freiburg and licensed exclusively to CytRx.

"Dr. Kratz is one of the most widely published researchers on the use of albumin as a targeting agent for cancer therapies, and he brings a tremendous wealth of experience and insight to the development programs at CytRx," said Steven A. Kriegsman, CytRx president and CEO. "Felix and André have worked side by side for many years, and we are quite fortunate to have the opportunity to bring their drug discovery potential in-house."

Mr. Kriegsman added: "With human clinical results successfully established with aldoxorubicin, our conjugates and albumin-binding approach has been shown to be a viable treatment pathway and one that has the potential to be used with multiple therapeutic agents. We believe that Dr. Kratz's and Dr. Warnecke's leading-edge scientific contributions on linker technologies will provide a platform for the generation of innovative product candidates that could be added to our future pipeline."

Prior to joining CytRx, Dr. Kratz was the head of the Division Macromolecular Prodrugs, which he founded in 1994, in the Clinical Research Department at the Tumor Biology Center (KTB TumorforschungsGmbH) in Freiburg, Germany. The Tumor Biology Center is a private cancer clinic and research institution within the University of Freiburg that focuses on the

development of novel drugs and drug delivery concepts for improving the efficacy and toxicity of anticancer agents. Dr. Kratz was in charge of preclinical drug development and organizing and managing translational research from the laboratory to the clinic. His research areas are drug targeting, drug delivery systems in oncology, prodrugs, receptor and antigen targeting, bioconjugate chemistry, polymer therapeutics, and nanocarriers.

Dr. Kratz graduated in chemistry from the University of Heidelberg in 1991. He carried out postdoctoral research at the University of Florence in the Bioinorganic Institute of Prof. Ivano Bertini and developed transferrin-based tumor-specific carrier systems with ruthenium(III) complexes. He serves on the editorial boards for *Bioconjugate Chemistry, Current Medicinal Chemistry, Current Bioactive Compounds,* and *Pharmacology & Pharmacy*. He has authored approximately 260 scientific publications and proceedings and is the inventor of 23 patents and patent applications.

Dr. Warnecke previously served on Dr. Kratz's research team as head of chemistry, Division Macromolecular Prodrugs in the Clinical Research Department at the Tumor Biology Center in Freiburg, Germany. Dr. Warnecke studied chemistry at the universities of Clausthal and Freiburg (Germany) and received his diploma in the field of metallocene chemistry in 1997. He then conducted his Ph.D. thesis research on albumin-binding prodrugs of anticancer agents. Dr. Warnecke has authored or coauthored 23 scientific publications.

CytRx is currently conducting a phase 2 clinical trial evaluating aldoxorubicin in patients with late-stage glioblastoma (brain cancer). In late 2013, the company reported highly statistically significant results from its global phase 2b clinical trial evaluating aldoxorubicin as a first-line therapy in patients with soft tissue sarcomas. In this trial, aldoxorubicin demonstrated 80–100% superiority over doxorubicin in progression-free survival (PFS). Median PFS, 6-month PFS, and overall response rates all significantly favored aldoxorubicin treatment over doxorubicin. Aldoxorubicin is also being studied in a phase 2 clinical trial in HIV-related Kaposi's sarcoma. CytRx plans to initiate, under a special protocol assessment, a pivotal phase 3 global clinical trial with aldoxorubicin as a therapy for patients with soft tissue sarcomas in the first quarter of 2014. ■

In the News

Compiled by Steven Giannos, Independent Consultant

May

Clearside Biomedical to Present Research on Proprietary Retinal Therapeutics Platform at 2014 ARVO Meeting

Business Wire: May 2, 2014 – ALPHARETTA, GA, U.S.A. – Clearside Biomedical, Inc., a privately held ophthalmic company developing and commercializing targeted therapeutics for the treatment of sight-threatening diseases, today announced that research on its proprietary retinal therapeutics platform will be presented at the 2014 Annual Meeting of the Association for Research and Vision in Ophthalmology (ARVO), May 4–8, 2014, in Orlando, FL.

Six poster presentations will occur during the ARVO Annual Meeting, including:

- Patel, SR, Verhoeven, RS, Burke, B, Viaud, K, Edelhauser, HF. Safety and Tolerability of Drugs Within the Suprachoroidal Space in Albino Rabbits.
- Noronha, G, Edelhauser, HF, Patel, SR, Burke, B, Verhoeven, RS. Safety and Toxicokinetics of Suprachoroidal Space Injections of Triamcinolone Acetonide Suspension in Albino Rabbits.
- Yoo, JI, Andino, RV, Zarnitsyn, V, Strudthoff, K, Patel, SR, Edelhauser, HF. Ultrasound Biomicroscopy to Visualize Suprachoroidal Injections in Enucleated Human Eyes.
- Zarnitsyn, V, Patel, SR, Verhoeven, RS, Lawrence, MS. Characterization of Sodium Fluorescein Administered into the Suprachoroidal Space of Nonhuman Primates Using a Microneedle.
- Edelhauser, HF, Verhoeven, RS, Burke, B, Struble, CB, Patel, SR. Intraocular Distribution and Targeting of Triamcinolone Acetonide Suspension Administered into the Suprachoroidal Space.
- Andino, R, Allen, EV, Patel, SR, Edelhauser, HF, Yoo, JI. Intraocular Pressure Changes Resulting from Suprachoroidal and Intravitreal Injections in Ex-Vivo Porcine Eyes.

Clearside Biomedical, Inc., headquartered in Alpharetta, GA, is a clinical-stage ophthalmic pharmaceutical company developing and planning to commercialize therapeutics targeting diseases of the back of the eye that can lead to blindness. We have developed a pipeline of ophthalmic drug candidates using our differentiated approach, which we believe can improve the efficacy and safety of those therapies. Clearside Biomedical was founded by an executive team with extensive development and revenue growth expertise. This team strives for better delivery and performance of its therapeutic agents to improve the standard of care for patients with choroidal and retinal diseases. Visit www.clearsidebio.com for more information.

