SFB Regenerative Medicine Symposium Registration Materials Inside

BIOMATERIALS FORUM

Third Quarter 2004 • Volume 26, Issue 3

Methods for Confirming Hydrogel Prepolymers

Letter from New SFB President

Bio-careers Job Site Launched

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Biomaterials Forum, the official news magazine of the Society For Biomaterials, is published quarterly to serve the biomaterials community. Society members receive *Biomaterials Forum* as a benefit of membership. Non-members may subscribe to the magazine at the annual rate of $48. For subscription information, or membership inquiries, contact the Membership Department at the Society office (e-mail: info@biomaterials.org) or visit the Society's Web site, www.biomaterials.org.

Editorial contributions to *Biomaterials Forum* are always welcome. Contributions should be sent to the Executive Editor, and are subject to the terms and conditions of the Editorial and Publication Release. Authors should refer to the Author Guidelines, which are available on the Society's Web site, when writing submissions. The publisher accepts no responsibility for return or safety of artwork, photographs, or manuscripts. Submission of editorial content does not guarantee acceptance or publication.

Address corrections should be sent to *Biomaterials Forum*, 17000 Commerce Parkway, Mt. Laurel, NJ 08054.

Requests for advertising information should be directed to Frank Scussa at fscussa@ahint.com or (856) 439-0500, ext. 3064. Information is also available on the Society's Web site, www.biomaterials.org.

Scientific photos may be submitted for cover consideration in future issues. Submit color photo no larger than 4" x 6", along with credit information and scientific description, to the Executive Editor.

BIOMATERIALS FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 26, Issue 3

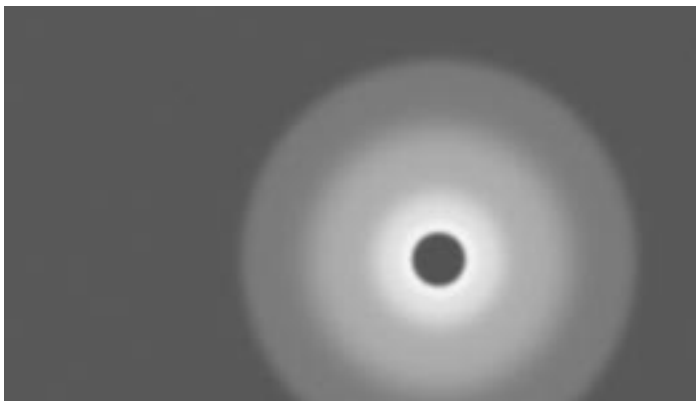
Special interest Group Reporters

Next Issue Deadline: September 1, 2004

BIOMATERIALS FORUM

Third Quarter 2004 • Volume 26, Issue 3

Features



A 10 percent PEGDM mass fraction hydrogel corresponding to a two-dimensional scattering pattern of 4k-PEGDM solution. Visual provided by Sheng Lin-Gibson to accompany the article on page 10 that is an official contribution of the National Institute of Standards and Technology.

Departments

The Torch

Special Interest Group News

University News

Government News

Industry News

From the Editor

Welcoming a New Council

For the past 31 years, the members of the Society For Biomaterials have elected officers annually. Even though the tasks associated with the positions are clearly defined in the bylaws of the Society, much more is expected from these individuals, including leadership, which is highly anticipated and regarded. There are many diverse definitions of leadership. John C. Maxwell defines leadership as "influence—nothing more, nothing less." Warren Bennis attributes leadership to the capability of the individual leader, "a function of having a vision that is well communicated, building trust among colleagues, and taking effective action." Even though leadership styles have been quite distinct during the years, all officers have passed the test and succeeded at motivating and inspiring members to make a difference. As a result, the Society has grown and matured, and become an organization that members can be proud to belong to. Each officer has been successful in engaging members to adapt, share, and move the mission of the Society. Each president has been a leader. This leadership is attributed to teamwork—teamwork with Council members.

