



Newsletter

A publication of the Controlled Release Society

Volume 28 • Number 5 • 2011

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Editor



Yvonne Perrie
Editor



Rod Walker
Editor

CRS Newsletter

Delivering Bioactives

Vol. 28 • No. 5 • 2011

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

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*Chuck Frey
Coating Place, Inc.
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Inspiration

The recent death of Steve Jobs of Apple Computer raised a feeling of sadness and cause to reflect on his influence. My thoughts took me back to my entrance into college carrying a slide rule and typing on a mechanical typewriter. A calculator replaced the slide rule by day two of class.

I started my first job just as my employer purchased seven Apple II computers. The purpose for these computers was yet unknown, but my first project involved developing for one. With an A/D converter, we were soon collecting and reducing real-time chromatographic data. Although successful, unrelated commercially available data systems soon became available and were employed by the lab.

About this same time, word processors were replacing typewriters and making their way to scientists. Management fought this to avoid relegating secretarial tasks to scientists – who, they argued, should be doing science. The word processor and its descendants were eventually accepted as tools for the scientist, and both scientific and secretarial duties morphed to improve efficiency.

Computer technology was often justified as a means to more personal free time. And it did free up time, time to do other tasks and move things along more quickly. The pace picked up and we developed the concept of multitasking, exercising the mind's (and the computer's) ability to quickly jump from task to task – juggling thoughts and filling in gaps. Many people have become quite adept at this, sometimes at the expense of memory. Information may not pass into long-term memory when we focus on it for so little time. Subsequently, we employ computers to maintain our memory and we push computers and possibly our minds to new limits.

And when we consider the current technology used in phones, it is hard to imagine Alexander Graham Bell with a vision of the iPhone, since he saw minimal value in his basic invention.

Each step extends our world to a hazy view of a new horizon. Perhaps Steve Jobs had a clear view of the hi-tech future. His ability to steer Apple in the early years and bring her back on course after his absence was amazing. Not only did he have vision, he shared it with us.

Steve Jobs was an inspiration to many. I expect he encountered opposition, an obstacle most visionaries deal with; their ideas are often counter to popular opinion. But he persevered, and if a majority of the developed world realized a sense of loss at his passing as I did, it was a remarkable life. He has taught us a great deal about motivation, optimism, and enthusiasm, and I expect he did much of it by just doing what he learned to love. Some words from an unknown author seem fitting: "A great teacher never strives to explain his vision – he simply invites you to stand beside him and see for yourself."

Enjoy this issue of the Newsletter. As you read, consider your mission, the mission of your affiliation, and the mission of the CRS: "CRS is the international, multidisciplinary society dedicated to delivery science and technology." Take note of CRS leadership efforts, the commitment to maintain and grow the society to its full potential, and the scientific work and ideas that are shared.

And when you finish reading this issue, consider your vision for the future of the CRS. Hopefully, it is a vision of a bright future and you are engaged in a positive way. ■



*Martyn C. Davies
University of Nottingham
Nottingham, United Kingdom*

It is with great pleasure that I write to you in this newsletter as the new President of CRS. It is a great honour for me to hold the office and it is not without more than a hint of trepidation that I follow my esteemed colleagues in this role. This is a remarkably diverse, multidisciplinary and global society and it is a great privilege to serve this community.

One of my first tasks as President must be to recognise those in the leadership who have done so much for us as a CRS community in the previous year. I want to give a big thank-you on behalf of the membership to Mark Tracy, who has led the CRS with great vision and worked tirelessly to ensure that new initiatives such as the change in governance structure were skilfully implemented during his tenure. I have worked closely with Mark to ensure a smooth transition for the coming year and we are fortunate to have his wisdom and help on the Board for the coming year. This summer also saw the end of Ijeoma Uchegbu's distinguished reign as Scientific Secretary and I wish to recognise her outstanding commitment to the role ensuring the highest scientific quality at our meetings and operations. Great job, Ijeoma.

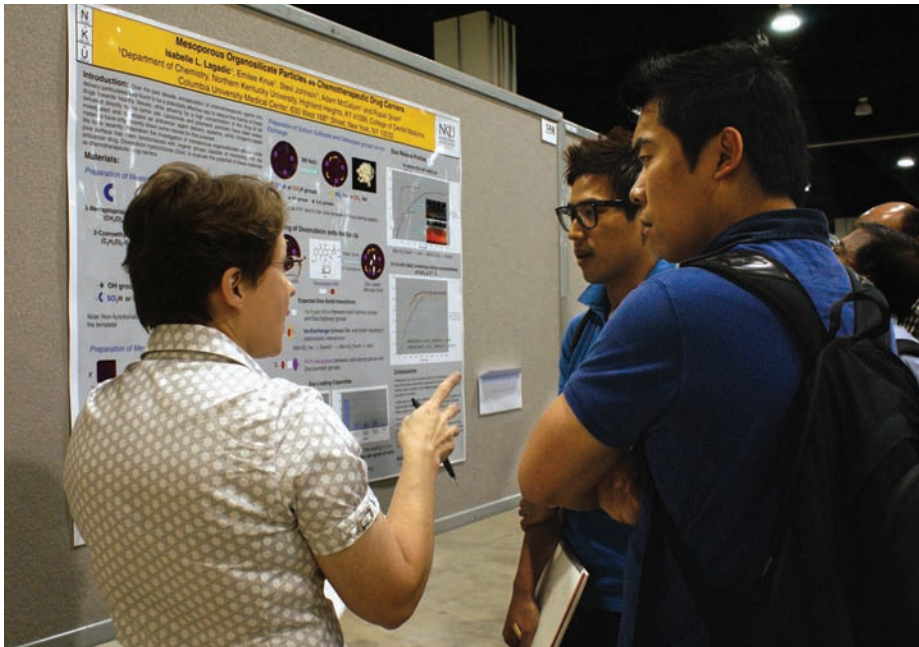
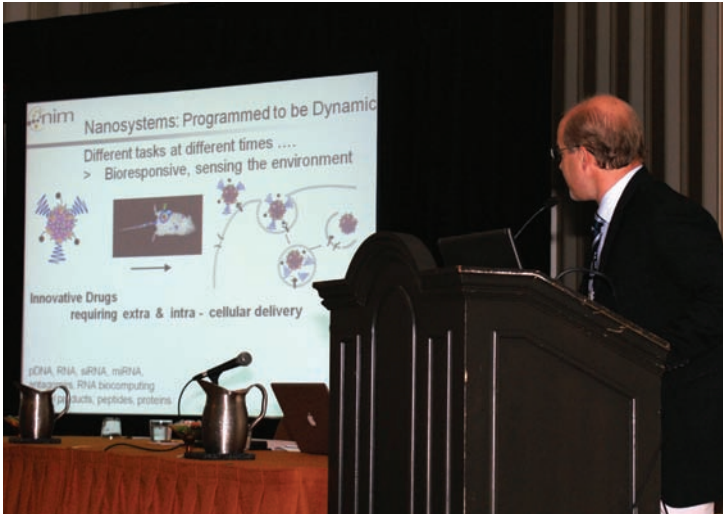
We also welcome new volunteers to the new expanded CRS Board, with Ian Tucker serving as the Board Secretary this year and Padma Devarajan, Marilyn Martinez, Tamara Minko, and Tom Redelmeier as new Members-at-Large.

There is an important year ahead of us as we continue to build on the successes of the last few years in growing our society and helping to improve the services that we provide to our membership. For example, this year will bring the growth of new website operations that will place it at the centre of our activities, including an expanded webinar series. The coming months will also see the creation of a task force lead by Immediate Past President Mark Tracy to review all aspects of the CRS Annual Meeting & Exposition to maximise the experience for all attendees. Many volunteers across the society are committing their time to a number of other initiatives during this year and I look forward to highlighting these in future editions of the newsletter.

There is no doubt that this is a difficult period for our industry, with uncertain financial markets worldwide. I hope we as a collective community make our contribution to the recovery through our activities. I hope you feel that you can make your mark within this society. We are looking for volunteers to join our committees. If you are interested, please contact Susan Kohn, our Executive Director, at skohn@scisoc.org. ■

Highlights of the 38th CRS Annual Meeting & Exposition





Five Hot Days of Delivery Science

Who knew delivery science could be so hot? It wasn't just the extreme temperatures and mugginess of National Harbor that kept meeting attendees indoors, as the science this year was top-notch, with 483 poster and 201 podium presentations on a multitude of hot topics including siRNA, CNS, quality by design, nanoparticles/nanopolymers, poorly soluble drugs, and more.

Attendees visited the registration desk early Saturday to "make it a weekend" and hurry to their workshops, covering CNS Drug Delivery or an introduction to encapsulation and controlled release technologies. Young Scientists joined the meeting Saturday to understand siRNA in the popular workshop, and all workshop attendees gathered to enjoy lunch and network mid-day. Many workshops continued Sunday, and young scientists were inspired by Teresa Virgallito and Buket Aksu through the professional and self development workshop starting that day.



CRS Annual Meeting attendees gather after receiving their registration materials and make their plans for the first day of the meeting.

Sunday also marked the second annual CRS Innovation Sunday, which was just as successful as the inaugural event in bringing together programming and speakers to instruct and inspire scientists to bring the best ideas to market. The Releasing Technology Workshops featured companies showcasing their latest and greatest. The Soapbox Sessions played to a packed room and were fast-paced and lively, featuring the best of the best of new technologies, ending in a buzz of one-on-one sessions and great new connections. The Industry Roundtable presenters from Novartis, Pfizer, and Johnson & Johnson shared what trends the industry is following and what they need from delivery scientists.

The Nanomedicine Product Development Summit was full as meeting attendees participated in panel discussions with leaders in the development, regulatory review, and commercialization of nanoparticle-based systems for the delivery of small molecules and siRNA. Sunday also marked the first chance for meeting

attendees to connect through CRS Partnering, a unique opportunity to collaborate with fellow scientists and meet with industry. The day ended with the Exposition Opening and Welcome Reception, filled with many reunions, wonderful food, the time to connect with fellow scientists, and exhibitors pleased to share their latest products and services.



CRS members and other attendees are welcomed to the 38th Annual Meeting during the Exposition Opening and Welcome Reception.

Excellent programming continued on Monday, with many attendees getting up to get educated about "Clearing the Nanotoxicity Hurdle." This was followed by the President Mark Tracy welcoming attendees and honoring award winners during the Opening Session, where award winners Mauro Ferrari and Molly Stevens shared their honorable work. The morning continued with top-notch science, including the very popular and interactive mini-symposia Application of Quality by Design



(L-R) Marcus Brewster, Johnson & Johnson; Anand Subramony, Novartis Institutes for BioMedical Research, Inc.; and Julia Rashba-Step, Pfizer BioTherapeutics R&D give their insights into industry's needs during the Industry Roundtable.

(QbD) to Development of Pediatric Formulations and Dosage Forms.

This year's Women in Science Luncheon provided excellent insight into the challenges of working in delivery science, while the Young Scientist Roundtable provided early career scientists information on peer review – working to create our next generation of *Journal of Controlled Release* and *Drug Delivery and Translational Research* reviewers! Monday came to a close with excellent opportunities to meet with colleagues – the Vet Get Together provided an entertaining presentation from Michael Rathbone, and the sold-out Young Scientist Networking Event Cruise provided a bounty of desserts and beautiful evening sights from the Potomac.



Leading women scientists took the chance to network and hear from speaker Sujuan Ba, National Foundation for Cancer Research, during the Women in Science Forum Luncheon.

Plenary speakers provided excellent insight throughout the meeting, with sessions Monday through Wednesday ranging from immunization policy to continual processing. Attendees were treated to additional insight from the plenary speakers with the new, intimate plenary panel discussions.

Additional networking opportunities for the young scientists came Tuesday with the Mentor/Protégé Meet and Greet, pairing experienced scientists with those new to the profession. All attendees had the chance to learn from one another during the busy poster sessions and the excellent networking held in the halls, restaurants, and night clubs of the Gaylord National Harbor. Many attendees took advantage of the new CRS Central to meet with one another and learn about the society.

Beyond CRS Central, CRS had much “new” to talk about at the meeting. This year's meeting was timed along with the launch of the new CRS website, which is now easier to navigate, letting users quickly find the science or colleagues they are seeking. The LATTE database – Linking Academic Technologies and Techniques to Everyone – was also launched just in time for attendees to start signing up. The new CRS book – “Controlled Pulmonary Drug Delivery” – debuted at the meeting at the



The Mentor/Protégé Meet and Greet provided excellent opportunities for young scientists to meet with and learn from more experienced delivery scientists.

Springer exhibit, available for purchase with a 25% CRS member discount. Issues of the new journal *Drug Delivery and Translational Research* (DDTR) were also available, along with all the other “new” CRS is bringing you. If you haven't seen any of these new offerings from CRS, be sure to check them all out on the new website!



The new book “Controlled Pulmonary Drug Delivery” premiered at this year's annual meeting. This first in the CRS series is available at a discount to CRS members.

The 2011 Annual Meeting & Exposition will be remembered as a success; it was a great combination of breakthrough science and connections of colleagues. Now is the time to keep things hot – use the research and findings from the meeting to elevate your work, and rely on CRS year-round as the place to find answers, link to experts, and enhance your career. And plan on saying “Bonjour” to CRS at the 2012 Annual Meeting in Québec! ■

The Controlled Release Society Thanks the Sponsors of the 38th Annual Meeting & Exposition



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Thank You to the Exhibitors of the 38th Annual Meeting & Exposition of the Controlled Release Society!

These exhibitors offered their latest products, services, and technologies that are integral to the work of CRS members during the 2011 meeting in National Harbor.

2011 CRS Exhibitors

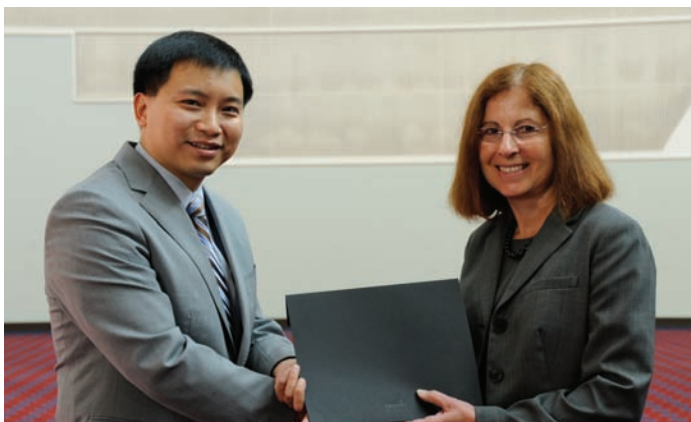
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On to Québec!