Envisia Therapeutics to Present New Glaucoma and AMD Data at ARVO 2014

Business Wire: May 1, 2014 – RESEARCH TRIANGLE PARK, NC, U.S.A. – Envisia Therapeutics today announced that it will present data for its next generation product candidates, ENV515 for glaucoma and ENV705 for age-related macular degeneration (AMD), as well as new data for the company's novel drug delivery systems designed for the posterior and anterior segments of the eye, at the Association for Research in Vision and Ophthalmology (ARVO) 2014 Annual Meeting. ARVO is globally recognized and respected as a leading provider of quality content and research, and the annual meeting is the industry's premier gathering place for information exchange and networking. ARVO 2014 is being held May 4–8, 2014, in Orlando, FL.

"Envisia is extremely proud to have such a great showing of data at the ARVO 2014 Annual Meeting, which is revered by both scientists and practitioners internationally," said Ben Yerxa, Ph.D., chief scientific officer of Envisia. "We believe our technology provides a white space of opportunity that will pave the way for the next generation of ophthalmology products that have the potential to improve patient safety and outcomes."

Tomas Navratil, Ph.D., Envisia's vice president of development, will give an oral presentation titled "Preclinical Evaluation of ENV515 (Travoprost) Intracameral Implant – Clinical Candidate for Treatment of Glaucoma Targeting Six-Month Duration of Action" on Tuesday May 6th at 4:15PM in Room S310A-D.

In addition, the company will present data supporting the following abstracts titled:

Glaucoma:

- Precisely Engineered Biodegradable Drug Delivery Systems for the Extended Release of Prostaglandin Analogues in the Anterior Chamber
- Intracameral Conversion of Travoprost to Travoprost Acid in the Normotensive Beagle Dog Model

AMD:

- Extended Release of Microfabricated Protein Particles from Biodegradable Hydrogel Implants for the Treatment of Age-Related Macular Degeneration
- Biodegradable Hydrophobic Intravitreal Implants for the Extended Release of Bevacizumab for Age-Related Macular Degeneration
- Development of Precisely Engineered Biodegradable Drug Delivery Systems for Posterior Ocular Drug Delivery: PRINT® PLGA Extended Release Implants for Anti-VEGF Biologics

- Photocurable Hydrogel Implants for the Extended Release of Bevacizumab for the Treatment of Age-Related Macular Degeneration

Postoperative Inflammation and Pain:

- Controlled and Extended Release of Difluprednate from Biodegradable Intraocular Implants Engineered using PRINT® Technology

Envisia uses the power of the proprietary PRINT® (Particle Replication In Non-Wetting Templates) technology to create particle-based ocular therapeutics that can deliver both small and large molecules in multiple formats.

Envisia's lead product, ENV515, is a marketed prostaglandin analogue that uses a proprietary, fully biodegradable PRINT particle formulation to provide sustained intraocular pressure (IOP) reduction over many months, offering the potential to address the poor compliance that exists today and to limit glaucoma progression and vision loss. Envisia is also exploring how the company's unique technology can address other important ocular diseases, such as AMD and ocular inflammation.

Envisia Therapeutics, formed by Liquidia Technologies in 2013, is a privately held biotechnology company focused on the development of novel ocular therapies. Envisia is leveraging the unique and powerful properties of the PRINT® technology to develop therapies for a variety of ocular conditions, beginning with ENV515 for glaucoma. ENV515 is a novel, implantable extended-release formulation of a marketed prostaglandin analogue with the potential to significantly limit disease progression and vision loss through improved product performance and patient compliance. Envisia is located in Research Triangle Park, North Carolina. For more information, please go to www.envisiatherapeutics.com.

April

Braeburn Pharmaceuticals to Initiate New Clinical Study for Probuphine Following Clear Guidance from FDA

Business Wire: April 30, 2014 – PRINCETON, NJ, U.S.A. – Braeburn Pharmaceuticals announced today the initiation of a new clinical trial for Probuphine® based on clear guidance from the U.S. Food and Drug Administration (FDA). The study, which was submitted for FDA review in mid-March, is expected to begin enrollment by mid-year and to be completed by the middle of 2015.

"The responsiveness and insightful guidance from the FDA have been helpful in solidifying our decision to move forward with building Braeburn's strong focus in addiction medicine," said Behshad Sheldon, president and chief executive officer of Braeburn Pharmaceuticals. "We are keen to begin the new trial for Probuphine, which if approved should lay a strong foundation for our company."

The clinical study is a randomized, double blind, double dummy design that is expected to enroll approximately 180 patients into two parallel treatment arms. The study population will be clinically stable patients who are receiving maintenance treatment with an approved sublingual formulation containing buprenorphine at a daily dose of 8 mg or less. Patients will be randomized either to receive four Probuphine implants or to continue daily sublingual buprenorphine therapy. In keeping with the double blind design, those receiving Probuphine implants will also take daily placebo sublingual pills, and those randomized to sublingual buprenorphine pills will receive four placebo implants. All patients are expected to be treated for six months, and the primary analysis will be a noninferiority comparison of responders in the two arms.

The Braeburn team has already revised the final study protocol to incorporate the FDA's guidance. Preparations are also under way to qualify investigator sites, obtain institutional review board (IRB) approvals and train the clinicians in study procedures.

"As the number of people living with opioid dependence in this country continues to rapidly increase, the development of medications like Probuphine is critical to addressing the need for new and effective treatment options," said Frank E. Young, M.D., Ph.D., executive vice president, clinical and regulatory affairs, Braeburn Pharmaceuticals. "Braeburn strongly believes in the potential for Probuphine to offer people living with opioid dependence a unique approach to achieving sustained, long-term recovery. We remain committed to working with the FDA and our partner Titan Pharmaceuticals toward the goal of adding Probuphine to the short list of proven medication-assisted treatment (MAT) options."