The essence of biomaterials research is collaboration and teamwork. All biomaterials scientists and researchers are aware that success in the field is based on true collaboration between clinicians, designers, engineers, and life scientists. From the beginning of their careers they are trained to communicate with others and appreciate the benefits of diversity. Members who volunteer to serve on Council have committed to serve the Society with dedication and motivation through teamwork. Dedication and motivation are not the sole keys to success. Another ingredient that is often neglected is input from the members of the Society. Council cannot speak on behalf of members if members do not voice their needs and opinions.

Biomaterials Forum congratulates all elected officers and welcomes the new Council for 2004-2005. It sincerely thanks these individuals for having committed to further the goals and mission of the Society despite their busy professional schedules. *Biomaterials Forum* also challenges members of the Society to actively participate in the Society by sharing their views with officers, directors, and Council committee chairs. *Biomaterials Forum* looks forward to serving as the official platform for exchange between the Council and Society members.

Letter from the President

The Torch
By Anne Meyer

It's Your Society – Come and Get It!

This is Anne Meyer, reporting in as your 31st president. Joining as new members of the Society For Biomaterials board this year are Michael Sefton (President-Elect), Tony Mikos (Member-at-Large), and Elaine Duncan (SIG Representative). Continuing on the board are Mauli Agrawal (Secretary-Treasurer), Lynne Jones (Secretary-Treasurer-Elect), Nicholas Peppas (1st Past President), and Jim Burns (2nd Past President). Getting back to full attention to his "day job" as an orthopaedic surgeon and researcher, after four years on the board, is Stuart Goodman. And Jennifer West is back to her busy research and teaching schedule after a year as Member-at-Large.

For those of you who participated in the Society's business meeting in Sydney, ensuring that we achieved a quorum—thank you!! In addition to committee reports, we accomplished several things: the 2004/05 Awards, Ceremonies, and Nominations Committee members were elected; new Society members were approved; all of the proposed bylaws amendments were passed; and, without missing a beat, President Peppas and Executive Director, Steve Echard, turned the agenda to election of the newly constructed Membership Committee for 2004/05. A big thanks, too, to the Australian Society for Biomaterials for hosting this very productive and enjoyable World Biomaterials Congress. Good on ya, guys!

Now that the swirl of the World Congress has passed, I want to take a few moments to share my deep appreciation of our immediate Past President, Nicholas Peppas. His leadership during the past year was exemplary as the Society not only transitioned to a new management company, but also moved through a year without our usual annual technical meeting. Nicholas' vision of the Society as the center of excellence in areas such as combination products and tissue engineering is the foundation for our upcoming symposium on Regenerative Medicine (October 2004) and for cooperative meeting planning on tissue engineering (spring 2006, Pittsburgh). His promotion of the leadership of talented, young Society members is something that we all will benefit from for many years to come. So, Nicholas, as you return to spend more time with the people and interests you hold most dear—your family, your friends … and opera—thank you!

This Society of ours has come a long way from the days when a small group of clinicians and engineers walked away from another technical society because as the story goes, biomaterials-related issues were not getting enough "podium time." A long way, to the point that we now have several well-established student chapters across the continent and several newly formed student chapters. What a great opportunity to get involved with our future leaders in industry, academia, and public service! This is neither a "one-size-fits-all" Society (witness the key role of the SIGs), nor a highly specialized technical "boutique" (note the increasing richness and scope of our meetings). In the coming year, with your all-important participation, we will continue to build quality programming and educational outreach initiatives. We will increase professional opportunities for you, be they forums for technical exchange (meetings, publications), professional development sessions (a "biomaterials business school"), opportunities to mentor and network, or resources for participating in public policy debate.

Just how can we do this? In my view, we must take every good opportunity to increase communication and collaboration among ourselves and our Council committees, and with other professional societies and agencies. We also must re-establish strong and productive connections to organizations such as the American Institute for Medical & Biological Engineering (AIMBE), Association for the Advancement of Medical Instrumentation (AAMI), and the National Research Council of the National Academies. Reports of our progress will be published in *Biomaterials Forum* and posted on our Web site (www.biomaterials.org).