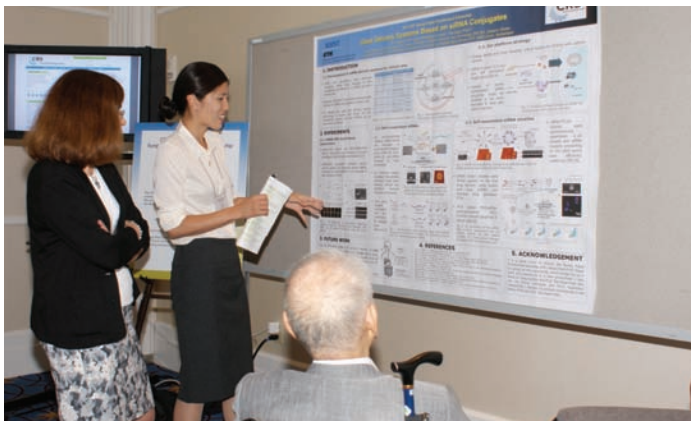
For 2012 exhibit materials, please visit www.controlledreleasesociety.org/meetings/annual/Pages/2012Exposition.aspx or contact Debby Woodard at +1.651.994.3817 or dwoodard@scisoc.org.

CRS Foundation—Supporting the Scientific Training of the Society’s Future Leadership

CRS Foundation fellowships are designed to identify, support, and acknowledge the next leaders of CRS. The goal of the fellowship is to accelerate the selected candidates in their careers in delivery science while carrying out the Foundation’s mission of providing a durable source of financial support for the advancement of educational and organizational activities that enrich and extend controlled release research and development. The foundation fellowships are given to individuals who demonstrate scientific excellence, scholarship, motivation, and leadership potential. ■



2010 Jorge Heller Postdoctoral Fellowship award winner Qun Wang (left) with Susan Cady, CRS Foundation Board Chair.



2011 Tsuneji Nagai Postdoctoral Fellowship award winner Soo Hyeon Lee (center) shares her research and poster with Susan Cady, CRS Foundation Board Chair (left) and Professor Tsuneji Nagai, whom the 2011 Fellowship Award honors (right).

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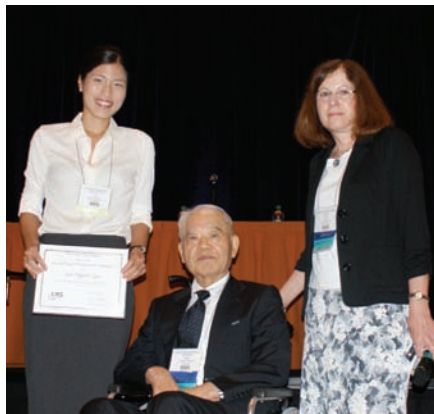
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The future fellowship award will honor CRS and delivery science leader Sung Wan Kim.

Two CRS Foundation Postdoctoral Fellowships Honored and Recognized at the 2011 CRS Annual Meeting & Exposition

Soo Hyeon Lee Honored with the Tsuneji Nagai Postdoctoral Fellowship 2011



Soo Hyeon Lee (left) with Professor Nagai (center) and Susan Cady (right), CRS Foundation Chair, after receiving the Tsuneji Nagai Postdoctoral Fellowship.

The Tsuneji Nagai Postdoctoral Fellowship was presented to Soo Hyeon Lee during the Tuesday morning Plenary Session at the 38th CRS Annual Meeting & Exposition. She graciously thanked Professor Nagai and the CRS Foundation for being honored with this prestigious award. Soo Hyeon Lee also conversed with meeting

attendees in CRS Central to discuss her anticipated fellowship year and use of the \$30,000 award.

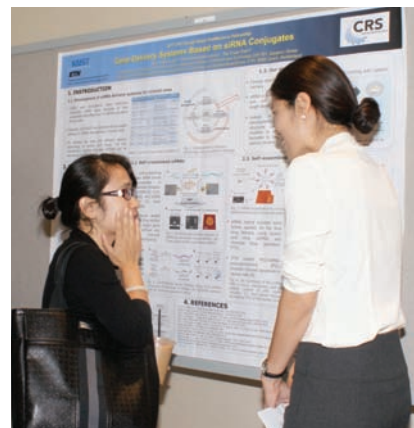
“The works of Professor Nagai have influenced so many students and scientists, including myself. Receiving this fellowship is a wonderful source of motivation: it boosts me to reach Professor Nagai’s level of expertise and build up scientific experiences by joining the group of Professor Leroux at ETH Zurich.”

After receiving her B.S. degree and a combined master’s and doctoral degree in biology from Korea Advanced Institute of Science and Technology (KAIST, South Korea), one of the leading universities in South Korea, Soo Hyeon Lee completed her Ph.D. studies under the supervision of the late Professor Tai Gwan Park. In her doctoral work, she developed an efficient siRNA delivery system by using novel siRNA-polymer conjugates. The coinventor of three patents in the United States and Korea, Soo Hyeon Lee has also published 25 papers in high-profile journals such as *Journal of Controlled Release* and *Biomaterials* and participated in several international conferences and symposia. She was also awarded the 3rd and 1st prizes for the poster presentation from the Roche Marco Polo Symposium in 2008 and 2009, respectively, and 1st prize from Bioneer Award in KAIST for contribution to academic-industrial cooperation with international patents (2010).

Until May of 2011, Soo Hyeon Lee was a postdoctoral fellow in the laboratory of Professor Tae Gwan Park. Beginning August 2011, she will join the group of Professor Jean-Christophe Leroux at ETH Zurich as a postdoctoral fellow. Soo Hyeon Lee’s research interests mainly focus on the design of polymer-based delivery systems for nucleic acid drugs and her fellowship year will be focused on the unique opportunity to diversify

knowledge on gastrointestinal diseases, pharmacology, and chemical synthesis.

Soo Hyeon Lee has great ambition to become a leading scientist in the field of drug formulation and biomaterials. With that ambition, she aspires to implement a strong research program bridging fundamental research to clinical applications and one day to contribute to the development of a product which will reach the clinical phase. Soo Hyeon Lee’s ultimate goal as a pharmaceutical scientist is to improve human health and become a leader in biomedical sciences.



Soo Hyeon Lee (right) discusses her research poster with an attendee in CRS Central at the 2011 CRS Annual Meeting & Exposition.

Qun Wang Presents Summary of his 2010 CRS Foundation Fellowship Year



Qun Wang presents a summary of his fellowship year during the Tuesday morning Plenary Session at the 2011 CRS Annual Meeting.

In 2010, Qun Wang was presented with the prestigious Jorge Heller Postdoctoral Fellowship and was welcomed back by the CRS Foundation to the 2011 CRS Annual Meeting & Exposition to present a summary addressing his fellowship year. During his presentation, Qun Wang discussed his fellowship year working in Professor Robert Langer’s laboratory at MIT and Harvard Medical School where his research involved using intestinal stem cells to treat colorectal cancer. He also thanked CRS, the CRS

Foundation, and his colleagues and advisors at MIT and Harvard for his successful fellowship year.

“To me, the Jorge Heller Postdoctoral Fellowship is more than financial support. It gives me a chance to get top level postdoctoral training at a top institution, thus augment my perspective and enrich my future career in academia. It’s my starting point to become a future leader in Controlled Release Society. Definitely, the Jorge Heller Postdoctoral Fellowship is changing my life.” ■

How Coatings of Silica Nanoparticles Improve the Performance of Lipid Based Encapsulation and Delivery Systems

Clive A. Prestidge^{1,*}, Spomenka Simovic¹, Nasrin Ghouchi Eskandar¹, Timothy J. Barnes², and Angel Tan¹

Introduction

Many commercial products (e.g., agrochemicals, paints, household products, foods, pharmaceuticals and cosmetics) contain active ingredients in lipid-based colloidal carriers. For example, emulsions, lipid nanoparticles, micelles, liquid crystals and liposomes are attractive as encapsulation and delivery systems for both oil- and water-soluble molecules (1). A challenge for the formulation scientist in optimizing such lipid-based carriers is to enhance their shelf lives and carrier performance without utilizing large quantities of surfactants that may have detrimental human toxicological and environmental concerns (2). More specifically, the following challenges need to be overcome if effective products are to be developed from lipid colloids:

- Non-ideal physical stability, i.e., aggregation, creaming and coalescence
- Stabilisation requires high levels of surfactant or polymer; these may be poorly tolerated for human use and add significant cost
- Release from colloidal lipids is typically diffusion-controlled and can be relatively fast, particularly in sink conditions
- Limited protection of encapsulated active ingredient against chemical degradation.

Interfacial engineering is required to minimize physical instabilities and reduce non-ideal delivery performance.

It is hypothesized that nanoparticles (either inorganic or organic) may be used to replace commonly used surfactants to produce lipid formulations with superior performance in a cost effective fashion. In this article, we demonstrate the effects of encapsulation of emulsion droplets and liposomes with hydrophilic silica nanoparticle layers on their physicochemical properties, *in vitro* performance and *in vivo* delivery of active agents. In addition, we show that novel silica-lipid hybrid materials are produced on drying nanoparticle coated liposomes and emulsions and these have enhanced encapsulation and delivery performance (Figure 1).

Nanoparticle Coatings on Emulsions and Liposomes

The formation and stability of silica nanoparticle-stabilised emulsions have been extensively characterised (3,4), but much less research has focused on nanoparticle-stabilised liposomes (5,6) or other colloidal lipid systems.

Typically, nanoparticle layers form around droplets or liposomes by self-assembly, e.g., electrostatic, hydrogen bonding or hydration effects provide the driving force for interfacial adsorption (4). For triglyceride oil-in-water emulsions, the emulsifier plays a key role in nanoparticle coating, e.g., oleylamine provides a strong electrostatic interaction and highly structured silica nanoparticle layers (7). Salt addition plays an important role in controlling the adsorbed nanoparticle layer structure and packing density (4). In addition, the nanoparticles can be incorporated from both aqueous or lipid phase and this may also influence the interfacial structure and formulation performance (7,8). The type of silica nanoparticles (e.g., Aerosil® or Ludox®) also influences the properties of the hybrid carrier.

Nanoparticle coated emulsions and liposomes can be dried using either spray drying, freeze drying or phase coacervation to create novel hybrid nanomaterials (Figure 1) (9–15). In addition to enabling the transformation of wet lipid colloids into preferable long-term stable storage powdered delivery forms, these silica lipid hybrid (SLH) nanocapsules or microcapsules may have specific encapsulation and delivery properties (see below).

Nanoparticle Coatings Influencing Molecular Transport

Silica nanoparticle layers have been shown to significantly influence molecular transport across the emulsion droplet-water (16,17) and liposome-water (6) interfaces. Figure 2 shows the sustained release of

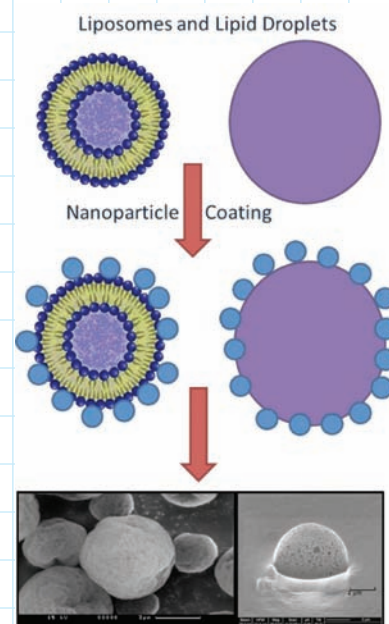


Figure 1. Schematic representation of nanoparticle-coated lipid colloids and hybrid materials formed by drying.

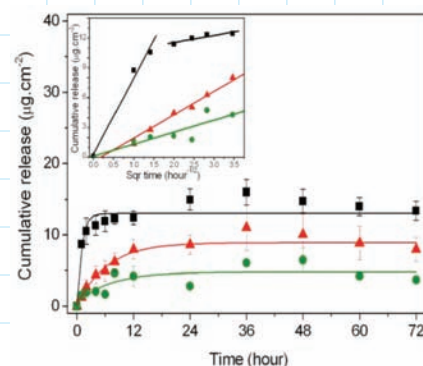


Figure 2. Vitamin A release from lipid oil emulsions with (red and green) and without (black) nanoparticle layers.

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retinol from lipid oil emulsions with nanoparticle layers. Figure 3 shows the controlled release of insulin from silica nanoparticle coated liposomes.

Improving Formulation Stability

A combination of silica nanoparticles and surfactant offers synergistic effects in emulsification processes and emulsion stability (Figure 4) (7). Nanoparticle coatings have been incorporated into a range of emulsion- and liposome-based formulations and significantly improve the shelf life under accelerated storage conditions.

Stabilization of Active Ingredients

All *trans*-retinol (vitamin A) is a highly unstable active ingredient. Interfacial coatings of silica nanoparticles significantly reduce degradation, both under storage (Figure 5) and photo irradiation (8).

Enhancing Topical Delivery

The skin uptake and transport of lipophilic active ingredients (e.g., vitamin A) are significantly increased for silica-encapsulated emulsions (Figure 6). Skin uptake levels are several times greater for nanoparticle-coated carriers and mechanisms for the improved dermal uptake and targeting have been proposed (17,18).

Controlling Lipid Digestion and Enhancing Oral Delivery

Silica-lipid hybrid (SLH) microcapsules, with an internal porous matrix structure (Figure 1, right image), are prepared by spray drying nanoparticle-coated lipid droplets. SLH

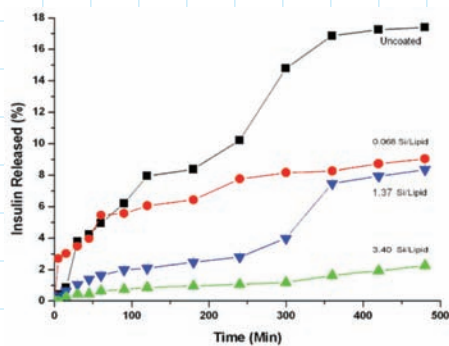


Figure 3. Release of insulin from liposomes (top) and silica nanoparticle-coated liposomes (at different silica to lipid ratios)

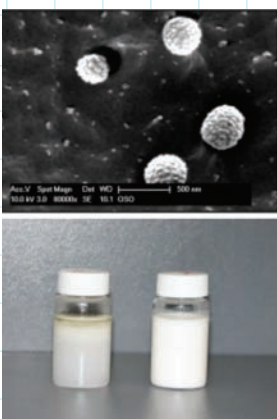


Figure 4. Nanoparticle-coated droplets (top) facilitate improved formulation stability performance (bottom).