According to recent estimates, there are approximately 2.7 million people with opioid dependence in the United States. Approximately 20 percent of this population is addicted to illicit opioids, such as heroin, and the other 80 percent to prescription opioids, such as oxycodone, hydrocodone, methadone, hydromorphone, and codeine. Before the year 2000, medication-assisted therapies for opioid dependence had been sanctioned to a limited number of facilities in the United States. The Drug Addiction Treatment Act of 2000 (DATA 2000) allowed medical office-based treatment of opioid dependence and greatly expanded patient access to medication-assisted treatments. As a result, an estimated 1.2 million people in the United States sought treatment for opioid dependence in 2011.

Probuphine is an investigational subdermal implant designed to deliver continuous, around-the-clock blood levels of buprenorphine for six months following a single treatment, and to simplify patient compliance and retention. Buprenorphine, an approved agent for the treatment of opioid dependence, is currently available in the form of daily dosed sublingual tablets and film formulations, with reported 2012 sales of approximately $1.5 billion in the United States. Probuphine was developed using ProNeura™, Titan's continuous drug delivery system that consists of a small, solid implant made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting

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construct is a solid matrix that is placed subdermally, normally in the upper arm in a simple office procedure, and removed in a similar manner at the end of the treatment period. The drug substance is released slowly and continuously through the process of dissolution resulting at a steady rate of release.

The efficacy and safety of Probuphine has been studied in several clinical trials, including a 163 patient, placebo-controlled study over a 24 week period (published in the *Journal of the American Medical Association*) and a follow-on study of 287 patients (published in the journal *Addiction*).

Braeburn Pharmaceuticals, an Apple Tree Partners company, develops and commercializes innovative medical products, with a focus on the field of addiction medicine. In December 2012, Braeburn licensed the development and commercialization rights for Probuphine®, a buprenorphine subdermal implant currently under development for the maintenance treatment of opioid dependence. To learn more, visit www.braeburnpharma.com.

InVivo Therapeutics Initiates First Clinical Trial of Neuro-Spinal Scaffold

Business Wire: April 28, 2014 – CAMBRIDGE, MA, U.S.A. – InVivo Therapeutics Holdings Corp. (NVIV) announced today that it has begun shipment of its innovative investigational device, a degradable polymer neuro-spinal scaffold for spinal cord injury (SCI) patients, for initiation of the company's first clinical trial. InVivo has pioneered a new treatment platform utilizing a biocompatible polymer-based device that is intended to promote structural support for spinal cord regeneration while improving functional recovery and prognosis after a traumatic SCI. In preclinical studies, the neuro-spinal scaffold promoted cell adhesion, neurite sprouting, the growth of remodeled spinal cord tissue containing myelinated axons, and improved motor function. There currently is no effective treatment for paralysis caused by SCI. The company estimates the worldwide market for treating acute complete SCI to be over $500 million annually, and the chronic SCI market to be over $10 billion. This is the first in-human trial of InVivo's novel investigational device, a critical step in addressing a major unmet need for patients with SCI.

This first clinical study, which is approved by the FDA, is a pilot trial to capture preliminary safety and effectiveness data of the neuro-spinal scaffold in five subjects with acute thoracic spinal cord injury. The company then expects to conduct a pivotal study to obtain FDA approval to commence commercialization under a humanitarian device exemption (HDE).

The initial clinical site, the University of Arizona Medical Center in Tucson, AZ, has received institutional review board (IRB) approval and has executed all necessary contracts with InVivo. Surgical training will occur upon receipt of the neuro-spinal scaffold, allowing the site to then begin subject enrollment. Ali A. Baaj, M.D., assistant professor of surgery and director of the Spinal Neurosurgery Program at the University of Arizona Medical Center, is the principal investigator. In commenting about the significance of this trial, Dr. Baaj said: "Spinal cord injury research is a priority for us at the University of Arizona Spinal Neurosurgery program. We are excited to collaborate with InVivo Therapeutics on this groundbreaking clinical trial as we strive to help patients who are affected by this devastating condition."

InVivo has received IRB approval from two additional sites and expects these two sites to be open for enrollment in the second quarter. "The InVivo team has put forth a tremendous effort to bring this innovative product to the clinic," InVivo CEO Mark Perrin said. "I anticipate continued momentum as additional sites are initiated in this important study. We are dedicated to patients whose lives have been forever changed by their traumatic injury. InVivo's neuro-spinal scaffold technology may again change their lives … this time for the better."

InVivo Therapeutics Holdings Corp. is a pioneering biomaterials company with unique technologies for drug delivery with a focus on treatment of spinal cord injuries. The company was founded in 2005 with proprietary technology coinvented by Robert Langer, Sc.D., professor at Massachusetts Institute of Technology, and Joseph P. Vacanti, M.D., who is affiliated with Massachusetts General Hospital. In 2011 the company earned the David S. Apple Award from the American Spinal Injury Association for its outstanding contribution to spinal cord injury medicine. The publicly traded company is headquartered in Cambridge, Massachusetts. For more details, visit www.invivotherapeutics.com.

Ocular Therapeutix to Present New Data on Sustained Release Drug Candidates Utilizing Proprietary Hydrogel Technology at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting

Business Wire: April 28, 2014 – BEDFORD, MA, U.S.A. – Ocular Therapeutix, Inc., which is developing sustained release ophthalmic drug products using a proprietary hydrogel technology, has announced six posters will be presented at the upcoming Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting taking place at the Orange County Convention Center in Orlando, Florida, from May 4 to 8, 2014.

Details of the poster presentations at the ARVO Annual Meeting:

- In Vivo Drug Delivery of Low Solubility Drugs from Biodegradable Hydrogel Punctum Plugs. Authors: Michael McGrath; Charles D. Blizzard; Ankita Desai; Michael Bassett; Peter Jarrett, Ph.D.; Arthur Driscoll; Amarpreet Sawhney, Ph.D.
- In Vitro/In Vivo Correlation of Travoprost Release from a Biodegradable Hydrogel Punctum Plug for the Treatment of Glaucoma. Authors: Monica O'Connor; Charles D. Blizzard; Michael Bassett; Ankita Desai; Steve Takach; Doug Molla; Bill Cowe; Jennifer Wittbold; Arthur Driscoll; Amarpreet Sawhney, Ph.D.