I will be in contact with you again soon. If you have any recommendations or concerns in the meantime, please do not hesitate to get in touch with me (aemeyer@acsu.buffalo.edu), Tony Mikos (mikos@rice.edu), or Steve Echard (sechard@ahint.com).

See you in Philadelphia from October 16 to 18!

Staff Updates from Headquarters

By Dan Lemyre,
Assistant Executive Director

Greetings from the headquarters office of the Society For Biomaterials! This article is the first installment of what we plan to be a regular feature in the *Biomaterials Forum*. By providing a regular update of staff and membership activities, it is our sincere wish that all of the Society's members stay abreast of current Society activities and that more members take an active role in the Society For Biomaterials!

Annual Business Meeting

The Society's Annual Business Meeting took place in Sydney, Australia, May 19, 2004. At the business meeting, several announcements were made and several issues were voted upon by the quorum of members that were present.

Election of Officers

Results of this spring's election were announced. The following individuals have been elected to serve as officers on the Society For Biomaterials board of directors:

Michael Sefton, ScD – President-Elect
Anthony Mikos, PhD – Member-at-Large

Bylaws Changes

The Society members present approved the proposed changes to the SFB bylaws, which were distributed to all members prior to the meeting. Updated bylaws have been posted on the SFB Web site, www.biomaterials.org.

Election of New Members

All of the active members presented for membership were voted into the Society. With the bylaws changes mentioned previously, this marks the last of these elections.

New Council

The following members were identified as chairs of the committees specified below, and together with the board of directors, comprise the SFB Council for 2004-2005:

Linda Lucas - Awards, Ceremonies & Nominations
Tim Topoleski - Bylaws
Kathleen White - Devices & Materials
K.C. Dee - Education & Professional Development
Lynne Jones - Finance
Jim Burns - Liaison
Michael Sefton - Long-Range Planning
Anne Meyer - Meetings
Alan Litsky - Membership
Nicholas Peppas - President's Advisory
Joel Bumgardner - Program
Rick Gemeinhart - Publications

Continuing on Council are the editors of SFB's official publications (Jim Anderson, Harold Alexander, and Martine LaBerge). With the bylaws change, Elaine Duncan joins the board as SIG Representative. Mauli Agrawal continues as SFB's Secretary-Treasurer.

Upcoming Events

The Society will be hosting the "Biomaterials in Regenerative Medicine: The Advent of Combination Products" meeting in Philadelphia at the Wyndham Franklin October 16-18, 2004. For complete program and registration information, please visit the SFB Web site (www.biomaterials.org) or see page 8 in this issue.

Save the Date

The Society For Biomaterials 2005 Annual Meeting will be held April 27-30, 2005, at the Memphis Cook Convention Center in Memphis, Tenn. Registration and program information is available on the SFB Web site and on page 7 in this issue.

Staff Overview

In the event you wish to contact the headquarters' office for any reason, below is a listing of the Society For Biomaterials headquarters staff, and a brief description of their areas of responsibility. The SFB headquarters main phone number is 856-439-0826; extensions and e-mails are listed below.

Steve Echard, CAE – Executive Director: Primary staff contact for SFB board of directors. Responsibilities include oversight of all executive office activities, including financial management, publications, membership services, meetings and public relations. (sechard@ahint.com; X3058)

Dan Lemyre – Assistant Executive Director: Primary staff contact for Council, SIGs, and committees, secondary staff contact for board of directors. Responsibilities include preparation of agendas, minutes and budgets, collaboration with board, council and committees on ongoing projects, and assisting executive director. (dlemyre@ahint.com; X3039)

Larissa Cahill – Administrative Director: All general inquiries, membership, mailing lists, student chapters, copyright, accounts payable/receivable, subscriptions, and SIGs. (lcahill@ahint.com; X3011)

Rhonda Flowers – Membership Coordinator: Membership and member inquiries, copyright, accounts payable/receivable. (rflowers@ahint.com; X3073)

Celeste McNair – Meetings Director: Handles all aspects of meeting planning and logistics, except for registration. (cmcnair@ahint.com; X3035)