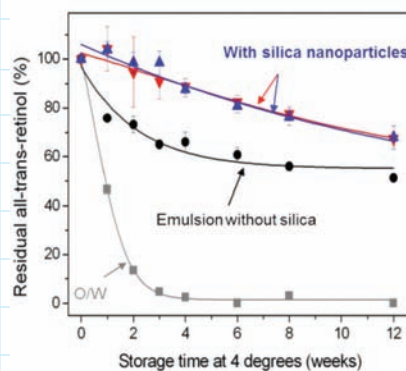


Figure 5. Chemical stability of all-trans-retinol incorporated in lipid carrier and emulsions (with and without silica nanoparticles).

microcapsules improve the oral pharmacokinetics of poorly soluble drugs (exemplified for celecoxib (CEL) in Figure 7). The mechanism of action is predominantly via enhancement of lipid digestibility and drug solubilisation (9,10,13). The ability to enhance or control the digestion of lipid-based vehicles is a powerful approach to manipulate the fate of drugs in the gastrointestinal environment, which leads to a more predictable drug absorption profile (19,20). It appears that the “positive food mimicking effect” of the SLH microcapsules is far greater than the conventional oily vehicles and thus implies the potential of SLH microcapsules in reducing fed/fasted state variability in drug absorption. Furthermore, the bioavailability enhancing effect is proportional to the dose of CEL administered under fasting conditions (15). SLH microcapsules are an attractive platform solid state delivery system for lipid soluble actives and can be further functionalized for bio-adhesion and formulated into tablets.

Conclusions and Future Prospects

Encapsulation of colloidal lipid vehicles (i.e., emulsion droplets

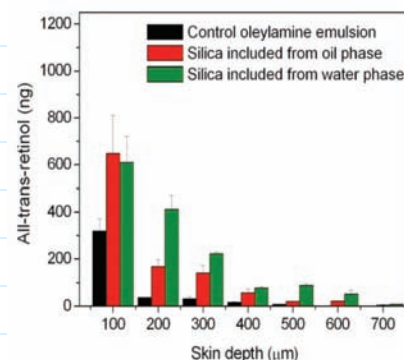


Figure 6. Skin distribution depth profiles of all-trans-retinol from emulsions without (black) and with (red and green) silica nanoparticle coatings.

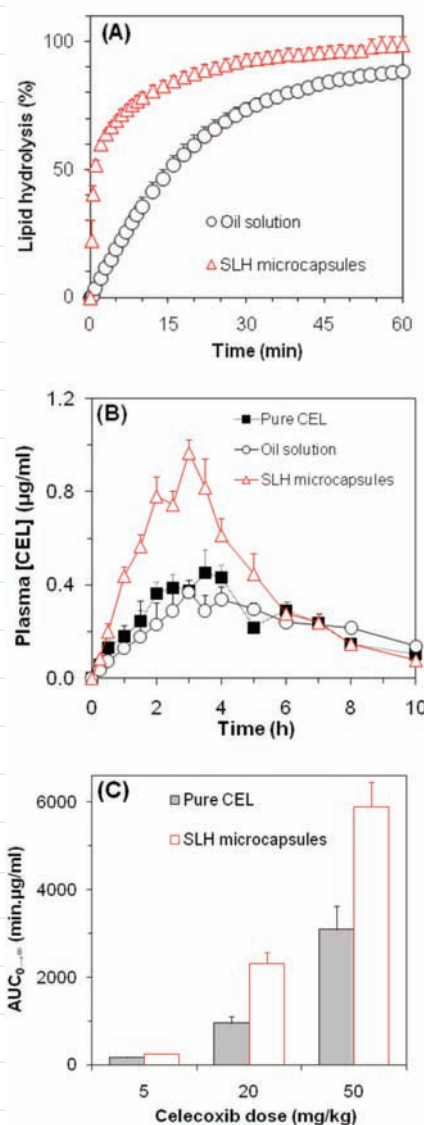


Figure 7. Biopharmaceutical performance of celecoxib-SLH microcapsules: (A) enhanced in vitro lipid digestibility, (B) increased oral absorption and (C) dose-proportional bioavailability enhancement in fasted rats.

and liposomes) with layers of silica nanoparticles offers a number of improvements in carrier performance, i.e.:

- Improved shelf life
- Controlled release of active ingredients
- Enhanced delivery, e.g., dermal or oral.

Nanoparticle-coated colloids form the basis for synthesis of a range of new nanomaterials. The opportunity now exists to design lipid hybrid capsules with porous internal structures with the ability to enhance the rate and extent of lipid digestion and hence increase the bioavailability of water insoluble drugs upon oral administration. In addition, nanoparticle-coated emulsion droplets and liposomes represent useful delivery systems for unstable compounds such as vitamin A and insulin due to protection against environmental conditions (e.g., UV light and storage) and also protect against lipid digestion in the intestine, respectively. We are now positioned to further develop SLH biomaterials with novel properties and in correlating *in vitro* and *in vivo* responses.

References

1. Porter, CJH, Trevaskis, NL, Charman, WN. Lipids and lipid-based formulations: optimizing the oral delivery of lipophilic drugs, *Nat. Rev. Drug Discov.* 6: 231-248 (2007).
2. Lanigan, RS, Yamarik, TA. Final report on the safety assessment of PEG-6, -8, and -20 sorbitan beeswax, *Int. J. Toxicol.* 20 S4: 27-38 (2001).
3. Aveyard, R, Binks, BP, Clint, JH. Emulsions stabilised solely by colloidal particles, *Adv. Colloid Interface Sci.* 100-102: 503-546 (2003).
4. Prestidge, CA, Barnes, T, Simovic, S. Polymer and particle adsorption at the PDMS droplet-water interface, *Adv. Colloid Interface Sci.* 108-109: 105-118 (2004).
5. Zhang, L, Granick, S. How to stabilize phospholipid liposomes (using nanoparticles), *Nano Lett.* 6: 694-698 (2006).
6. Mohanraj, VJ, Barnes, TJ, Prestidge, CA. Silica nanoparticle coated liposomes: A new type of hybrid nanocapsule for proteins, *Int. J. Pharm.* 392: 285-293 (2010).
7. Ghouchi-Eskandar, N, Simovic, S, Prestidge, CA. Synergistic effect of silica nanoparticles and charged surfactants in the formation and stability of submicron oil-in-water emulsions, *Phys. Chem. Chem. Phys.* 9: 6426-6434 (2007).
8. Ghouchi-Eskandar, N, Simovic, S, Prestidge, CA. Chemical stability and phase distribution of all-*trans*-retinol in nanoparticle-coated emulsions, *Int. J. Pharm.* 376: 186-194 (2009).
9. Tan, A, Simovic, S, Davey, AK, Rades, T, Prestidge, CA. Silica-lipid hybrid (SLH) microcapsules: A novel oral delivery system for poorly soluble drugs, *J. Controlled Release* 134: 62-70 (2009).
10. Simovic, S, Heard, P, Hui, H, Song, Y, Peddie, F, Davey, AK, Lewis, A, Rades, T, Prestidge, CA. Dry hybrid lipid-silica microcapsules engineered from submicron lipid droplets and nanoparticles as a novel delivery system for poorly soluble drugs, *Mol. Pharm.* 6: 861-872 (2009).
11. Simovic, S, Heard, P, Prestidge, CA. Hybrid lipid-silica microcapsules engineered by phase coacervation of Pickering emulsions to enhance lipid hydrolysis, *Phys. Chem. Chem. Phys.* 12: 7162-7170 (2010).
12. Simovic, S, Hui, H, Song, Y, Davey, AK, Rades, T, Prestidge, CA. An oral delivery system for indomethacin engineered from cationic lipid emulsions and silica nanoparticles, *J. Controlled Release* 143: 367-373 (2010).
13. Tan, A, Simovic, S, Davey, AK, Rades, T, Boyd, B, Prestidge, CA. Silica nanoparticles to control the lipase-mediated digestion of lipid-based oral delivery systems, *Mol. Pharm.* 7: 522-532 (2010).
14. Lim, LH, Tan, A, Simovic, S, Prestidge, CA. Silica-lipid hybrid microcapsules: Influence of lipid and emulsifier type on *in vitro* performance, *Int. J. Pharm.* 409: 297-306 (2011).
15. Tan, A, Davey, AK, Prestidge, CA. Silica-lipid hybrid (SLH) versus non-lipid formulations for optimising the dose-dependent oral absorption of celecoxib, *Pharm. Res.* 28: 2273-2287 (2011).
16. Simovic, S, Prestidge, CA. Nanoparticle layers controlling drug release from emulsions, *Eur. J. Pharm. Biopharm.* 67: 39-47 (2007).
17. Ghouchi-Eskandar, N, Simovic, S, Prestidge, CA, Nanoparticle coated submicron emulsions: Sustained *in-vitro* release and improved dermal delivery of all-*trans*-retinol, *Pharm. Res.* 26: 1764-1775 (2009).
18. Ghouchi Eskandar, N, Simovic, S, Prestidge, CA. Mechanistic insight into the dermal delivery from nanoparticle-coated submicron O/W emulsions, *J. Pharm. Sci.* 99: 890-904 (2010).
19. Kaukonen, AM, Boyd, BJ, Porter, CJH, Charman, WN. Drug solubilization behavior during *in vitro* digestion of simple triglyceride lipid solution formulations, *Pharm. Res.* 21: 245-253 (2004).
20. Fatouros, DG, Mullertz, A. *In vitro* lipid digestion models in design of drug delivery systems for enhancing oral bioavailability, *Expert Opin. Drug Metab. Toxicol.* 4: 65-76 (2008). ■



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**We congratulate Professor Molly M. Stevens,
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Left to right: **Mark A. Tracy**, Past President, CRS; **Erin O'Brien**, Director of Marketing, Aptalis Pharmaceutical Technologies; **Professor Molly M. Stevens**, Research Director for Biomedical Materials, Imperial College London; **Martyn C. Davies**, President, CRS

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Formulation Solutions, Delivered on Time

Vicki Ronaldson
Drug Delivery International Ltd

Drug Delivery International (DDi) delivers innovative and practical solutions to complex formulation problems. They are also developing a growing IP portfolio, offering exciting licensing opportunities in novel controlled release technologies.

The company is part of the Bio-Images Group, which expands upon the established clinical scintigraphic imaging expertise of Bio-Images Research. Based in Glasgow, DDi was founded in February 2011 by well known leaders in pharmaceuticals, Professors Howard Stevens and Alex Mullen. The company pools together extensive experience in pharmaceuticals, underpinned by over 100 years' combined research experience in academia and industry from its staff and demonstrated by an already impressive track record of innovative science.

Clinically Demonstrated Controlled Release Technology

DDi has developed a series of novel delivery systems that can be readily configured to provide immediate, biphasic or time-delayed release patterns of one or more drugs for a wide range of medical applications. This compressed tablet technology is unique and distinct from other delivery technologies in the marketplace, offering the following advantages:

- Widespread applicability to different drugs and dosages
- High degree of flexibility in manipulating drug release profiles
- Simple assembly and production processes
- Formulations are not pH sensitive

The tablets allow delayed release, or dual pulsed release if desired, with a controllable time lag.

These patented formulations have been demonstrated in three

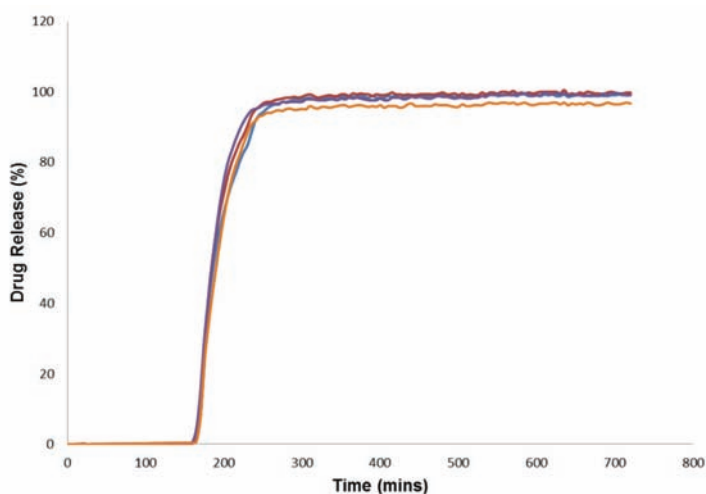


Figure 1. Dissolution profile of controlled release hypnotic sleep tablets ($n = 3$). USP II, sodium phosphate buffer (pH 7, 900 mL), $37 \pm 1^\circ\text{C}$, 50 rpm.

therapeutic areas: sleep maintenance, cardiovascular disease and pain management. Figure 1 shows the reproducible *in vitro* dissolution profile of the delayed release sleep maintenance formulation.

A clinical trial in six healthy male volunteers demonstrated the *in vivo* behaviour of these formulations and good *in vitro*-*in vivo* correlation was observed. Gamma scintigraphy allowed visualisation of the gastrointestinal transit and breakup of the tablets. For this purpose, the tablets were radiolabelled with the gamma emitter $^{99\text{m}}\text{Tc}$. Figure 2 shows scintigraphic images of key events in the gastrointestinal transit of the controlled release hypnotic sleep tablet in a healthy volunteer.

Quantitative analysis of sequential scintigraphic images showed the mean time to onset of radiolabel release from the sleep tablets to be 97.5 ± 9.5 min, and the mean time to completion of radiolabel release was 152.6 ± 7.8 min. This gave a mean time to complete release of 55.1 ± 15.5 min. These results showed that

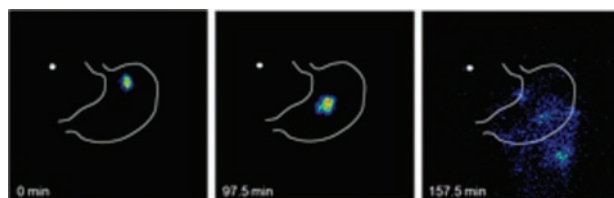


Figure 2. Scintigraphic images of Subject 001 at various times post-dose: 0 min (immediately post-dose); 97.5 min (onset of $^{99\text{m}}\text{Tc}$ release); 157.5 min (complete $^{99\text{m}}\text{Tc}$ release). Outline of the stomach is drawn for visualisation only.