- Pharmacodynamics of Dexamethasone Delivery from a Punctum Plug in Cataract Patients. Authors: Michael Bassett; Samuel Masket, M.D.; Thomas D. Walters, M.D.; Michael Endl, M.D.; Jeffery Levenson, M.D.; Parag Majmudar, M.D.; Deepa Mulani; Stephen Curwen; Charles D. Blizzard; Amarpreet Sawhney Ph.D.
- Safety of the Dexamethasone Punctum Plug Is Demonstrated in a Canine Toxicity Study. Authors: Charles D. Blizzard; Ankita Desai; Amarpreet Sawhney, Ph.D.; Michael McGrath; Peter Jarrett; Arthur Driscoll; Bill Cowe; Doug Molla; Monica O'Connor; Jennifer Wittbold.
- 90-Day Canine Toxicity Study Demonstrating the Safety of a Sustained Release Travoprost Punctum Plug. Authors: Monica O'Connor; Charles D. Blizzard; Michael Bassett; Steve Takach; Doug Molla; Arthur Driscoll; Amarpreet Sawhney, Ph.D.; Peter K. Jarrett, Ph.D.
- Sustained Release of Bevacizumab from Hydrogel Depots for Intravitreal Injections. Authors: Rami F. El-Hayek, Ph.D.; Amarpreet Sawhney, Ph.D.; Peter Jarrett, Ph.D.; Sarah Guedez; Courtney Rosales.

We believe that our sustained release drug candidates offer potential advantages over current topical ophthalmic medications by improving patient compliance and eliminating the peaks and valleys of treatment associated with drops administered topically. This may improve the safety profile of certain drugs and improve disease control. Ocular Therapeutix is in phase 3 clinical trials for its sustained release dexamethasone punctum plug and plans to enter phase 2b clinical trials for its travoprost punctum plugs later this year.

pSivida Reports Australia/New Zealand Distribution Agreement for ILUVIEN® for DME

Business Wire: April 28, 2014 – WATERTOWN, MA, U.S.A. – pSivida Corp. (NASDAQ: PSDV) (ASX: PVA), a leader in the development of sustained release drug delivery products for treating eye diseases, today announced that its licensee Alimera Sciences has signed an exclusive agreement with Specialised Therapeutics Australia (STA) for the distribution in Australia and New Zealand of ILUVIEN® for the treatment of diabetic macular edema (DME). Under the agreement, STA also will handle all regulatory and commercial activities for ILUVIEN in those countries.

The agreement between Alimera and STA will include a milestone payment to Alimera for achievement of a public reimbursement listing and royalties based on net sales that will increase if a sales target is met. pSivida is entitled to 20% of royalties and 33% of all other payments received by Alimera, including milestones.

"We are pleased to see this agreement for the commercialization of ILUVIEN for DME in Australia and New Zealand and the potential for patients in those countries suffering from chronic DME to be treated with ILUVIEN," said Dr. Paul Ashton, president and CEO of pSivida.

STA is a biopharmaceutical company dedicated to working with leading biotechnology and pharmaceutical companies worldwide to make specialized therapies available to people living in Australia and New Zealand. The STA therapeutic portfolio and pipeline currently encompasses oncology, hematology, ophthalmology, and infectious diseases. STA also has interests in the therapeutic areas of respiratory, dermatology, endocrinology, and central nervous system.

pSivida Corp., headquartered in Watertown, MA, develops tiny, sustained release drug delivery products designed to deliver drugs at a controlled and steady rate for months or years. pSivida is currently focused on treatment of chronic diseases of the back of the eye utilizing its core technology systems, Durasert™ and BioSilicon™, including Tethadur™. pSivida has instituted the first of two planned pivotal phase III clinical trials for its lead development product, Medidur™, an injectable sustained release micro-insert for the treatment of posterior uveitis, a chronic back-of-the-eye disease. ILUVIEN® for the treatment of chronic DME considered insufficiently responsive to available therapies, which uses the same micro-insert as Medidur and is licensed to Alimera Sciences, Inc., is marketed in the United Kingdom and Germany and has also received marketing authorization in Austria, France, Portugal, and Spain and is awaiting authorization in Italy. Alimera has filed for 10 additional EU country approvals through the Mutual Recognition Procedure. Alimera is seeking approval of ILUVIEN in the United States. An investigator-sponsored clinical trial is ongoing for an injectable, bioerodible micro-insert to treat glaucoma and ocular hypertension, a product candidate on which Pfizer Inc. has an option. pSivida's FDA-approved Retisert®, licensed to Bausch & Lomb Incorporated, provides long-term, sustained drug delivery to treat posterior uveitis.

Neos Therapeutics Announces $20 Million Loan Facility and Updated Total of $18 Million for Its Additional Series C Financing

Business Wire: April 23, 2014 – DALLAS/FORT WORTH, TX, U.S.A. – Neos Therapeutics, Inc. ("Neos" or "the company"), a highly differentiated oral drug delivery company with an exciting portfolio of proprietary technologies and a late-stage pipeline of innovative controlled release (CR) products for ADHD, announced today that it has entered into a $20 million loan facility with Hercules Technology Growth Capital, Inc. (NYSE: HTGC). The company also reported that the total amount raised in the recent additional Series C financing increased to $18 million from the $15.5 million previously announced on March 4, 2014.

The funds will support the company's efforts to obtain FDA approval of its three ADHD products, to expand the use of the proprietary controlled release technologies in the development of additional CR orally disintegrating tablet and CR liquid products, and to refinance its existing debt facility.

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"We continue to make solid progress toward our upcoming clinical and regulatory milestones in the next 12–15 months. This additional funding extends our runway beyond that period and gives us financial flexibility," stated Vipin K. Garg, Ph.D., chief executive officer of Neos. "We appreciate the support of Hercules, and their confidence in our product pipeline and management team."

"We are pleased to be a financial partner for Neos," said Chad Norman, managing director at Hercules. "With its novel drug delivery technology and late-stage ADHD drug candidates, Neos offers a portfolio of attractive products in a well-established, growing market."