Rebecca Haines – Registration Services Director: Handles all meeting registrations. (rhaines@ahint.com; X3061)

Frank Scussa – Publications Manager: Managing Editor of *Biomaterials Forum*. (fscussa@ahint.com; X3064)

Education and Professional Development Committee:

By Joel D. Bumgardner and Education and Professional Development Committee

Bio-careers Internet Job Site Up and Running

The Society's staff, working with BioJobNetwork, has launched the Bio-careers Internet job site (Biomat Careers section of www.biomaterials.org). The BioJobNetwork group was identified after a review of several Internet job sites and organizations by members of the Education and Professional Development Committee. This selection was based on ease of use for posting information, site navigability, most relevant jobs for biomaterial scientists and engineers, and for potential payback to the Society. BioJobNetwork focuses on jobs in biotechnology, pharmaceuticals, medical devices, nanobiotechnology, and the life sciences. A cursory search of the site produced listings for clinical research, regulatory officer, quality control, and post-doctoral positions. It is free for Society members to post resumes/CVs and search for positions, while the fees for posting job positions are very reasonable ($100-$125 for 60 days).

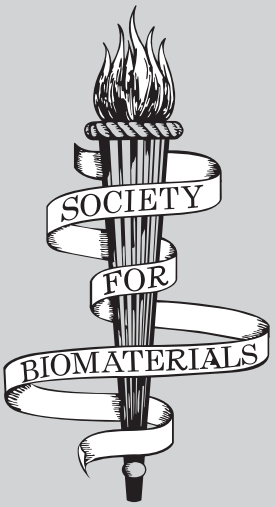
For those seeking a job or posting information, there are guidelines and advice for creating cover letters and editing resumes. The site provides flexibility for the job seeker in displaying personal and contact information, and individuals may elect to have new job posting notifications sent to their e-mail address. And of course, job seekers can go back and edit and update information at any time.

For companies and institutions, advertisements or listings for positions are distributed to a wide range of scientific centers in biotechnology, pharmaceuticals, medical devices, nanotechnology, and the life sciences. Job listings are for 60 days; allow for thumbnail logo display; may assign a job listing to one of the seven Biotech Markets such as academia, regulatory and compliance, biotech, and medical devices; and list jobs in specific geographical locations, work disciplines, or areas of expertise. Listings are made available for Job Alert notices that are sent to job seekers and all job listings may be edited, suspended, and/or extended by the employer at any time while active.

It is also noted that BioJobNetwork regards the privacy and security of user information as critical to the integrity of its business and endeavors to ensure that no information will be provided to any third party in any form that will personally identify an individual, unless specifically and knowingly authorized to do so. Nor is the information on the site knowingly sold or rented to, or shared with, other third parties.

The staff at the Society's headquarters should be notified of any problems encountered while searching job listings or posting information. Comments and suggestions regarding the site are also welcome and can be directed to members of the Education and Professional Development Committee. So, dust off those resumes and advertisements and happy job/employment hunting!

CALL FOR NOMINATIONS



The Society For Biomaterials is soliciting nominations for the 2005 Awards listed below, and for the following board of directors positions:

Board of Directors:
(Deadline: Sept. 1, 2004)

- President - Elect
- Secretary/Treasurer Elect
- Member-at-Large

To nominate a colleague, or yourself, for an award or position on the SFB board of directors, please visit the SFB Web site at: www.biomaterials.org

2005 Awards:
(Deadline: Sept. 15, 2004)

- Founder's Award
- C. William Hall Award
- Clemson Award for Applied Research
- Clemson Award for Basic Research
- Clemson Award for Contributions to Literature
- Technology Innovation and Development Award
- Young Investigator Award
- Student Award for Outstanding Research
- Outstanding Research by a Hospital Intern, Resident, or Clinical Fellow Award

2005 Annual Meeting

New and Expanded Topics for Program Development

The Torch

by Joel D. Bumgardner, Jack Parr, Shah Jahan, Paul Kovacs, and Anne Meyer

As the Society prepares for its fall symposium, planning for the 2005 Annual Meeting is beginning. The meeting will be held from Wednesday, April 27, to Saturday, April 30, 2005, at the Memphis Cook Convention Center in Memphis, Tenn. The convention center is located in historic downtown Memphis adjacent to The Pyramid and the Downtown Trolley Line, and within walking distance of numerous hotels, attractions, and the world-famous Beale Street. The convention center and hotels are 20 minutes from the Memphis International Airport.