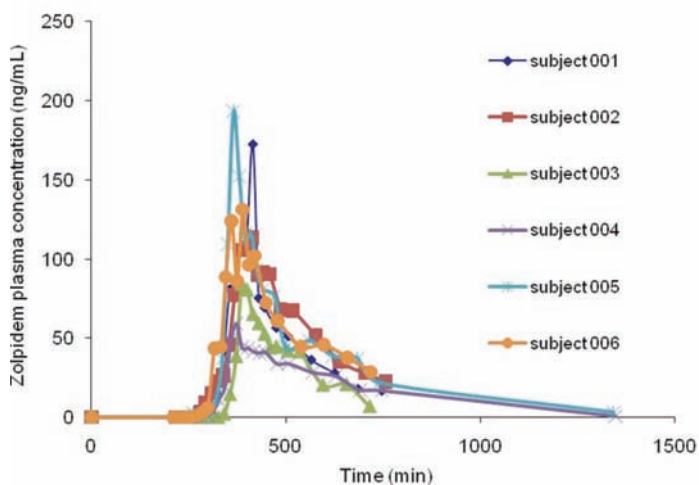


Figure 3. Plasma hypnotic drug concentration in 6 subjects, following administration of a time-delayed sleep tablet.

the delayed release formulation successfully prevented drug release until close to the target time of 2 h.

PK analysis allowed comparison of the observed physical behaviour of the tablets with plasma concentration of the drug (Figure 3), which was shown to be reproducible amongst the six subjects for the sleep tablet.

This example illustrates the innovative technologies developed by DDi to address unmet drug delivery needs.

Commercial Formulation Service

The knowledge and experience that has seen DDi's IP portfolio expand so rapidly can also help clients achieve practical and timely formulation solutions where others have failed. DDi offer a comprehensive service including:

- **Complete reformulation package** - intelligent solutions for most formulation types, particularly poorly soluble drug substances and those which require controlled release preparations.
- **'Rescue' formulations** - overcoming formulation problems where clients' in-house strategies or those of previous external contractors may not have met their objectives.
- **Technology transfer** - to ensure that all manufacturing processes and scale-up are optimised in the clients' own laboratories.
- **Formulation advice** - a troubleshooting advisory service to help highlight potential pitfalls and problem areas in clients' formulation strategies.

Access to the scintigraphic imaging expertise of DDi's sister company, Bio-Images Research, provides a unique integrated approach to pharmaceutical development, combining formulation expertise with quantitative data on the performance of dosage forms in man. This greatly assists decision making at critical stages, accelerating product pipelines.

Collaborative Research Opportunities

Integral to the advancement of pharmaceuticals is collaboration, and DDi always welcomes opportunities for partnerships to address the exciting and important challenges in drug delivery. Licensing opportunities are available in the following areas:

- Sleep maintenance
- Morning stiffness
- Colon targeted delivery
- Cardiovascular medicine

There is potential to incorporate most drugs into DDi's controlled release systems to provide temporal patterns of drug delivery. The time delays can be controlled as required and the drug can be released as either a pulse or as sustained release. It could therefore provide an innovative solution to your drug delivery requirements.

We are always interested in hearing about your formulation requirements and are actively seeking partners for collaborative development of our patented technology. Visit us at www.dd-int.com or contact us at enquiries@dd-int.com.
Tel: +4 (0)141 552 0126. ■

Thirsty for Information?

Check out the new LATTE database—your link to scientific experts within CRS

LATTE—Linking Academic Technologies and Techniques to Everyone—is a searchable database designed to help you identify experts in specific areas of CRS-related technologies and techniques.

CRS Members

You are invited to create your LATTE profile and offer your expertise to the membership, and search LATTE to find the experts you are looking for.



www.controlledreleasesociety.org



Interested in Hosting a Workshop?

If you have a great topic for a CRS workshop, submit it to CRS by November 30, 2011. Pair it with the CRS Annual Meeting, another meeting, or have it separately. Applications are available at www.controlledreleasesociety.org. Workshop proposals will be judged on scientific merit, industrial relevance and scope, and economic viability of the workshop.

2011–2012 CRS Board

The following CRS members make up the 2011–2012 Board. Members wishing to interact with board members can find contact information in the member directory or can simply email crspresident@scisoc.org.



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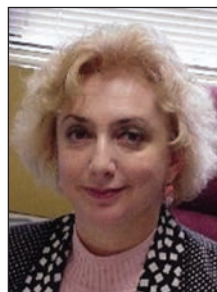
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From the Chapters Committee Co-chairs

Paolo Caliceti and Claudio Ortiz, CRS Chapters Committee Co-chairs

One initiative that emerged from this year's Chapters Committee meeting that took place at the 2011 CRS Annual Meeting is the importance of inter-chapter information exchanges and collaborations concerning local activities. Such communication and collaboration encourages the participation of members of other chapters as an additional value of external contribution, thereby enhancing the overall value that chapters contribute to CRS. Please be sure to keep this initiative in mind as future local activities are planned.

Change in Chapters Committee Leadership

After three successful years as Chapters Committee Co-chair, Biana Godin Vilentchouk will be stepping out of this role and into the position of Webinars Committee Chair. Claudio Ortiz of Colgate Palmolive has stepped in to co-chair the Chapters Committee along with current co-chair Paolo Caliceti. CRS would like to thank Biana for her hard work and dedication to the success of CRS Chapters.

"A vibrant chapter network is very important to the CRS and our ability to support the advancement of delivery science worldwide. Biana has done an outstanding job over the last three years as co-chair of the CRS Chapters Committee and has played a key role in building our network of chapters including supporting the establishment of several new chapters during her term as chair," said Mark Tracy, CRS Immediate Past President.

Chapter of the Year Awards Presented in National Harbor

CRS was proud to present the CRS Outstanding Local and Student Chapter of the Year Awards to the Australian Chapter and New Jersey Student Chapter, respectively. These chapters have coordinated successful events and activities for many years through which they have demonstrated hard work, continuous



Australian Local Chapter representatives Ben Boyd (center) and Pavla Simerska (left) accept the award for Outstanding Local Chapter of the Year from Mike Rathbone, CRS Chapters Committee Board Liaison (right).



New Jersey Student Chapter representative Sujata Sundara Rajan (left) accepts the award for Outstanding Student Chapter of the Year from Mike Rathbone, CRS Chapters Committee Board Liaison (right).

involvement, and great enthusiasm. Congratulations to these two chapters.

Become Involved in Your Local Chapter

With 25 active CRS Chapters across the globe, becoming involved in the one nearest you is the perfect opportunity to connect and discover with local colleagues in the field of controlled release.

Connect: Network with individuals in your region who have an interest in the area of controlled release and with other CRS chapters around the globe. Meet other scientists, students, engineers, professors, and industry leaders – and develop lasting friendships and professional contacts.

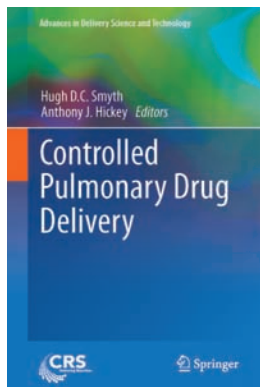
Discover: Take an active part in organization of conferences, inviting speakers, workshops, etc. – your CRS Chapter is a great umbrella for these activities with a variety of opportunities to expand your knowledge and get involved.

Visit the CRS Chapters webpage for more information on the CRS Chapters: www.controlledreleasesociety.org/community/chapters or contact Megan Pagel at mpagel@scisoc.org with questions and information requests.

Can't locate a CRS Chapter near you? We will help you create a new one

Whether you are looking to create a new CRS Local Chapter or new CRS Student Chapter, guidelines and application form can be found on the CRS webpage www.controlledreleasesociety.org/community/chapters and by clicking on the Resource Portal link on the left side of the page. ■

CRS Launches Its Book Series with Controlled Pulmonary Drug Delivery



CRS Annual Meeting & Exposition attendees were among the first to examine and purchase the new book from the Controlled Release Society, *Controlled Pulmonary Drug Delivery*. The first in a series, this book, edited by Hugh Smyth and Anthony Hickey, presents the latest knowledge in this challenging area of delivery science. The various chapters cover many areas of pulmonary drug delivery systems, providing both theoretical and practical insight.

Chair Michael Rathbone and the Books Advisory Board and the CRS Books Subcommittee are working hard to make a robust book publishing program that will support all aspects of delivery science. Additional books planned for the series include *Fundamentals of Applications of Controlled Release Drug Delivery*, *Long Acting Injections and Implants*, and *Controlled Release in Oral Drug Delivery*. The books will be introduced throughout 2011 and 2012.

Stated Rathbone, "The CRS Books Series represents a unique opportunity for CRS members to provide a lasting contribution to their field by editing books specific to the discipline of delivery science and technology. The scope of the series is wide, covering all aspects of delivery science from fundamentals to applications, and provides experts in the field an opportunity to compile volumes on a topic of general or specific interest to scientists working in the field of delivery science." Other subjects identified for possible titles include long acting controlled release in animal health products, RNA interference therapeutics, and vaginal drug delivery. Expressions of interest in editing a volume for the CRS Books Series are welcome and should be directed to Rathbone, series editor, at m.rathbone@griffith.edu.au.

CRS members qualify for a 25% discount on CRS book titles, and all Springer book titles if purchased through Springer's online site. An exclusive CRS member discount token is available on the CRS website. Be sure to log in to access these special savings, and take a look at the new CRS title today! ■

A Resource Library of Knowledge is Available with CRS's Expanded Webcasts Section

The CRS webcasts are a valuable resource for CRS members – featuring a library of peer-reviewed material spanning four categories: educational, research papers, industrial, and presentations from annual meetings. By watching the webcasts, viewers will be able to learn from leaders in the field, keep up to date on issues affecting the industry, and see presentations missed at annual meetings.

All of these webcasts will be available 24 hours a day, 7 days a week – whenever it is most convenient to you. These multimedia scientific presentations include audio, video, and informational slides from experts on a broad range of topics. This is more than just professional development, this is your chance to connect with great minds.

The webcasts will bring you face to face with leading experts in a variety of areas and put you in touch with key meeting presentations. The database itself will be updated every month with new content, so the resource will continue to grow and evolve according to your needs and interests. These multimedia presentations provide the reliability and integrity of a journal, vetted by experts, but in a more flexible, interactive, and inviting format.

Overview

The goal in the first year is to roll out approximately 70 webcasts, using CRS annual and chapter meetings to source the content.

CRS will offer these webcasts on-demand and free to members as a means to build member value. This new password-protected area is currently available with the unveiling of the new CRS website. Twenty-three webcasts have already been created and are available for viewing. These webcasts feature highlights from the last two annual meetings. The first of the webcasts from the 2011 CRS Annual Meeting are now available as well.

In the future, CRS intends to send out invitations to other experts in order to solicit more webcasts and expand the library. Recommendations will also be made to solicit certain College of Fellows inductees for live webcasts. These webcasts will then be archived in the on-demand library.

In addition, live single webcasts will be added, which will then be archived in the on-demand library. The plan is to charge viewers according to content value and delivery and production costs. These costs will be based on member and nonmember pricing. In the future, education modules will be added consisting of multiple webcasts related to single topics.

CRS aims to keep the standards high and webcasts will be peer-reviewed. A webcast editorial board was created to identify and review the presentations, along with a professional development subcommittee that identifies and reviews the seminars themselves.

Sign Up Today

All CRS members will have access to the webcasts library. The value of these new tools grows each time a new webcast is added. All of these webcasts are available for free at www.controlledreleasesociety.org. Log in to learn more about the new webcasts now! ■

Watch for JCR Topic Collections

The *Journal of Controlled Release (JCR)* provides high quality papers of various topics in the drug delivery field. To help CRS members and other readers find relevant papers, *JCR* started "Topic Collections," designed to provide an easy way for the researchers to identify papers relevant to their own research. The collections are published online only.



JCR already has developed several Topic Collections available on nanomedicine, protein delivery, and hydrogels. All abstracts in the Topic Collections and citation information can be accessed for free at the *JCR* website at www.elsevier.com/wps/find/L06.cws_home/topiccollections. Citation information of all papers can be directly downloaded to Reference Manager or EndNote.

JCR will continue producing Topic Collections in new interest areas. Potential topics for future Collections include targeted drug delivery, molecular imaging, oral delivery, PEGylation, tissue engineering, transdermal delivery, and vaccination.

The most recent Topic Collection on Nucleic Acid Delivery, edited by Prof. Yu-Kyoung Oh and Prof. Chae-Ok Yun, was announced to CRS members in August 2011, with the next topic collection expected to be sent the end of September. All CRS members automatically receive these e-mails; if you are not receiving a Topic Collection e-mail, please contact CRS Headquarters at crs@scisoc.org.

***Journal of Controlled Release's* Impact Factor Climbs!**

The impact factor of *JCR* increased to 7.164 in 2010, making it one of the most influential journals in the pharmaceuticals, biomaterials, and drug delivery fields. The impact factor is a measure of the average number of times recent articles in a specific journal are cited by others, reflecting the quality of science published in *JCR*. A big thank you to the authors, reviewers, and the readers for making *JCR* one of the most-read and cited journals in this area of science. ■

Discover state-of-the art approaches appropriate for the next generation of controlled drug delivery systems for the lung.

Developing Pharmaceutical Products for Controlled Pulmonary Delivery

A workshop co-sponsored by the American Association of Pharmaceutical Scientists and the Controlled Release Society

This workshop is intended to provide a framework for interested researchers to aid them in finding solutions to their drug delivery questions, providing bridges among multiple disciplines that are needed to successfully achieve controlled pulmonary drug delivery. Presentations by experts will include:

- Formulation design and delivery systems
- Excipient selection
- Particle engineering technologies
- Regulatory issues
- Low-cost inhalation technologies for the developing world
- And much more

October 23, 2011

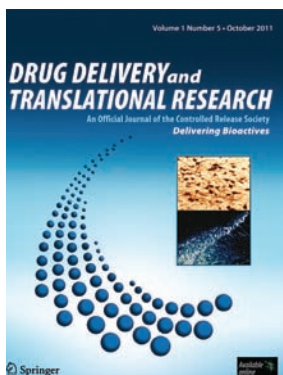
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Drug Delivery and Translational Research

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



I hope you all had an exciting time at the CRS Annual Meeting & Exposition in Maryland. The *DDTR* focus group, consisting of *DDTR* editors, CRS leadership, and Springer staff, met during the annual meeting to review strategies to further enhance the impact of our journal. The primary focus of *DDTR* is to advance the science and technology of delivering

actives, and provide a unique forum for publication of high quality translation drug delivery research. We intend to provide our readers with the latest research in this area.

The *DDTR* focus group decided to expand the editorial team of the journal. I am pleased to announce the appointment of **Martyn Davies**, Ph.D., FRPharmS, CChem, FRSC, as an Associate Editor of *DDTR*. He is Professor of Biomedical Surface Chemistry within the Laboratory of Biophysics and Surface Analysis at the University of Nottingham's School of Pharmacy, UK. Professor Davies is a well-known personality in the CRS community for his sustained contributions and service to the society. He is currently CRS President and was the society's Scientific Secretary (2001–07). Professor Davies' research interests are in drug delivery, new-generation biomaterials, bio-nanotechnology, and the characterization of drug delivery systems. His expertise in translational drug delivery research strengthens the editorial team of *DDTR*. Read more on Davies' background on the next page.