Neos Therapeutics Inc., is a specialty pharmaceutical company focused on the development and manufacture of FDA approved drug products that utilize the company's proprietary and patented delivery technologies. The Neos drug products are being developed using the Dynamic Time Release Suspension® (DTRS®) and Rapidly Disintegrating Ionic Masking™ (RDIM™) technologies that deliver controlled release (CR) small-molecule active pharmaceutical ingredients (APIs) in either liquid or orally disintegrating tablet (ODT) dosage forms. By utilizing APIs that are already FDA approved, Neos can reduce development and regulatory risk and efficiently advance targeted proprietary Rx products through the FDA's New Drug Application (NDA) approval process. For more information, visit www.neostx.com.

Dynamic Time Release Suspension® and DTRS® are registered trademarks of Neos Therapeutics, LP, an affiliate of Neos Therapeutics, Inc., and Rapidly Disintegrating Ionic Masking™ and RDIM™ are trademarks of Neos Therapeutics, Inc.

Nitto: New Antifibrosis Drug with Molecular Targeting DDS Completed Phase 1a Dose Escalation

Business Wire: April 22, 2014 – OSAKA, Japan – Nitto Denko Corporation (Nitto) (TOKYO: 6988) (ISIN: JP3684000007) has been developing a new RNAi based drug for treating fibrosis in liver and other organs since 2008 in collaboration with Prof. Yoshiro Niitsu of Sapporo Medical University. In June 2013, Nitto initiated a phase 1 clinical study in the United States, and it is happy to announce that dosing in healthy volunteers has been completed. Currently, Nitto is advancing the drug to phase 1/2 clinical study in patients for the assessment of safety and efficacy.

Nitto's new antifibrotic therapy consists of siRNA that specifically inhibits the cause of fibrosis as well as a targeted lipid nanoparticle delivery system that can deliver the siRNA to the cells responsible for fibrosis. Therefore, the new drug has a dual targeting mechanism in both drug delivery and action. Furthermore, this antifibrosis therapy can be a revolutionary drug that leads to complete resolution of liver fibrosis and other organ fibrosis, which is not available so far. Nitto also obtained relevant granted intellectual properties of therapeutic modality in Japan, the United States, Europe, China, Canada, Australia, and Korea, as well as drug formulations including siRNA and DDS.

Nitto is also pursuing research activities in tissue regeneration mechanisms related to our therapeutic modality, in addition to new oncology programs, which were derived from fibrosis drug development. Those research activities are carried out with collaborations and supports from Sapporo Medical University and Hokkaido University and others.

Nitto plans to initiate phase 1/2 clinical study in the United States this year to assess safety and efficacy in patients, and expects to collaborate with a pharmaceutical company from late phase 2 stage toward approval from the agency in 2018 or after. Nitto continues to put all efforts to deliver new drugs for fibrosis and other intractable diseases to patients in need.

Definitions:

- Molecular targeting DDS: A drug delivery system that targets to a specific molecule, which enables delivering the desired amount of drug to only preferable site(s) to be delivered.
- Phase 1 clinical study: Assessment of drug safety in human.
- Phase 2 clinical study: Assessment of drug efficacy in human.

Nitto produces various products across a broad range of industries through a combination of technologies based on polymer synthesis, such as industrial tapes and electronics-related materials (e.g., optical films for LCDs.) In the medical field, Nitto has also been developing businesses related to transdermal drug delivery patches and nucleic acid synthesis. Nitto will capitalize on its experience in these areas to develop therapeutic agents in the future. Nitto will continue to create new value and businesses in the green (environmental), clean (new energy), and fine (life sciences) business domains.

OPKO Acquires Next-Generation Dry Powder Inhaler to Treat Respiratory Disorders

Business Wire: April 17, 2014 – MIAMI, FL, U.S.A. – OPKO Health, Inc. (NYSE: OPK) has entered into a definitive agreement to acquire Inspiro Medical Ltd. ("Inspiro"), an Israeli medical device company developing a new platform to deliver small-molecule drugs such as corticosteroids and beta agonists or larger molecules to treat respiratory diseases. Inspiro's Inspiromatic™ is a "smart" easy-to-use dry powder inhaler with several advantages over existing devices.

Inspiromatic™ offers improved drug deposition to the lower airways of patients and real-time data for patient compliance monitoring. The device has an internal microcontroller and flow sensor that controls the delivery of the medication and, using micro-pump technology, dispenses the drug particles at the right speed without the need for forceful inhalation. It also provides instant feedback to the patient with a green or red flasher light to indicate proper inhalation and a beeper after the dose has been delivered. For physicians, Inspiromatic™ provides a built-in logger that stores patient use data for easy access and transmission by electronic devices such as smart phones.

In a recently completed, first-in-man double-blind clinical study conducted in 30 asthmatic children comparing Inspiromatic™ to a market-leading dry powder inhaler, Inspiromatic™ demonstrated superior pulmonary delivery of the active drug.

"We are pleased to add this next-generation inhaler to OPKO's growing product portfolio," stated Phillip Frost, M.D., OPKO's CEO and chairman. "We expect this innovative device to play a valuable role in the improvement of therapy for asthma, chronic obstructive pulmonary disease, cystic fibrosis, and other respiratory diseases. We plan to use the Inspiromatic™ device to test the inhaled form of OPKO's new sulfated disaccharide drug against these disorders. This drug product is still undergoing preclinical testing prior to submission of an IND, but animal data indicates safety and efficacy for both inhaled and orally delivered forms. Of course, we believe that Inspiromatic™ can improve outcomes of treatment with other drugs, those presently available in more 'standard' type inhalers, as well as new inhalation drugs being developed. This acquisition fits our strategy of developing new products that address large markets in need of more effective therapeutic solutions."

Nimrod Kaufmann, CEO and cofounder of Inspiro, commented, "We are extremely proud of Inspiro's success in bringing our smart Inspiromatic™ respiratory drug-delivery device to market. With Inspiro now a part of OPKO, we will be able to help more people faster. Inspiro joining OPKO is a big win for the shareholders of both Inspiro and OPKO, as well as good news for our patients and physicians."