The Meeting Leadership team consists of Anne Meyer, SFB President and chair of the Meetings Committee; Joel D. Bumgardner, program chair; Jack Parr, local corporate liaison; Shah Jahan, local academic liaison; and Paul Kovacs, local government and business liaison. Strong support for the meeting from the local Memphis business community, including Wright Medical Technologies Inc., Smith & Nephew Orthopaedics, Medtronic Sofamor Danek, and St. Jude Children's Research Hospital, as well as from local universities (University of Memphis, University of Tennessee Health Science Center, Rhodes College, Christian Brothers University, Southwest Tennessee Community College, and Arkansas State University) is anticipated. Interactions with the Memphis Regional Chamber of Commerce, Memphis Development Bioworks Council, the FedEx Institute of Technology, and local governments are being developed to provide support for the meeting, to highlight biomedical businesses, business opportunities, education and training, and quality of life in the Memphis region.

The Program Committee will work closely with Society members, Special Interest Groups, and staff at the Society's headquarters to develop the meeting program. Tentative programming discussions include new and expanded biomaterial topics in pharmaceuticals and material-drug interactions as a follow-up from the Fall 2004 symposium, membranes, biofouling, and re-use of single use devices, to name a few. All are encouraged to submit ideas and suggestions on new and expanded topics, keynote speakers, and useful and constructive advice to any or all members of the Meetings Leadership Team. The meeting announcement and the call for papers will be published in July/August and the deadline for abstracts is tentatively scheduled for late October or early November 2004.

Members and friends of the Society are invited to work on their Elvis impersonation and an appetite for BBQ, the blues and Rock'n Roll, and come on down for a walk in Memphis!

A Heartfelt Invitation to Memphis

The Torch

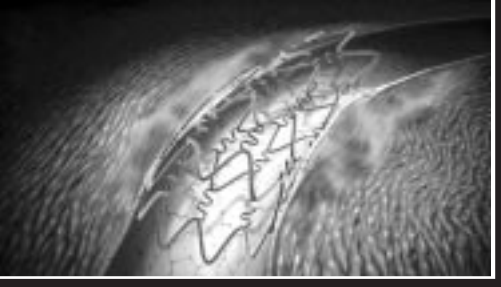
By Jerry Klein, Chairman, Memphis Convention & Visitors Bureau

The music. The history. The food. The stories. The deep unrelenting Mississippi River seems to fill Memphis with a powerful soul that overflows into the restaurants and historic sites. It makes for a rich, one-of-a-kind meeting destination that will give the Society For Biomaterials a trip to remember.

Memphis music has had a unique impact on worldwide culture. Memphis is a sound and a rhythm that races through your soul, making it the Home of the Blues and the Birthplace of Rock'n Roll. On July 5, 1954, Elvis Presley recorded "That's All Right" at the legendary Sun Studio in Memphis ... and rock'n roll took off. Fifty years later, Memphis is marking the 50th anniversary of rock'n roll with a yearlong celebration.

There is just something real about Memphis. From the holy grails of music landmarks to the restaurants, from the basketball court to the acclaimed zoo, from the elegant hotels to the mystical nightclubs on legendary Beale Street, there's an irresistible soul that has drawn people here for more than a century.

Memphis is delighted to host the 2005 Annual Meeting of the Society For Biomaterials and to offer a unique travel experience to its attendees. Come on in. Take a closer look at the online home of the Memphis Convention & Visitors Bureau (www.memphistravel.com) and plan on visiting us next April. On behalf of the people of Memphis, the Memphis Convention & Visitors Bureau extends a heartfelt invitation to the members, friends, and guests of the Society For Biomaterials.