Professor **Justin Hanes**, Associate Editor of *DDTR*, is to chair the committee to select the recipient of the *DDTR* Outstanding Research Paper Award. The outstanding paper award is selected from the research articles published in *DDTR* during 2011. Consider submitting your best translational drug delivery research to compete for the award.

Focus on Cancer Therapy

DDTR covers drug delivery research in various disease conditions. Here are some selected papers published in *DDTR* with a focus on cancer therapy:

Argonaute2 is a potential target for siRNA-based cancer therapy for HT1080 human fibrosarcoma. Tatsuaki Tagami, Takuya Suzuki, Kiyomi Hirose, Jose Mario Barichello, Naoshi Yamazaki, Tomohiro Asai, Naoto Oku, Tatsuhiro Ishida and Hiroshi Kiwada. Volume 1, Number 4, Pages 277-288, DOI: 10.1007/s13346-011-0025-3.

Phospholipid–polyethylenimine conjugate-based micelle-like nanoparticles for siRNA delivery. Gemma Navarro, Rupa R. Sawant, Sean Essex, Conchita Tros de Ilarduya and Vladimir P. Torchilin. Volume 1, Number 1, Pages 25-33, DOI: 10.1007/s13346-010-0004-0.

Convection-enhanced delivery of camptothecin-loaded polymer nanoparticles for treatment of intracranial tumors. Andrew J. Sawyer, Jennifer K. Saucier-Sawyer, Carmen J. Booth, Jie Liu, Toral Patel, Joseph M. Piepmeier and W. Mark Saltzman. Volume 1, Number 1, Pages 34-42, DOI: 10.1007/s13346-010-0001-3.

Nanoparticle-mediated p53 gene therapy for tumor inhibition. Blanka Sharma, Wenxue Ma, Isaac Morris Adjei, Jayanth Panyam, Sanja Dimitrijevic and Vinod Labhasetwar. Volume 1, Number 1, Pages 43-52, DOI: 10.1007/s13346-010-0008-9.

A new approach for skin tumor treatment: from delivery system characterization to *in vivo* evaluation. Denize Ainbinder and Elka Touitou. Volume 1, Number 1, Pages 53-65, DOI: 10.1007/s13346-010-0006-y.

Liposomes as multicompartamental carriers for multidrug delivery in anticancer chemotherapy. Donato Cosco, Donatella Paolino, Jessica Maiuolo, Diego Russo and Massimo Fresta. Volume 1, Number 1, Pages 66-75, DOI: 10.1007/s13346-010-0007-x. ■

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Meet *DDTR*'s New Associate Editor



Martyn C. Davies
Associate Editor

Professor Davies has over 30 years' experience in pharmaceutical and biological analysis and controlled drug delivery. He is Professor of Biomedical Surface Chemistry within the Laboratory of Biophysics and Surface Analysis at the University of Nottingham's School of Pharmacy. His research expertise is in the fields of drug delivery, new generation biomaterials, bio-nanotechnology, and the characterization of drug delivery systems. Professor Davies is also co-founder and Chairman of Molecular Profiles Ltd, which provides pharmaceutical development services and consulting expertise to pharmaceutical companies worldwide. He received his bachelor degree in Pharmacy from Brighton Polytechnic and his Ph.D. from the London School of Pharmacy. He joined the University of Nottingham in 1985, and was Head of School between 2000 and 2003. He sits on the editorial boards the European Journal of Pharmaceutical Sciences, the Journal of Pharmaceutical Sciences, and the Journal of Controlled Release. He has mentored and supervised over 100 postgraduates and postdoctoral fellows, 20 of whom now hold academic positions. Professor Davies is the co-author of more than 370 peer-reviewed papers, reviews, and book chapters. He is currently the President for the Controlled Release Society (CRS) and was the CRS Scientific Secretary (2001–07). Professor Davies is a Fellow of the Royal Society for Chemistry, the Controlled Release Society, the UK Association of Pharmaceutical Scientists, and the Royal Pharmaceutical Society of Great Britain. His research group and company have received numerous awards, including the 2003 GSK International Achievement Award. In 2007, he was part of the Molecular Profiles and University of Nottingham's Pharmacy School teams which won two Queens' Awards for Enterprise in the category of Innovation – the highest UK business accolade. Molecular Profiles Ltd was awarded a second Queens Award for Enterprise this year. ■

ERRATUM

Theresa Allen was incorrectly listed as being affiliated with the University of Texas, U.S.A. on page 5 in the *CRS Newsletter*, Vol. 28, No. 4 issue. Her correct affiliation is the University of Alberta, Canada. CRS regrets this error.

Save the Date!

The 39th Annual Meeting & Exposition of the Controlled Release Society

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Fontaine de Tourney in front of the Parliament. La Maison Simons

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www.controlledreleasesociety.org

Report on the 3rd Annual Symposium of CRS-IL Student Chapter

Subair Sunoqrot, President, CRS-IL

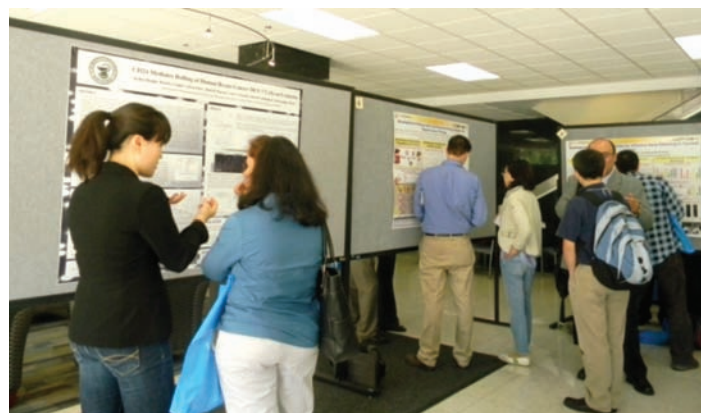
The 3rd Annual Symposium of the Controlled Release Society – Illinois Student Chapter was held on Friday, August 12, 2011, at the University of Illinois at Chicago College of Pharmacy, with the topic: “Recent Advances in Nanotechnology for Cancer Therapy”. Dr. Jindrich (Henry) Kopecek, Distinguished Professor of Pharmaceutics and Pharmaceutical Chemistry at the University of Utah, was the invited keynote speaker, and provided a comprehensive overview of *Smart and Drug Free Macromolecular Therapeutics*. Other speakers included Dr. Philip Messersmith, Professor of Biomedical Engineering at Northwestern University, who talked about *Catechol Based Materials for Drug Delivery*, Dr. Jianjun Cheng, Associate Professor of Materials Science and Engineering at the University of Illinois at Urbana-Champaign, who gave a talk about *Polymer and Silica Therapeutic Nanoconjugates*, and Dr. Seungpyo Hong, Assistant Professor of Pharmaceutics and Bioengineering at the University of Illinois at Chicago, whose talk was entitled *Bio-mimetic Nanotechnology to Tackle Cancer: Targeted Drug Delivery and Tumor Cell Isolation*.



Symposium Keynote Speaker Dr. Jindrich Kopecek addressing the audience.

We are proud to announce that the Symposium was a success with over 60 students, post-docs, faculty, and industry representatives in attendance. We were able to bring together people with an interest in drug delivery from Northwestern University, Purdue University, Loyola University, Midwestern University, University of Michigan, University of Illinois at Chicago and University of Illinois at Urbana-Champaign, as well as attendees from Argonne National Laboratory, Baxter Healthcare, and VWR. Additionally, the symposium offered an opportunity for students to showcase their research in a poster competition. With generous support from our CRS parent society, we were able to offer a travel award worth \$500 to the first place winner, Seung-Young (Steve) Lee of Purdue University, to support his attendance at the 2012 CRS Annual Meeting, in addition to cash prizes to 1st, 2nd, and 3rd place winners supported by CRS and TCF Bank.

In the 2011–2012 year, the Chapter hopes to gain more members and continue to host activities that will promote interactions between students, faculty, and scientists in industry. We also aspire to host a fourth symposium where our members can invite prominent speakers in yet another area of controlled drug delivery. This event has helped us recruit more members and expand our membership base to other universities and we hope that this expansion can be continued so that our chapter can include more universities in our region. We are also planning on hosting a fun, social activity this coming fall in an effort to promote interaction among our members as well as create further awareness of our organization throughout the UIC community. ■



Symposium attendees participate in the poster competition.

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Winner of the 1st Place Poster Award, Seung-Young (Steve) Lee with CRS-IL Chapter President Subair Sunoqrot and Dr. Kopecek.

This event has helped us recruit more members and expand our membership base to other universities and we hope that this expansion can be continued so that our chapter can include more universities in our region. We are also planning on hosting a fun, social activity this coming fall in an effort to promote interaction among our members as well as create further awareness of our organization throughout the UIC community. ■

Symposium organizers with Dr. Kopecek (L to R): Amy Ross (back row), Subair Sunoqrot (front row), Dr. Jindrich Kopecek, Ryan Pearson, and Mary Tang.



Symposium organizers with Dr. Kopecek (L to R): Amy Ross (back row), Subair Sunoqrot (front row), Dr. Jindrich Kopecek, Ryan Pearson, and Mary Tang.

Career Day at the Hebrew University CRS Student Chapter

Oren Giladi, Sarit Greenberg

CRS Student Chapter at The Institute for Drug Research, The Hebrew University of Jerusalem

The CRS supports its chapters worldwide in a variety of activities, from academic and professional events to social activities. One such event was held on the 28th of March, 2011, with a career day at the Ein Kerem campus of the Hebrew University of Jerusalem. The day concentrated on both professional and social skills in an effort to assist graduate students in coping with one of their major concerns – the search for a job post-graduation. The objectives of the event included equipping students with proficiencies to assist in their future search for a job in a friendly and enjoyable environment, and familiarizing them with the various job opportunities in the local and international pharmaceutical field.

The day was divided into two main sessions. Throughout the morning, the students attended workshops dealing with job interviews: how to adequately prepare for them and excel at them. Those who participated were graduate students in the School of Pharmacy, The Institute for Drug Research of the Hebrew University in Jerusalem, and the day was planned by the Institute's CRS student chapter. The workshops were made possible thanks to the generosity of the Jerusalem municipality, which helped fund the event in association with the Office of the Dean of Students of the Hebrew University.

The workshops provided the students with essential and useful tools to be successful in job interviews and included discussions on effective ways of preparing for their entry into the job market. Emphasis was given to the various career paths available, how to correctly write a resume, phone interviews, and the various stages of face-to-face interviews. In addition, pointers were given on how a candidate should properly conduct him or herself in the interview and the importance of both the interviewer's and candidate's body language during the interview session. The significance of the candidate's preparation for the



HUJI students in the frontal lectures session.

interview was also stressed, including a review of the job requirements and of the specific characteristics that might be needed for such a position from the point of view of the interviewer. Accordingly, the candidate should emphasize his or her capabilities and skills, the reasons he or she is most suitable for the job, what he or she may contribute to the position, and in general to promote him or herself as the ideal candidate. The workshops were held in small groups and were carried out interactively, allowing discussions among the participants and interview simulations. The simulations were filmed and further analyzed by the instructor and participants during the workshop. The instructors conducted the workshops professionally and the students expressed satisfaction both from the content and from the manner in which they were conveyed.

The second part of the day was opened with greetings from the Head of the Institute for Drug Research, Prof. Simon Benita, who stressed the importance of the contents of the day and of the cooperation between academia and industry. The keynote speaker of this session was the head of the pharmaceuticals department of Danel Ltd., a large human resources company in Israel, who gave an overview of the various types of companies in the field of pharmaceuticals, the different positions available, and the ranges of possible salaries. The program also touched on the wide range of positions available and the importance of matching a specific position with the suitable candidate.

Anna Elgart, a Ph.D. student who participated in the event, summed up the feelings of the participants in her comments to the chapter: "We thank the chapter for the opportunity to be exposed to the various aspects of our future career possibilities, provided uniquely and specifically for our academic skills and needs." In short, Career Day was a success on all levels. It was enjoyable, insightful, educational, and informative, and the students left feeling inspired, encouraged, and confident with their newly gained knowledge. ■



HUJI students participating at a job interview workshop.

People in the News

*Compiled by Steven Giannos
Industrial Editor*

James Nightingale Named New President of Bend Research Inc.

PRNewswire-USNewswire: July 27, 2011 – BEND, OR – Bend Research Inc. (www.bendresearch.com), a leading independent drug-formulation development and manufacturing company, has named a new president. Jim Nightingale, who has worked at the company since 1993, will be the fourth president in the firm’s 36-year history.

Nightingale will succeed Rod Ray, who will continue in his capacity as Bend Research Chief Executive Officer (CEO) and chairman of the board of directors.

Ray announced Nightingale’s promotion from Senior Vice President for Business Development and Strategic Alliances, calling the new president “a dogged pursuer of quality and timeliness for our customers.”

“Jim cares deeply about the company and our mission of advancing our clients’ best new medicines,” Ray said.

He credited Nightingale with being instrumental in developing and implementing the business development strategy that

transformed the company from an exclusive relationship with Pfizer to the multi-client success it now enjoys. In the two years since Bend Research and Pfizer ended the exclusive contract, the company has built a base of more than 70 clients, including most of the largest pharmaceutical companies in the world.

Nightingale will be responsible for nearly all operational aspects of the company, working with Ray and Lisa Graham, the company’s Chief Operating Officer (COO). David Lyon, Vice President of Research, will assume Nightingale’s business development duties. The changes free Ray to focus more on strategic planning and future opportunities for the company. Ray served as president of the privately held company since 2002. Previous presidents were Chris Babcock (1987–2002) and Harry Lonsdale (1975–1987).