Eran Feldhay, M.D., CEO of Trendlines Medical, Inspiro's largest shareholder, added, "The acquisition of Inspiro is our third exit in eight months, all to U.S.-based multinational corporations. This success brings continuing confirmation of the strength of the Trendlines team in fulfilling our vision of creating and developing companies to improve the human condition. We are very pleased to see OPKO take the Inspiro opportunity forward."

OPKO is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development, and commercialization expertise and novel and proprietary technologies.

Inspiro Medical Ltd. is a medical device company dedicated to the development of a next-generation dry powder inhaler platform. The Inspiromatic™ dry powder inhaler, developed by Inspiro, is the first active dry powder inhaler (DPI) that delivers drugs effectively at extremely low inhalation flow rates, instructs the patient in real time, and enables efficient physician follow-up to substantially improve medication delivery and compliance.

Moberg Pharma Acquires Global Rights to Novel Topical Formulation for Treatment of Oral Pain

Business Wire: April 14, 2014 02:42 – STOCKHOLM, Sweden – Moberg Pharma AB (OMX: MOB) (STO: MOB) announced that the company has entered into a definitive agreement with Oracain II Aps (Denmark) to acquire all assets and global rights to a novel and patent pending oral formulation of the proven substance bupivacaine, for the treatment of pain in the oral cavity. The initial target indication is pain management for patients suffering from oral mucositis during cancer therapy.

Oracain has generated promising clinical data supporting safety and efficacy in several pilot studies—most importantly that the novel lozenge formulation provides significantly longer and better pain relief than currently available nonopioid treatment alternatives for patients with oral mucositis. Moberg Pharma plans to gain additional efficacy data through a phase II study during this year, to be followed by pivotal studies and registration.

Under the terms of the agreement, Oracain is entitled to an upfront payment of 1 MSEK, additional 5 MSEK after successful phase II data have been generated and a share of future revenues after such revenues have exceeded Moberg's accumulated development costs incurred prior to launch. The acquisition and cost for the phase II study are financed through available cash resources.

Moberg Pharma plans to pursue several routes to generate near term revenues from the product, including through licensing marketing rights to partners in select territories after completion of phase II as well as through sales for compassionate use for individual patients. Since there is a pressing unmet medical need for pain relief in oral mucositis, the product can be supplied for such compassionate use in certain markets prior to regulatory approval. Moberg Pharma will also examine the possibility for orphan drug status, in the United States as well as in EU.

Furthermore, Moberg Pharma has identified several additional potential indications for the product beyond oral mucositis, both in the acute and chronic setting, such as Sjögren's syndrome, burning mouth syndrome, endoscopic procedures, oral intubations, and also long-term OTC use. The company estimates the peak sales potential of the product to $50–100 million assuming successful commercialization in oral mucositis and at least one additional indication.

"We are excited of the opportunity to create a best-in-class product for a pressing medical need and to make it available to patients within the next few years. Oral mucositis is a debilitating side effect of cancer therapy. Oracain's clinical data is highly promising and indicates a potential to provide better and longer pain relief to patients. The acquisition is in line with our strategy of providing niche products that can create significant value based on proven molecules with limited development cost,

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risk, and time to market," said Peter Wolpert, CEO of Moberg Pharma AB.

"Years of clinical practice in oral mucositis—and frustration of inadequate treatments for patients suffering severe and disabling mouth pain—were the driving forces behind our innovation. We are excited to partner with Moberg Pharma, who has the capabilities to bring this important medical innovation to practical use and benefit for patients. The scientific team of Oracain is fully dedicated to support the continued development," said Ove Andersen, chairman of Oracain and inventor.

Oral mucositis (OM) is a painful inflammation and ulceration of the mucous membranes lining the mouth. OM is a common and often debilitating complication of cancer treatment, which affects 80% of patients with head and neck cancer receiving radiotherapy, almost all patients undergoing bone marrow transplantation, and a wide range of patients receiving chemotherapy. OM makes the patient less likely to comply with their cancer treatment, increases mortality and morbidity, and contributes to rising health care costs. In the United States, every year approximately 400,000 patients suffer from OM during cancer therapy.

The technology encompasses novel lozenge formulations of bupivacaine, a local anesthetic with a well-established long-acting effect, currently available on the market for other indications as an injectable. The original innovation came out of work by clinicians at Hvidovre Hospital, Copenhagen, Denmark, facilitated by XOventure GmbH and SEED Capital Denmark.

Moberg Pharma AB (publ) is a rapidly growing Swedish pharmaceutical company with a direct sales and marketing organization in the United States and an extensive distributor network in more than 40 countries. The company's OTC portfolio includes the brands Kerasal®, Jointflex®, Kerasal Nail™, Domeboro®, Vanquish®, Fergon®, and Kaprolac®. Kerasal Nail™ (Nalox™ in certain ex-U.S. markets) is the leading product for the treatment of nail disorders in the U.S. and Nordic markets. The current portfolio will be supplemented by the acquisition and in-licensing of additional products as well as product development with a focus on innovative drug delivery of proven compounds. Moberg Pharma has offices in Stockholm and New Jersey, and the company's shares (OMX: MOB) are listed on the Small Cap list of the NASDAQ OMX Nordic Exchange Stockholm. For further information, please visit www.mobergpharma.com.

Novaliq GmbH Announces Launch of a Phase 1 Study Following U.S. and European Patent Approval of CyclASol® (Cyclosporin) Eye Drops

Business Wire: April 3, 2014 – HEIDELBERG, Germany – Novaliq GmbH today announced the commencement of a phase 1 study for CyclASol (cyclosporin solution) following U.S. and European patent approval of the solution for the treatment of dry eye syndrome.

While conventional cyclosporin formulations are emulsions, CyclASol is the first and only 0.05% clear cyclosporin solution. CyclASol is available in multidose and preservative-free bottles for the treatment of dry eye syndrome. CyclASol has demonstrated long-term stability plus superior wettability, pharmacokinetics, and biocompatibility compared to conventional emulsions.