October 16-18, 2004

Wyndham Philadelphia at Franklin Plaza

Philadelphia, PA

Society For Biomaterials

Biomaterials in Regenerative Medicine: The Advent of Combination Products

This meeting has been organized to emphasize the underlying scientific and regulatory problems that transcend specific clinical applications of regenerative medicine. The symposium will be held immediately after the annual meeting of the Biomedical Engineering Society (BMES) in Philadelphia.

Schedule of Events

Saturday, October 16, 2004

8:00 AM - 5:00 PM	Registration
1:30 PM - 3:00 PM	**Chris Chen**, PhD, Johns Hopkins University "Cell-surface adhesive interactions and the regulation of stem cell fate" **Jeffrey Hubbell**, PhD, EPFL (Lausanne) "Hydrogel display systems for morphogenetic signals"
3:00 PM - 4:00 PM	Poster Session and Coffee Break
4:00 PM - 5:30 PM	Oral Presentations

Sunday, October 17, 2004

7:00 AM - 5:00 PM	Registration
8:00 AM - 9:30 AM	**Industry/FDA Forum: "Translation from Discovery to Development"** **Robert Nerem**, Georgia Institute of Technology (Chair) Keynote Speaker: Mark Kramer, Director, Office of Combination Products, FDA Participants: TBA
9:30 AM - 10:00 AM	**Duncan Stewart**, MD, St. Michael's Hospital, Toronto Title: TBA
10:00 AM - 11:00 AM	Poster Session and Coffee Break
11:00 AM - 12:00 PM	Oral Presentations
12:00 PM - 1:30 PM	"Welcome" Lunch
1:30 PM - 3:00 PM	Oral Presentations
3:00 PM - 4:00 PM	Poster Session and Coffee Break
4:00 PM - 5:30 PM	Oral Presentations

Monday, October 18, 2004

7:00 AM - 12:00 PM	Registration
8:00 AM - 9:30 AM	**Ann Marie Schmidt**, MD, Columbia University "RAGE: Diabetic Complications & The Inflammatory Response" **Samuel Stupp**, PhD, Northwestern University "Crafting Nanoscale Bioactivity in Biomaterials with Supramolecular Chemistry" **Julia Babensee**, PhD, Georgia Institute of Technology "Biomaterial Control of Immune Responses"
9:30 AM - 10:30 AM	Poster Session and Coffee Break
10:30 AM - 12:00 PM	Invited speaker: TBA **Robert Langer**, PhD, Massachusetts Institute of Technology "Novel Biomaterials"

Schedule of Events is subject to change. Please check the SFB Web site for updated program.

Early registration (Member $300; Student $100) is available on the SFB Web site **www.biomaterials.org**

Or contact SFB office at:

Society For Biomaterials • 17000 Commerce Parkway, Suite C • Mount Laurel, NJ 08054

Phone: 856-439-0826 • Fax: 856-439-0525 • E-mail: info@biomaterials.org

Society For Biomaterials
Registration Form

Pre-registration Deadline is September 15, 2004
Biomaterials in Regenerative Medicine: The Advent of Combination Products
October 16 – 18, 2004

Please type or print clearly

Name: _____

Title: _____

Specialty/Discipline: _____

Institution/Affiliation: _____

Department: _____

Address: _____

City: _____

State: _____ _____

Country: _____

Zip/Postal Code: _____

Phone: _____

Fax: _____

E-mail: _____

Special Requests (ADA, Dietary, etc.): _____

Member in which Society?

❑ Society For Biomaterials, USA

❑ Other WBC Society (list): _____

Member Number: _____

Registration Fees (on or before September 15, 2004)

❑ Member	$300
❑ Non-Member	$350
❑ Student	$100

Registration Fees (after September 15, 2004)

❑ Member	$350
❑ Non-Member	$400
❑ Student	$150

Registration Total: $_____
Transactions Book $50
Total Amount: $_____

Student status verification required
__I attest that the named individual is a full-time, degree-seeking student.