Nightingale holds a master’s degree and doctorate in bioengineering from the University of Washington, where he also received a bachelor’s degree in chemical engineering. Before coming to Bend Research in 1993, he worked for the Pharmaceutical Division of Ciba-Geigy Corporation. He holds five U.S. patents (and numerous foreign patents) and has authored 16 scientific publications. ■

Welcome New Members

Caroline Ailhas

Ali Athab Al-kinani

Ganesh Kumar Appavu

Raymond T. Bartus

Balaji Bharatwaj-Subraman

Vincent Billoet

Kenneth H. Carson

Grace Chew

Younjee Chung

Bailey M. Cooper

Yong Dai

Jing Fu

Pablo Golfari

Mari L. Groves

Ahmed Ibrahim

Veeran Gowda Kadajji

Min-Hyo Ki

Anthony J. Kim

Chandana Kolluru

Aadithya Krishnan

Nicolette A. Louissaint

Thomas Piccariello

Anthony Qu

Jose Rios

Vicki Ronaldson

Craig S. Schneider

Hyejin Seo

Joseph Shieh

Mingchee Tan

Rajeshwar Thota

Robert Hans Tromp

Subhash Vaghani

Liu Wan Hui

Yoshiko Yamazaki

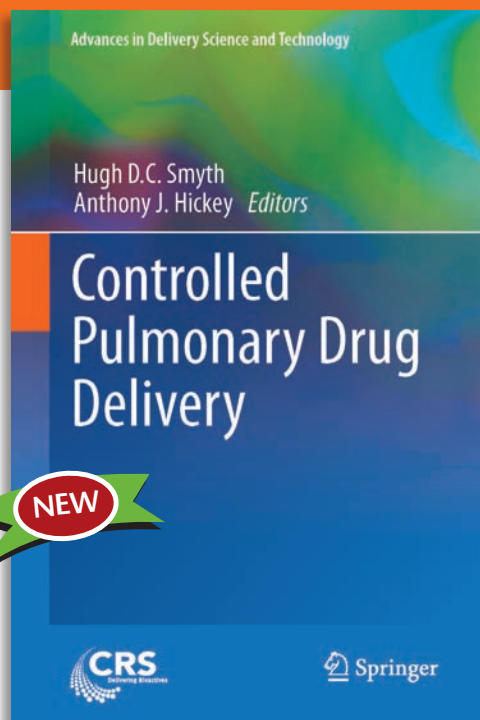
Minji Yoon

Patricia Zadnik



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- Overcoming Lung Clearance Mechanisms for Controlled Release Drug Delivery
- Targeted Drug Delivery Through the Respiratory System: Molecular Control on Lung Absorption and Disposition
- Controlled Transport for Pulmonary Drug Delivery
- Science and Technology of Pressurized Metered-Dose Inhalers
- Science and Technology of Dry Powder Inhalers
- Science and Technology of Nebulizers and Liquid-Based Aerosol Generators
- Excipients Utilized for Modifying Pulmonary Drug Release
- Polymers for Pulmonary Drug Delivery
- Particle Engineering Technologies for Pulmonary Drug Delivery
- Liposomes for Pulmonary Drug Delivery
- Nanoparticles for Pulmonary Delivery
- Pulmonary Delivery of Plasmid DNA for Disease Prevention and Therapy
- In Vitro Performance Testing for Pulmonary Drug Delivery
- In Vitro Cell Culture Models for Evaluating Controlled Release Pulmonary Drug Delivery
- In Vivo Animal Models for Controlled-Release Pulmonary Drug Delivery
- Imaging Pulmonary Drug Delivery
- Development and Approval of Inhaled Respiratory Drugs: A US Regulatory Science Perspective
- Developing Performance Specifications for Pulmonary Products

In the News

*Compiled by Steven Giannos
Industrial Editor*

August 2011

ORTHOCON Announces Signing of Exclusive, Worldwide License Agreement With Bezwada Biomedical

PRNewswire: August 31, 2011 – IRVINGTON, NY – ORTHOCON, Inc., a privately held therapeutic device company, today announced the signing of an exclusive, worldwide license agreement with Bezwada Biomedical to develop and commercialize Bezwada's technology for bone applications.

Bezwada Biomedical is an innovation-driven company with proprietary technology platforms comprised of bioabsorbable and biocompatible polyurethanes and polyamides derived from hydrolyzable isocyanates. This technology can be utilized to create absorbable surgical devices for a variety of applications including structural support, fixation, and drug delivery, with the potential to address significant limitations of existing therapeutic modalities.

John J. Pacifico, President and Chief Executive Officer of ORTHOCON, commented, "This strategic partnership is another important milestone for ORTHOCON as it significantly enhances the company's technological capabilities and product pipeline." He added, "Bezwada Biomedical has invented new technology that clearly improves upon existing marketed products, and we are very pleased to be working with Dr. Bezwada and his team to develop and commercialize additional devices that address the needs of our surgeon customers."

"We are delighted to partner with ORTHOCON to develop and commercialize an important part of our technology for bone applications," stated Rao Bezwada, Ph.D., President and Chief Executive Officer of Bezwada Biomedical. "Given ORTHOCON's financial, technical, and commercial capabilities, we believe this is the right step to move our technology forward and we are thrilled to be working with the ORTHOCON team."

Richard Kronenthal, Ph.D., ORTHOCON's Founder, Chief Scientific Officer, and principal technology inventor, previously worked with Dr. Bezwada to develop several market-leading products. Commenting on this strategic partnership, Dr. Kronenthal stated, "Having known and worked with Dr. Bezwada for many years, and having assessed the advantages of his materials relative to other marketed technologies, I am enthusiastic about the new roads we are taking together to overcome important problems in orthopedic and other surgical specialties." ORTHOCON recently initiated development programs to advance the Bezwada technology towards commercialization. For more information, please visit www.orthocon.com or www.bezwadabiomedical.com.

Pearl Therapeutics Announces Positive Results for Phase 2b Dose-Ranging Study of Formoterol MDI

PRNewswire: August 30, 2011 – REDWOOD CITY, CA – Pearl Therapeutics Inc. today announced positive results from a randomized, double-blind, Phase 2b, dose-ranging study of its formoterol fumarate metered dose inhaler (FF MDI; PT005), a long-acting beta-2 agonist (LABA) compared to placebo and Foradil® Aerolizer® in patients with moderate-to-severe COPD. All doses of FF MDI tested produced highly statistically significant improvements in lung function (FEV1 AUC 0-12) compared to placebo (p<0.0001). Dose ordering (incremental increase in efficacy with increasing doses) was observed across the three FF MDI doses evaluated, and the two lower doses tested were comparable to 12 mcg Foradil, the currently approved dose. This study marks the fourth in a series of detailed clinical evaluations of FF by Pearl in its novel MDI formulation platform, and significantly expands the safety and efficacy database of FF MDI. Detailed results of this study will be presented at a future conference.

"Successful completion of this study is an important milestone in the development of PT003, Pearl's combination of FF with glycopyrrolate, a long acting muscarinic antagonist (LAMA). The dose ordering and consistent response observed in this study confirm the robustness of Pearl's breakthrough formulation platform, and strengthen the value of FF MDI as the LABA arm of the PT003 program," commented Colin Reisner, Pearl's chief medical officer and executive vice president of clinical development. "The totality of data from this and previous studies provides Pearl with the confidence to select a dose of FF MDI to progress into PT003 Phase 3 studies."

Chuck Bramlage, Pearl's chief executive officer, added, "This study was completed in only three months, demonstrating the drive of the Pearl development organization, enthusiasm of Pearl's clinical investigators, and our overall commitment to capital efficiency while generating high quality clinical data. In the next few months, we look forward to presenting results from the remaining three studies in our ongoing Phase 2b program, which is funded by our 2010 Series C financing. We intend to meet with the FDA in the first half of 2012, in preparation for PT003 registrational studies targeted to start in late 2012."

BioDelivery Sciences Announces Commercial Launch of ONSOLIS in Canada

PRNewswire: August 22, 2011 - RALEIGH, NC - BioDelivery Sciences International, Inc. (Nasdaq: BDSI) today announced that the commercial launch and availability of ONSOLIS (fentanyl buccal soluble film) in Canada would take place this quarter.

ONSOLIS is approved in the U.S., Canada, and the E.U. (where it will be marketed as BREAKYL) for the management of breakthrough pain in opioid tolerant, adult patients with cancer. ONSOLIS will be marketed in Canada by Meda Valeant Pharma Canada Inc., a joint venture between BDSI's commercial partner for ONSOLIS, Meda, and Valeant Canada Limited.

"We are excited about the upcoming commercial launch of ONSOLIS in Canada," said Dr. Mark A. Sirgo, President and Chief Executive Officer of BDSI. "The achievement of this important milestone provides an opportunity for growth of ONSOLIS outside of the U.S. market, particularly where commercial efforts will not be impacted by a REMS requirement."

Dr. Sirgo continued, "The Canadian market is also of particular importance as ONSOLIS will be among the first products available for the management of breakthrough pain in opioid tolerant individuals with cancer in that country. We remain highly confident based on the attributes of ONSOLIS that we can effectively compete in any market and believe that our partner Meda Valeant will leverage these attributes to build an important new market for ONSOLIS in Canada. We also look forward to introducing ONSOLIS into additional markets in the future."

NovaDel Signs Exclusive License and Distribution Agreement with Rechon Life Science AB to Manufacture and Commercialize Zolpimist® outside the US and Canada

Business Wire: August 22, 2011 - BRIDGEWATER, NJ - NovaDel Pharma Inc. (OTC BB: NVDL), a specialty pharmaceutical company that develops oral spray formulations of marketed pharmaceutical products, today announced its entry into an exclusive license and distribution agreement with Rechon Life Science AB to manufacture and commercialize Zolpimist® outside the United States and Canada. Zolpimist is our oral spray formulation of zolpidem tartrate approved by the FDA in December of 2008.

Under the terms of the agreement, Rechon will assume responsibility for manufacturing and marketing Zolpimist outside the United States and Canada. In addition, Rechon will pay a royalty on each unit shipped from Rechon's manufacturing facility. Under the terms of the agreement, Rechon is required to complete and submit a regulatory filing for Zolpimist in the European Union. In addition, Rechon is required to launch Zolpimist in at least three countries outside the European Union within 12 months.

Steven B. Ratoff, Chairman and CEO, said, "This agreement expands the market opportunity for Zolpimist to the world outside the U.S. We believe that Rechon, with its relationships with pharmaceutical marketers around the globe, has the ability to build a solid position for Zolpimist in the market for prescription sleep aids."

Roland Holmqvist, CEO of Rechon Life Science AB, expressed that, "This license and distribution agreement is offering a great opportunity for a successful introduction of Zolpimist outside the United States and Canada. We look forward to this extended partnership with NovaDel and we are impressed with NovaDel's efficient oral spray drug delivery technology as used in Zolpimist." Rechon Life Science AB is a complete pharmaceutical company also providing manufacturing services for pharmaceutical and life sciences companies. To find out more about Rechon Life Science AB, visit the website at www.rechon.com.

Santarus and Depomed Announce New U.S. Commercialization Agreement for GLUMETZA Prescription Products

Business Wire: August 22, 2011 – SAN DIEGO & MENLO PARK, CA – Santarus, Inc. (NASDAQ:SNTS) and Depomed, Inc. (NASDAQ:DEPO) today announced that they have entered into a new commercialization agreement for GLUMETZA® (metformin hydrochloride extended release tablets) under which Santarus will assume broad commercial, manufacturing, and regulatory responsibilities to replace a promotion agreement that the companies entered into in July 2008. Under the new agreement, Santarus will record revenue from GLUMETZA sales in the U.S. effective September 1, 2011, and over the next few months Depomed will transition most U.S. commercial activities for GLUMETZA to Santarus including managed care contracting, pricing, certain manufacturing activities and distribution.

In addition, Depomed will transfer to Santarus the New Drug Application (NDA) for GLUMETZA and Santarus will be responsible for the product's pharmacovigilance activities in the U.S. Depomed will have an option for expanded rights to co-promote GLUMETZA to physicians not called on by Santarus.

"We are pleased to expand our commercial activities for GLUMETZA, a product that we believe has significant potential in the type 2 diabetes market," said Santarus president and chief executive officer Gerald T. Proehl. "After promoting GLUMETZA for almost three years, our commercial organization is eager to manage contracting and pricing to maximize the potential for the brand. Given our focus on the GLUMETZA brand and the internal resources we have allocated to its promotion, it makes good business sense to transition certain manufacturing activities, distribution, and ownership of the NDA for GLUMETZA to our organization. We also believe this agreement will result in greater financial value for both Santarus and Depomed."

He added, "We are moving forward with new eVoucher and savings card programs for GLUMETZA, which we plan to introduce in the coming months. We believe these new programs will significantly increase patient access to our products for adult patients with type 2 diabetes by reducing the out-of-pocket cost for GLUMETZA to a level roughly equivalent to a Tier 1 copay for patients with commercial insurance."

In the News continued from page 29

Depomed president and chief executive officer Jim Schoeneck said, “This is a good deal for both companies. For Depomed, it should add meaningfully to our bottom line and should lead to further growth in revenues for Depomed as Santarus grows the franchise. We have a great deal of confidence in the Santarus team and their ability to take on expanded commercial activities for GLUMETZA. This transaction allows our commercial, regulatory, and manufacturing teams to focus energies on the successful launch of GRALISE™ (gabapentin), our once-daily formulation of gabapentin for the management of postherpetic neuralgia, while also providing us the option to promote GLUMETZA with our new sales force.”

Fuisz Pharma Announces Publication of U.S. Patent Pending for a System that Confirms Drug Compliance

PRNewswire: August 17, 2011 – MIAMI, FL – Fuisz Pharma (www.fuisz.com) today announced the publication of U.S. Patent Application US 20110182827 (“Method and Dosage Form to Confirm Compliant Use of a Bioactive Agent”).

This patent pending is directed towards a dosage form that includes a substance that is visible to a normal light or to a special light source in the buccal or vaginal cavity in order for medical personnel to confirm compliant use of a medication. The substance leaves behind a temporary stain for a predetermined period for compliance assessment.

Joseph Matus Fuisz, Managing Member of Fuisz Pharma, stated, “This patent application sets forth a highly effective method of confirming compliant use of medications for the buccal or vaginal cavities. Its disclosure and claims are highly complimentary to the Gruber patent (US 7,214,385 “Pharmaceutical Formulation Containing Dye”) previously acquired by Fuisz Pharma, which covers the use of a dye to show the misuse of an opioid dosage form, such as by snorting.”

Diamyd Medical: Diamyd Puts Focus on Pain Projects and Reduces Costs

Business Wire: August 17, 2011 – STOCKHOLM, SWEDEN – Diamyd Medical AB (STO: DIAMB)(Pink Sheets: DMYDY) is concentrating its resources on the Company’s drug candidates for the treatment of pain and diseases of the nervous system. The termination of the Phase III program with the diabetes therapy Diamyd® means significantly lower costs for the Company which creates strategic leeway.