CyclASol was developed from Novaliq's broad range semifluorinated alkane (SFA) drug delivery platform EyeSol®, offering significant competitive advantages for multiple drug candidates within ophthalmology, primarily by enhancing the therapeutic effect of poorly soluble drugs.

"We are pleased to receive the U.S. and European patent and to announce the start of phase 1 CyclASol study," said Bernhard Günther, CEO of Novaliq GmbH. "These are both significant new milestones for Novaliq as we build our innovative drug delivery portfolio." In 2013 Novaliq finalized their fifth round of financing for €13.9 million ($18.1 million) with the intent to strengthen both their prescription and OTC product development programs based on SFA technology.

"We congratulate Novaliq on obtaining patent approval for CyclASol and start of their clinical trials," commented Mathias Hothum, managing director of Dievini Hopp BioTech Holding GmbH & Co. KG, the investment company of SAP cofounder Dietmar Hopp. "We are pleased to support Novaliq as it pioneers new topical ocular drug delivery technology. We endorse Novaliq's strategy to establish a portfolio of consumer and prescription product portfolios within ophthalmology. These products are intended to cover unmet needs with one major advantage being they will be preservative-free," Mathias Hothum added.

Novaliq is a drug delivery company whose goal is to develop innovative pharmaceutical formulations. Its patented semifluorinated alkanes (SFAs) can be used in various routes of administration for the transport of drugs or oxygen for therapeutic purposes. Novaliq currently develops innovative ophthalmic formulations as well as solutions for organ preservation and has several product candidates with excellent market potential in various stages of development. Novaliq welcomes invitations from interested parties to enter into discussions about significant additional development or partnership opportunities.

March

Baxter Announces Plans to Create Two Separate Leading Global Healthcare Companies

Business Wire: March 27, 2014 – DEERFIELD, IL, U.S.A. – Baxter International Inc. (NYSE: BAX) today announced plans to create two separate independent global healthcare companies—one focused on developing and marketing innovative biopharmaceuticals and the other on life-saving medical products. Both will be global leaders in their respective markets.

Baxter has positioned both businesses to be successful, profitable, and sustainable independent companies, and this decision reflects further evolution of Baxter's multifaceted strategies emphasizing a commitment to innovation and operational excellence. To date, this has led to the development of a robust pipeline of novel and cost-effective therapies and numerous in-licensing collaborations within the biopharmaceuticals business, and the medical products portfolio was recently bolstered by the acquisition of Gambro AB, a global provider and leader of dialysis products, providing a number of longer-term growth opportunities as well as significant commercial and cost synergies.

"Baxter has an established history of executing successful spinoffs, and we have continued to evaluate the separation of these two businesses in response to diverging business dynamics and the rapidly changing macro-environment," said Robert L. Parkinson, Jr., chairman and chief executive officer. "This decision underscores Baxter's commitment to ensuring its long-term strategic priorities remain aligned with shareholders' best interests, while improving our competitive position and performance, enhancing operational, commercial, and scientific effectiveness and creating value for patients, healthcare providers, and other key stakeholders."

The two businesses operate in distinct markets with corresponding underlying fundamentals, and each possesses unique and compelling growth prospects, investment requirements, and risk profiles. The spinoff will create two well-capitalized independent companies with strong balance sheets, investment grade profiles, and disciplined approaches to capital allocation. In addition, Baxter believes that the separation will result in other material benefits to the stand-alone companies, including:

- Greater management focus on the distinct businesses of biopharmaceuticals and medical products
- Ability to more effectively commercialize new and existing product offerings
- Ability to drive innovation across the franchises and allocate necessary resources to the areas presenting the highest growth potential
- Flexibility to pursue respective growth and investment strategies resulting in revenue acceleration, improved profitability, and enhanced returns

The biopharmaceuticals business, with 2013 annual revenues of approximately $6 billion, consists of a diverse portfolio of recombinant and plasma-based proteins to treat hemophilia and other bleeding disorders, and plasma-based therapies to treat immune deficiencies, alpha-1 antitrypsin deficiency, burns and shock, and other chronic and acute blood-related conditions. This business's strategy is aimed at improving diagnosis, treatment, and standards of care across a wide range of bleeding disorders and chronic diseases, enhancing capacity to meet growing demand for biotherapeutics, leveraging expertise into new emerging therapeutics through acquisitions and collaborations, and developing a robust new product pipeline focused on new and effective treatments that address unmet medical needs.

"Today's news represents a significant milestone that will result in material benefits for key stakeholders," said Ludwig N. Hantson, Ph.D., president, BioScience. "We are confident that this decision not only strengthens our outlook, it positions us well to execute on our future growth prospects, new product pipeline, and other opportunities as we enter a new era in the journey to achieve our aspiration as a premier biopharmaceuticals company."

The medical products business, with 2013 annual sales of more than $9 billion, offers a broad portfolio of intravenous (IV) solutions and nutritional therapies, drug delivery systems and administration sets, premixed and other injectable drugs, as well as inhalation anesthetics and hospital-based biosurgery products. This business is also integrating the Gambro AB acquisition, which complements Baxter's existing renal therapies franchise and provides customers a comprehensive portfolio of products and services to treat end-stage renal disease across the full continuum of care. The medical products company will focus on strengthening its market leadership through geographic expansion and increased penetration, leveraging its extensive hospital presence and global footprint, developing comprehensive solutions to improve patient outcomes and safety, and enhancing profitability through a more streamlined and flexible cost structure.

The corporate headquarters of both companies will be located in northern Illinois. Robert L. Parkinson, Jr., will serve as chairman and chief executive officer of the medical products company, which will retain the Baxter International name. Ludwig N. Hantson, Ph.D., who currently serves as president, BioScience, will be named chief executive officer of the new biopharmaceuticals company, which will be named at a later date. Hantson joined Baxter in 2010 from Novartis Pharmaceuticals Corporation, where he served in a number of roles of increasing responsibility, the most recent of which was chief executive officer, Pharma North America. Prior to Novartis, Hantson spent 13 years at Johnson & Johnson. Wayne T. Hockmeyer, Ph.D., who joined Baxter's board in 2007, has agreed to serve as nonexecutive chairman of the board of the new biopharmaceuticals company. Dr. Hockmeyer founded MedImmune, Inc., and served as its chairman and chief executive officer.