The primary development focus of Diamyd Medical is shifted from the diabetes therapy Diamyd® to the Company’s portfolio of drug candidates for the treatment of chronic pain. The pain portfolio is based on the patented technology Nerve Targeting Drug Delivery System (NTDDS). NTDDS represents a new type of treatment that delivers gene-based drugs directly to nerve cells, providing a local effect in the cells targeted by the treatment. Besides pain relief the technology has potential to be used for the treatment and prevention of diseases in the nervous

system, such as neuropathy, erectile dysfunction (impotence), neurodegenerative diseases, and cancer. Research and development of NTDDS is mainly being carried out by the subsidiary Diamyd, Inc. in Pittsburgh, USA.

Results from a Phase II study with the furthest developed drug candidate, NP2 Enkephalin for the treatment of severe cancer pain, is expected around year end. At the same time the next drug candidate in the portfolio, NG2 GAD for the treatment of diabetes pain for instance, is planned to be ready to enter clinical phase, the phase of drug development, which comprises studies in humans. The portfolio also includes several projects in earlier stages of development.

“The shift of the Company’s primary development focus to the unique NTDDS technology gives us a fresh start before fall,” says Peter Zerhouni, President and CEO of Diamyd Medical. “The next milestone will be the results from the Phase II trial with NP2 Enkephalin, which we hope will establish proof of principle for this new method of treating pain as well as the entire NTDDS platform.”

The two parallel Phase III studies with the diabetes therapy Diamyd® in Europe and the US are being closed since Diamyd®, as previously reported, did not demonstrate sufficient efficacy neither in the European Phase III study nor in a similar, smaller study conducted by the research consortium TrialNet. Diamyd Medical is also terminating most of the employees in Sweden since they have mainly worked on the Phase III studies with Diamyd® and in related areas. The Phase III program with Diamyd® has accounted for approximately two thirds of the Company’s costs which will, consequently, decrease substantially going forward. The Company expects to have approximately SEK 400 million in liquid assets at the end of the calendar year.

“Through strict cost control we safeguard our favourable financial position, which represents a strength in the current turmoil of the capital markets,” says Peter Zerhouni. “Having plenty of cash on hand gives us valuable strategic leeway, not least when we get the results from the Phase II study with NP2 Enkephalin.”

The interest in Diamyd® and the active substance GAD65 is still high among diabetes researchers. GAD65 plays an important role in type 1 diabetes and continues to have potential to be used against the disease. Important discussions are ongoing within the research field about why the studies with Diamyd® did not meet the endpoints and how lessons learned from these and other studies in type 1 diabetes can guide the future development of GAD65 towards a diabetes drug. One approach being tested is to treat earlier in the disease process, before the onset of the disease. An externally funded and researcher-initiated Phase II study with Diamyd® is ongoing since 2008 in order to prevent type 1 diabetes in children at high risk of developing the disease, and that study continues. Other potential ways forward are giving more or higher doses of Diamyd®, or combining Diamyd® treatment with other drugs.

Work still remains in analyzing the large amounts of data collected in the Phase III studies with Diamyd® and new data is still being collected. To complete the safety database of the U.S. Phase III study and in consultation with the U.S. Food and Drug Administration (FDA), the Company has decided to follow the patients who received injections of Diamyd®, but not the ones who received placebo, for six months after the last injection. The last follow-up visit is planned to take place in December. In the European Phase III study, all of the patient visits have been completed.

pSivida Announces an Evaluation Agreement with Hospital for Special Surgery to Investigate Bioerodible Sustained Release Systems in Orthopedic Surgery

Business Wire: August 16, 2011 - WATERTOWN, MA & NEW YORK, NY - Drug delivery company pSivida Corp. (NASDAQ: PSDV) (ASX: PVA) today announced it has entered into an evaluation agreement with Hospital for Special Surgery (HSS), a world leader in orthopedics, rheumatology, and rehabilitation, to investigate pSivida’s drug delivery technologies in orthopedics.

This agreement follows pSivida’s announcement in June that it has renegotiated its collaboration agreement with Pfizer to focus solely on developing a bioerodible sustained release implant for glaucoma and ocular hypertension (this program is already in clinical trials).

“We believe this orthopedic evaluation agreement is important for pSivida as our drug delivery technology, originally developed for ophthalmology, is being investigated in broader areas of medicine,” said Dr Paul Ashton, President and CEO of pSivida. “We are excited to be working with Hospital for Special Surgery because of their long history of innovation and research in orthopaedic surgery.”

pSivida has two products approved by the FDA for sustained release delivery of drug to treat chronic back-of-the-eye diseases: Retisert® for the treatment of posterior uveitis and Vitrasert® for the treatment of AIDS-related cytomegalovirus (CMV) retinitis. pSivida has licensed both of these products and the technologies underlying them to Bausch & Lomb Incorporated. pSivida’s intellectual property portfolio consists of over 50 patent families, more than 100 granted patents, including patents accepted for issuance, and more than 150 patent applications. pSivida conducts its operations from Boston in the United States and Malvern in the United Kingdom.

Starpharma Commences Bacterial Vaginosis Prevention Study of VivaGel®

PRNewswire-Asia: August 15, 2011 – MELBOURNE, AUSTRALIA – Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) today announced the commencement of its Phase 2 study of VivaGel® for the prevention of bacterial vaginosis (BV), following receipt of ethics approval.

The prevention of BV is the second area of investigation of the VivaGel® product for this condition. In May 2011, Starpharma announced the positive results of its first study of VivaGel® for the treatment of BV, which showed that the product successfully treated patients suffering the illness, with very high levels of patient acceptability. Further discussions with the US Food and Drug Administration (FDA) and other regulators on the development of VivaGel® for the treatment of BV will occur over the next few months, with Phase 3 studies for BV treatment expected to commence in late 2011 or early 2012.

This new phase of the program will investigate the ability of VivaGel® to prevent recurrence of BV, which clinicians identify as a major unmet need. The trial will be conducted in women with a prior history of recurrent BV, and the product will be used every second day.

The study will be conducted under an investigational new drug application (IND) at sites in the U.S. and will enroll approximately 200 women. Clinical trial sites have been fully assessed, and the first patient is expected to be enrolled later this month, following final initiation of the sites. The primary objective of the study is to determine the efficacy of two strengths of VivaGel® (1% and 3%) compared with a placebo gel in preventing recurrence of BV. Whilst the duration of use of the product in this study is 16 weeks, it is intended that women would use the product as a long-term prevention tool if proven effective.

The global market for topical BV treatments alone is estimated at approximately US\$350M. Starpharma’s modeling suggests the addressable global market for prevention of recurrence of BV is potentially in excess of \$1 billion, due to the long term usage associated with such a product.

Dr. Jackie Fairley, Chief Executive Officer of Starpharma, said, “There are currently very few proven options for women who wish to prevent recurrence of BV. Clinical experts in this field have repeatedly expressed the need for products to prevent the recurrence of this condition and so the commencement of this program is an important step in the development of VivaGel® and the management of the condition.”

“In addition to the obvious unmet market need for the recurrence indication, we were very encouraged by the results obtained in our Phase 2 BV treatment trial of VivaGel® reported in May, and the implications of these results for recurrence. These included high rates of cure and rapid resolution of symptoms together with excellent patient acceptability,” she said.

VivaGel® is also being developed as a topical microbicide for the prevention of HIV and genital herpes and as a condom coating. Prevention of human papillomavirus is also under assessment.

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Intersect ENT Announces U.S. Food and Drug Administration Approval for First Drug Releasing Implant for Chronic Sinusitis Patients

Business Wire: August 15, 2011 – PALO ALTO, CA – Intersect ENT, Inc., an innovator in treatment alternatives for ear, nose, and throat clinicians and patients, today announced that the U.S. Food and Drug Administration (FDA) has approved the company’s Premarket Approval (PMA) application for the Propel™ mometasone furoate implant offering localized, controlled drug delivery for chronic sinusitis patients.

Chronic sinusitis is a condition in which patients’ sinuses become swollen and inflamed, leading to difficulty breathing, facial pain or headache, and reduced sense of smell and taste. The condition is common, affecting one in seven adults in the U.S.¹, and greatly impacts quality of life.

Chronic sinusitis often requires a complex combination of surgical and medical treatments. Each year, 500,000 patients undergo sinus surgery to treat the condition². Although sinus surgery is effective, the majority of patients experience recurrent symptoms within the first year; as many as 25 percent then undergo revision surgery due to recurrent obstruction of the sinus cavity³.

Propel is the first of a new category of products offering localized, controlled delivery of steroid directly to the sinus tissue. Inserted by a physician following endoscopic sinus surgery, the spring-like implant expands to prop open the sinus and gradually delivers an advanced corticosteroid with anti-inflammatory properties directly to the sinus lining to maintain sinus patency. The Propel system has been clinically proven to prevent obstruction of the ethmoid sinus following surgery. The result is improved post-operative outcomes, reducing the need for additional surgical procedures and systemic steroids that can have serious side effects.

“The FDA approval of this innovative new product is great news for ENT clinicians and patients,” said David W. Kennedy, M.D., F.A.C.S., professor of Otorhinolaryngology at the University of Pennsylvania Health System in Philadelphia, PA, a widely recognized pioneer in functional endoscopic sinus surgery. “Propel reduces the occurrence of inflammation and scarring in the post-operative period. As a result, it promises to substantially improve long-term outcomes for sinus surgery and, as my research has demonstrated, reduced scarring and inflammation correlates with absence of the need for further surgery. I believe the combination of minimally invasive techniques and local drug delivery will be the wave of the future in sinus treatment.”

“The FDA approval of Propel marks an exciting milestone for Intersect ENT as well as sinus sufferers and their physicians, who will now have an important new treatment option clinically proven to maintain the benefits of sinus surgery,” said Lisa Earnhardt, the company’s president and CEO. “We look forward to launching our product to clinicians and their patients in select U.S. locations this fall.”

Propel is clinically proven to maintain sinus patency after surgery by propping open the sinuses in a spring-like fashion and providing for safe, effective, and localized delivery of steroid directly to the sinus lining. The self-expanding implant conforms to the highly variable sinus anatomy then effectively delivers anti-inflammatory medication where it’s needed most as the implant dissolves. For more information please visit www.intersectENT.com.

- 1 Pleis et al. National Health Interview Survey, 2006. Vital Health Stat Series 10, Number 235
- 2 Rosenfeld et al. Otolaryngology–Head and Neck Surgery (2007) 137, S1-S31
- 3 Shaitkin et al. Laryngoscope 103, Oct 2003

Echo Therapeutics Announces Multiple Patents and Trademark Grants

PRNewswire: August 8, 2011 – PHILADELPHIA, PA – Echo Therapeutics, Inc. (NASDAQ: ECTE), a company developing the Symphony™ tCGM System as a non-invasive, wireless, transdermal continuous glucose monitoring (tCGM) system and the Prelude™ SkinPrep System for transdermal drug delivery, today announced the receipt of notices of issuance for two patents covering its Symphony tCGM System and notices of registration for the trademarks PRELUDE and SYMPHONY.

Echo Therapeutics received notice that its patent application entitled, “System and Method for Continuous Non-Invasive Glucose Monitoring” will issue as U.S. Patent No. 7,963,917. As a result of a patent term adjustment that is expected to add nearly 4 years to the term of the patent, it is expected to expire in 2025. Echo Therapeutics also received notice that its patent application entitled “Transdermal Analyte for Monitoring Systems and Methods for Analyte Detection” was issued as South Africa Patent No. 2009/06959 and will expire in 2028. Additionally, Echo has received notice that its applications for the trademark PRELUDE have been registered for use in International Class 10 in South Korea and Mexico, and its application for the trademark SYMPHONY has been registered for use in International Class 10 in Israel.

“We have long recognized the unique value that our non-invasive, glucose monitoring technology can provide, and these patents reinforce this belief, further demonstrating the proprietary nature of our technology,” stated Patrick Mooney, M.D., Echo’s Chairman and CEO. “We believe that our intellectual property portfolio will provide our products with long-term market protection and will add significantly to our shareholder value.”

These patents join 11 U.S. patents and 28 foreign patents already obtained by Echo Therapeutics. Over 40 patent applications by Echo are pending in the U.S. and foreign countries.

Femina Pharma Announces CALJ's Initial Determination Finding Certain Internet Pharmacies in Default in Patent Dispute Concerning NuvaRing®

PRNewswire: August 2, 2011 – MIAMI, FL – Femina Pharma Inc. announced that Order No. 16 in Investigation No. 337-TA-768 (In the matter of Certain Vaginal Ring Birth Control Devices) was issued by the Chief Administrative Law Judge (“CALJ”) at the United States International Trade Commission (“ITC”) finding 14 parties (13 Canadian Internet pharmacies and one U.S. Internet pharmacy) in default.

On February 11, 2011, Femina Pharma Incorporated filed a complaint with the ITC for infringement of the 6,086,909 patent through the importation of certain vaginal ring birth control devices, including NuvaRing®. On June 20, 2011, CALJ Luckern issued a show cause order why the non-responding respondents should not be held in default. These parties did not respond and on July 12, 2011, Femina moved for entry of an Initial Determination. The Commission Investigative Staff did not oppose Femina's motion and Merck & Co., Inc., Schering Plough Corporation, Organon Inc. and N.V. Organon, Wal-Mart Stores, Inc., CVS, Inc., and Walgreen Inc. did not respond to Femina's motion. On July 28, 2011, CALJ Luckern issued Order 16: “Initial Determination Finding Certain Respondents in Default and certified the initial determination to the Commission.” The initial determination will become the determination of the Commission unless within 30 days the Commission grants a petition for review or orders its own review of the initial determination.

This development follows the issuance of Order 14 by the CALJ that denied Merck's Motion for Summary Determination of Invalidity of U.S. Patent No. 6,086,909.

The defaulting parties include: The Canamerican Drugs Inc., The Canamerican Global Inc., Canadian Med Service, Panther Meds Inc., Canada Drugs Online, Drug World Canada, CanDrug Health Solutions Inc., Big Mountain Drugs, BestBuyRx.com, Blue Sky Drugs, ABC Online Pharmacy, Canadadrugs.com LP, North Drug Store, and Canada Pharmacy.

Joseph Matus Fuisz, CEO of Femina, stated: “We are pleased to see the case progress. After denial of Merck's Summary Determination of Invalidity, we now have an Initial Determination of default against 14 parties that should eventually slow the unlawful importation of infringing NuvaRing® products from Canada. Certainly, the ability of Femina to discourage unlawful importation of the NuvaRing® using the '909 patent is a tangible indication of the '909 patent's value to proper, legal licensees.”

NuvaRing® was acquired by Merck through its 2009 acquisition of Schering Plough. Merck & Co., Inc., Schering Plough Corporation, Organon U.S.A., Inc., N.V. Organon, CVS Pharmacy, Inc., Wal-Mart Stores, Inc. and Walgreen Co.'s are represented in the action by Covington & Burling, LLP (www.cov.com). Femina Pharma Incorporated is represented in the action by the Fuisz-Kundu Group LLP (www.fuiszkundu.com).

July 2011

PharmaCline™ to Launch New Over-The-Counter Antibiotic and New Investment Round

PRNewswire: July 28, 2011 – SIOUX FALLS, SD – South Dakota-based technology and pharmaceutical company, PharmaCline™, announced several exciting developments following the International BIO Conference in June.

PharmaCline™ (www.pharmacline.com) has exclusively licensed the worldwide rights for drug delivery technology and existing antibiotic products from Phillips Company, an FDA-registered pharmaceutical manufacturer located in Oklahoma. This innovative drug delivery technology enables highly effective delivery of active pharmaceutical ingredients through pathogen cell walls. When combined with tetracycline, the resulting PharmaCline product is a well-tolerated and highly effective broad spectrum antibiotic available for over-the-counter topical use.

“We are pleased to fully activate this license agreement and strategic alliance,” said Steven Keough, PharmaCline™ CEO. “Phillips Company's innovation, manufacturing and rapid prototyping is a great asset to PharmaCline™.” A company spokesperson for Phillips added, “This license and technology transfer will fund the development of additional drugs and new technology.”

Many people have unwanted allergic responses and localized dermatitis from ingredients in conventional triple antibiotic products. There have been no such problems to date with the PharmaCline™ products, due to the use of tetracycline and its historically safe profile. Combined with a site-specific delivery system having excellent emollient qualities, there have been very favorable responses from users of the PharmaCline™ products. Tests have shown that this new antibiotic product is highly effective against topical Gram-positive and Gram-negative bacteria. Based on these unique attributes and human field studies, PharmaCline™ believes its products will have rapid adoption and strong brand loyalty following commercial launch.

Additionally, PharmaCline™ announced that it is seeking Series C funding partners to support upcoming U.S. and international over-the-counter product launches. CEO Steven J. Keough remarked, “PharmaCline has had great success to date with our early fund-raising efforts. We are excited by the sizable market gap our products fill and the positive impact on peoples' lives that our medications have provided.” Human field studies are ongoing, as well as pre-clinical work at a leading pharmacy school in the United States. Products will be initially available online, and will then be launched into specific U.S. markets with more traditional campaigns directed at healthcare providers and pharmacies. Upon that success, an international launch emphasis will then begin in the Americas.

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Pharmaceutics International, Inc. (Pii) Expands Drug Formulation and Manufacturing Capabilities with Hot Melt Extrusion Technology

PRNewswire: July 27, 2011 – HUNT VALLEY, MD – Pharmaceutics International, Inc. (Pii), a leading contract development and manufacturing organization, today announced that it has added hot melt extrusion (HME) to its portfolio of formulation and process development solutions. The company has purchased 16mm and 18mm Leistritz twin screw extruders. This investment enables Pii to carry out feasibility studies, using just a few grams of active pharmaceutical ingredient, to pilot scale cGMP productions for Phase I and II clinical trials using HME.

A well known processing technology, hot melt extrusion offers a number of benefits to optimize drug formulation, including the development of solid dispersions for bioavailability enhancement of poorly soluble compounds and controlled release drug delivery.

“Pii’s investment in hot melt extrusion is part of the company’s goal of providing our clients with a comprehensive package of bioavailability enhancement capabilities,” said Steve King, senior vice president of Pii. “This proven technology further enables us to meet the challenges of poorly soluble compounds and advance our client’s compounds through the development pipeline.”

In addition to the new hot melt extrusion capability, Pii’s solutions for bioavailability enhancement include spray drying, solvent-based fluid bed processing, soft gels, and liquid filled hard capsules.

Pharmaceutics International, Inc. (Pii) is a privately held drug delivery solutions company providing dosage form development and GMP manufacturing services to the global pharmaceutical industry. Pii’s vision is to become the benchmark in pharmaceutical product development outsourcing. Headquartered in Hunt Valley, Maryland, USA, with European facilities in the UK, Pii offers preformulation testing, formulation development, and clinical trial material and commercial manufacture of parenteral, solid, semi-solid, and liquid dosage forms. For further information about Pii visit www.pharm-int.com.

Micell Technologies Completes Enrollment in DESSOLVE II Study of the MiStent® Drug-Eluting Coronary Stent

PRNewswire: July 26, 2011 – DURHAM, NC – Micell Technologies, Inc. today announced that it has completed patient enrollment in its DESSOLVE II CE Mark clinical study of the MiStent® Drug-Eluting Coronary Stent System. The MiStent DES is an ultra-thin drug-eluting stent distinguished by a rapid-absorbing drug/polymer coating formulation. Enrollment of 183 patients across 26 study centers throughout Europe and New Zealand was accomplished ahead of schedule.

Micell previously announced that, based on results observed in the DESSOLVE I first-in-human trial, the sample size in the DESSOLVE II CE Mark study was reduced from 270 to 171 subjects.

“We believe that by exceeding the projected enrollment rate for this study and completing enrollment in just 5 months, participating clinicians have demonstrated their enthusiasm for the novel MiStent drug-eluting stent,” commented Dennis J. Donohoe, M.D., Micell’s Chief Medical Advisor. “We extend our gratitude to the investigators and in particular the principal investigators of the study, William Wijns, M.D. and John Ormiston, M.D., for their support throughout the enrollment phase of this important trial.”

The DESSOLVE II CE Mark trial is a multi-center study of patients with documented stable or unstable angina pectoris. The primary endpoint is superiority of the MiStent DES in minimizing in-stent late lumen loss at nine months, compared to Medtronic’s Endeavor® Sprint DES, as measured by the angiography core laboratory in *de novo* lesions ranging in diameter from 2.5 to 3.5 mm and amenable to treatment with a maximum 30 mm length stent.

Arthur J. Benvenuto, Chairman and Chief Executive Officer of Micell, said, “The coating on the MiStent DES differs substantially from those associated with commercially available DES technologies. The coating is engineered to clear the stent within 45 to 60 days and provide controlled and sustained delivery of sirolimus over a period of months, while limiting vascular exposure to the polymer coating to less than 90 days. As a result, we expect the MiStent DES could optimize sirolimus therapy by reducing the risk of complications such as late stent thrombosis, while suppressing neointimal hyperplasia and related healing responses to arterial injury that lead to restenosis.”

BioDelivery Sciences Announces Completion of BEMA Buprenorphine Phase 3 Chronic Pain Study

PRNewswire: July 25, 2011 – RALEIGH, NC – BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced today that the last patient has completed the randomized portion of its Phase 3 clinical trial assessing the efficacy and safety of BEMA Buprenorphine for the treatment of moderate to severe chronic pain, signifying completion of the trial.

“We are very pleased to have brought to completion our Phase 3 efficacy study for BEMA Buprenorphine in the management of chronic pain,” stated Dr. Andrew Finn, Executive Vice President of Product Development at BDSI. “We have achieved our aggressive recruitment and enrollment goals and anticipate reporting top line results in mid to late September of this year. Over the next several weeks, we will be completing the administrative activities that will lead to a database lock followed by statistical analysis and the availability of top line results. Assuming positive study results, we would hope to be in a position to file a New Drug Application (NDA) for this product in the first half of 2012.”

Femina Pharma Announces ALJ’s Denial of Merck’s Motion for Summary Determination of Invalidity in Patent Dispute Concerning NuvaRing®

PRNewswire: July 20, 2011 – MIAMI, FL – Femina Pharma Inc. announced that Order No. 14 in Investigation No. 337-TA-768 (In the matter of Certain Vaginal Ring Birth Control Devices) was issued by the Chief Administrative Law Judge at the United States International Trade Commission (“ITC”) denying Merck’s Motion for Summary Determination of Invalidity of U.S. Patent No. 6,086,909.

On February 11, 2011, Femina Pharma Incorporated filed a complaint with the ITC for infringement of the ‘909 patent through importation of certain vaginal ring birth control devices, including NuvaRing®. On June 30, 2011, Merck & Co., Inc., Schering Plough Corporation, Organon U.S.A., Inc., N.V. Organon, CVS Pharmacy, Inc., Wal-Mart Stores, Inc., and Walgreen Co.’s moved to invalidate the ‘909 patent. That motion was denied by Order No. 14. NuvaRing® was acquired by Merck through its 2009 acquisition of Schering Plough.

Life Technologies Develops Potent Drug Delivery Technology for Therapeutics Market

PRNewswire: July 14, 2011 - CARLSBAD, CA - Life Technologies Corporation today announced that it has developed new drug delivery technology specially designed for therapeutic applications that is 100-fold more potent than previous formulations. The technology is available for licensing as part of a new out-licensing program.

Scientists at Life Technologies have developed the novel proprietary siRNA delivery reagents by using new lipid molecules and formulation design to drastically improve potency and minimize toxicity *in vivo*. A single dose of 12.5mg siRNA per kilogram can achieve 50 percent knock down of a target gene, said Keith Farnsworth, product management leader at Life Technologies.

“Historically, delivery of siRNA has been problematic due to the high risk of toxicity and hampered efficiency,” he said. “Life Technologies’ new formulations provide the pharmaceutical and biotech industries a viable platform to help develop siRNA drugs that overcome these challenges.”

The availability of the new formulations follows Life Technologies’ 2010 launch of Invivofectamine 2.0®, a lipid-based siRNA delivery technology for the research market that can knock down up to four genes *in vivo* in lab models for extended periods with a single application. The novel formulations available through the out-licensing program use different molecules that make it ideal for therapeutic applications.

For more information, contact Maya Tanaka, Sr. Manager, Business Development and Licensing, (760) 268-7982; Maya.Tanaka@lifetech.com

Particle Sciences and Absorption Systems Form Relationship to Offer Clients Enhanced Services

PRNewswire: July 12, 2011 - BETHLEHEM, PA - Particle Sciences Inc. (PSI), a leading pharmaceutical CRO, and Absorption Systems, a leading provider of pre-clinical pharmacokinetic services, announced today that the two companies are working together to provide their clients with enhanced drug development services by integrating pre-clinical pharmacokinetic data into the dosage form development scheme.

According to Robert Lee, Ph.D., Particle Sciences’ Vice President Pharmaceutical Development, “Particle Sciences has always had a methodical approach to drug product development. Dosage form design is best done when informed by the *in vivo* solubility, permeability, and metabolism of the drug. This is true for oral drug products as well as other routes of administration. Absorption Systems has put in place a scaled *in vitro* / *ex vivo* / *in vivo* approach to obtaining this data, which lends itself to our needs. For those clients that desire it, Particle Sciences can integrate this data stream into our drug product development plan. Ultimately, this should prove to be a cost-effective way to drive efficiency and minimize time to the clinic.”

Chris Bode, Ph.D., Vice President Scientific & Corporate Communications at Absorption Systems, adds that “Our portfolio includes a number of physicochemical and biological tests that can make formulation development a more rational and efficient process. Particle Sciences is a leader in drug formulation and manufacturing, and we are very pleased that they are leveraging our toolset in their efforts. I believe this is consistent with their overall innovative and comprehensive approach to drug product development”.

Absorption Systems, founded in 1996, assists pharmaceutical and medical device companies in identifying and overcoming ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) barriers in the development of drugs and medical devices. The company’s mission is to continually develop innovative research tools that can be used to accurately predict human outcomes or to explain unanticipated human outcomes when they occur. The CellPort Technologies® platform, a suite of human cell-based test systems for drug transporter characterization, exemplifies Absorption Systems’ commitment to innovation and is soon to be an industry assay standard for *in vitro* drug interaction assessment. Absorption Systems has facilities near Philadelphia, PA, and San Diego, CA, and serves customers throughout the world. For information on the company’s comprehensive contract services and applied research programs, please visit www.absorption.com.

Particle Sciences is an integrated provider of drug development services. Particle Sciences focuses on emulsions, gels, particulates, and drug/device combination products with additional specialized capabilities in topical and mucosal drug delivery. Through a full range of formulation, analytic, and manufacturing

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services, Particle Sciences provides pharmaceutical companies with a complete and seamless development solution that minimizes the time and risk between discovery and the clinic. The company was founded in 1991 and is headquartered in Bethlehem, Pennsylvania. Visit www.particlesciences.com, email info@particlesciences.com or contact us at (610) 861- 4701 for information.

EffRx Announces Issuance of U.S. Patent Providing Further Protection to EX101, Effervescent Alendronate Weekly Dosing Form

PRNewswire: July 11, 2011 – LAUSANNE, SWITZERLAND – EffRx Pharmaceuticals SA, an Epalinges/Lausanne, Switzerland based drug delivery company, announces that US patent 7,964,212 was issued on June 21, 2011, enhancing the protection of EX101.

This patent grants significant additional intellectual property concerning the EffRx Lead Program, EX101 (70 mg effervescent alendronate for the treatment of osteoporosis).

The extended range of intellectual property in this patent protects effervescent formulations of all the orally administered bisphosphonate osteoporosis medications including risedronate and ibandronate, when delivered in the highly buffered EX101 formulation. The formulation is unique in that it delivers the bisphosphonate to the stomach in a proprietary buffered solution, which prevents exposure of the stomach or esophagus to strongly acidified bisphosphonate forms, which are believed to be damaging forms of this drug class.

Additional claims related to the buffering composition and method of manufacturing were also granted.

An NDA for EX101 has been filed by the FDA. Nycomed has licensed EX101 for territories outside the United States, Canada, and Japan, and the product is in registration in many countries. “There are more and more reports around the world that generic alendronate products have even more GI-side effect problems and thereby less patient compliance than branded bisphosphonate products. We strongly believe that EX101 fills an unmet need of patients, doctors, and payers around the world since poor compliance leads to escalating health costs due to osteoporosis related fractures” stated Christer Rosén, Chairman and CEO.

EffRx is a privately held drug delivery technology company specializing in the utilization of proprietary effervescent technology to develop formulations that improve efficiency, compliance, and convenience of existing prescription drugs. For additional information please visit the EffRx website <http://www.effrx.com> ■

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Washington, DC, U.S.A.

[www.aapspharmaceutica.com/
meetings/annualmeet/AM11](http://www.aapspharmaceutica.com/meetings/annualmeet/AM11)

Joint Indo-US Symposium on Nanomedicine: Prospects and Challenges

November 14–15

Mumbai, India

[www.ictmumbai.edu.in/newsFiles/
Indo-US-Symposium.pdf](http://www.ictmumbai.edu.in/newsFiles/Indo-US-Symposium.pdf)

2012

Microneedles 2012 – 2nd International Conference on Microneedles

May 13–15

Cork, Ireland

<http://www.microneedles.ie>

9th World Biomaterials Congress

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