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Preceres LLC Formed to Develop Technologies to Support Breakthrough Agricultural Biological Products

Business Wire: March 24, 2014 – CAMBRIDGE, MA, U.S.A. – Monsanto announced today the creation of Preceres LLC with founders Daniel Anderson, Ph.D., associate professor in the Department of Chemical Engineering and the Institute of Medical Engineering and Science at MIT and intramural member of the Koch Institute for Integrative Cancer Research, and Arturo Vegas, Ph.D., research associate at MIT. Under the terms of the agreement, Preceres LLC will have access to technology licensed from MIT to develop delivery agents to support the development of innovative biological solutions for farmers.

"The technology from MIT is centered on developing new materials for medicine," said Anderson. "Working with Monsanto gives Preceres a unique opportunity to showcase methods developed to allow rapid synthesis, formulation, analysis, and biological testing of large libraries of biomaterials for use in medical devices, cell therapy, and drug delivery and apply them in a global agricultural context. Through this work we hope to demonstrate the broad applicability of our platform and the ability to apply our scientific discoveries to a critically important area of research."

The combined use of Preceres's novel delivery discovery assets with Monsanto's BioDirect™ technology has the potential to provide new biological options for sustainable pest, virus, and weed control.

"The goal of Preceres is to help create highly specific biological control of damaging pests to improve and protect crop yields," added Roger Wiegand, CEO of Preceres.

This announcement is an investment supported by Monsanto's corporate venture group, Monsanto Growth Ventures. Financial terms were not disclosed.

"Monsanto is known for a long history of innovation, but part of our commitment to bringing new technologies to agriculture is also recognizing other innovators we can work with to deliver solutions for our farmer customers," said Steve Padgette, Monsanto R&D investment strategy lead. "That's why we look forward to working with the team through this new collaboration, which will complement our own research capabilities and other collaborations in this important space. We have the potential to cocreate products that are very precise and specific in how they work, which is consistent with our vision to create products that enable our customers to produce more in an environmentally sustainable way."

The newly created company, Preceres LLC, is a delivery company focused on agriculture biologicals, harnessing cutting-edge research of MIT founders Daniel Anderson Ph.D., and Arturo Vegas, Ph.D. Preceres LLC has a world-class board of managers with Daniel Anderson (MIT), Robert Langer (MIT), Stephen Padgette (Monsanto), Robert McCarroll (Monsanto), Jacqueline Heard (Monsanto), and Roger Wiegand (Preceres). To learn more, visit www.Preceres.com.

EffRx Pharmaceuticals and Kadmon Corporation Announce Global Collaboration

Business Wire: March 18, 2014 – ZURICH, Switzerland, and NEW YORK, NY, U.S.A. – EffRx Pharmaceuticals SA, a leader in innovative drug delivery technologies that improve efficacy and tolerability of existing compounds, has established a worldwide collaboration with Kadmon Corporation, LLC, a global biopharmaceutical company, under which EffRx will generate effervescent formulations of products to be developed by Kadmon in both adult and pediatric orphan indications. Financial terms of the agreement were not disclosed.

"Our collaboration with Kadmon, a world-class biopharmaceutical company, further validates our thesis that there is an acute need for alternative drug delivery methods. Our effervescent technology is an innovative delivery option that provides patients with convenience and reduces pill burden," said Christer Rosen, EffRx chairman and chief executive officer.

"Alternative drug delivery strategies can be an important part of treatment success," said Samuel D. Waksal, Ph.D., Kadmon chairman and chief executive officer. "We are excited to partner with EffRx to develop formulations of certain therapies aimed at adult and pediatric orphan indications, with the goal of designing treatments that are more tolerable and ensure better treatment compliance. We look forward to describing these programs in detail as they approach the commercial setting."

EffRx Pharmaceuticals is an innovative specialty pharmaceutical company that exploits its proprietary technology platform to create novel therapeutic entities. EffRx strives to make existing good medicines better and thereby improve the quality of life of patients. EffRx targets improvements to leading medications, focused on tolerability, absorption, compliance, and convenience, thus creating best-in-class products. It also has established its proprietary pipeline in metabolic bone disease and pediatric medications. EffRx is currently partnering with pharmaceutical companies to create life cycle management opportunities in their portfolios.

Kadmon Corporation, LLC, is a global company built on a 21st-century paradigm for the translation of innovative science into treatment. The company currently offers products and services for the treatment and management of liver diseases, and is pioneering novel medicines in areas of other serious disease, including oncology, infectious diseases, immunology, and neurodegenerative diseases. Emphasizing emerging concepts in molecular biology and genomics, Kadmon is developing treatments and treatment combinations that target the metabolomics and signaling pathways associated with disease, with the goal of addressing some of today's most pressing areas of unmet medical need. ■

Controlled Release Society
3340 Pilot Knob Road
St. Paul, MN 55121
United States of America

Calendar of Events

2014

IWPCPS-16
June 16–19
Prague, Czech Republic
www.assainternational.com/workshops/iwpcps-16

41st Annual Meeting & Exposition of the Controlled Release Society
July 13–16
Chicago, IL, U.S.A.
controlledreleasesociety.org

***In Vivo* Predictive Dissolution Conference**
August 4–6
Ann Arbor, MI, U.S.A.
https://pharmacy.umich.edu/invivodissolution

17th International Pharmaceutical Technology Symposium
September 8–10
Antalya, Turkey
www.ipts-hacettepe.org

Third Symposium on Innovative Polymers for Controlled Delivery
September 16–19
Suzhou, China
www.sipcd.cn

Formulation & Drug Delivery Congress 2014
October 2–3
London, United Kingdom
www.formulation-congress.com

Animal Health Drug R&D: Formulation, Delivery & Development to Market
Sponsored by CRS
November 1–2
San Diego, CA, U.S.A.
controlledreleasesociety.org/AnimalHealth