X_____
Signature of advisor or department chair

Advisor's Printed Name: _____

Advisor's Telephone: _____

Advisor's E-mail: _____

There are three ways to register for this event:

1. **Internet** - Register online through the SFB Web site at www.biomaterials.org. Payment must be made by credit card.

2. **Fax** – Complete this registration form, including complete contact and credit card information, and fax to Rebecca Haines, registration manager, at 856-439-0525.

3. **Mail** – Complete this registration form and include either credit card information or a check for your registration fee. Mail registration form and payment to:
   Rebecca Haines, SFB Registration
   17000 Commerce Parkway
   Suite C, Mt. Laurel, NJ 08054

Checks must be payable in U.S. dollars and drawn from a U.S. bank. Please make checks payable to the Society For Biomaterials (SFB).

Cancellations/Refunds
Requests for refunds must be submitted in writing on or before September 15, 2004, and will be assessed a $75 cancellation fee. Refund requests received after September 15, 2004, will forfeit 100 percent of monies paid. All refunds will be considered on a case-by-case basis. Refunds will be processed after the meeting.

Alternate Representative
Registration assignments must be in writing and bear the signature of the original registrant. Such assignments may be made at any time during the registration process, including at the on-site registration desk. A $75 transfer fee will be applied for alternate representative assignments.

Payment Information

❑ Check

OR

❑ Credit Card
❑ VISA ❑ Mastercard ❑ AMEX

Credit Card Number: _____

Exp. Date: _____

SOCIETY FOR BIOMATERIALS

The Use of MALDI-TOF MS and ^{1}H NMR as Complimentary Methods for Confirming Composition and Purity of Hydrogel Prepolymers

Feature
by Sheng Lin-Gibson

Photopolymerizable poly(ethylene glycol) dimethacrylates (PEGDM) and similar PEGDM derivatives of various molecular mass were synthesized and characterized. PEGDM hydrogels were studied as model tissue engineering scaffolds for soft tissue regeneration because PEG alone is bio-inert, but can be easily modified to become bioactive. In addition, photopolymerization of dimethacrylates are relative fast reaction, and the resulting hydrogels have been shown to be biocompatible with the unreacted methacrylates having relatively low cytotoxicity. Cells that generate cartilage, chondrocytes, encapsulated in hydrogels retain their native form and over time can generate native cartilage tissue. Despite the large number of studies currently available, there is still a lack of a clear understanding of the correlation between material properties and cell response.

The PEG hydroxyl endgroups react with methacrylic anhydride to form PEGDM or with 2-isocyanatoethyl methacrylate to form poly(ethylene glycol) urethane-dimethacrylates PEGUDM (Figure 1). Triethylamine (TEA) was used to catalyze the reaction. PEGDMs were also prepared

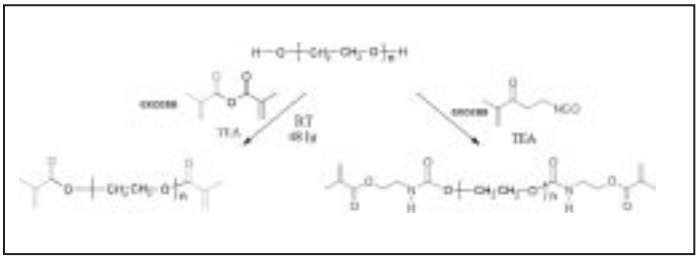


Figure 1. *Synthesis of PEGDM and PEGUDM.*

by a microwave-assisted route to achieve fast reaction conversions (five minutes for microwave reactions vs. four days for solution reactions) under solvent-free conditions. Hydrogels were prepared by photopolymerization. PEGDM or PEGUDM and aqueous initiator (Irgacure 2959) solution were mixed in distilled, deionized water or growth medium when chondrocyte is encapsulated in the hydrogel. Cylindrical samples were cured with a long wavelength UV source (365 nm, 300 μW/cm2) for 10 minutes to obtain hydrogels.

The dimethacrylate products were characterized by proton nuclear magnetic resonance (^{1}H NMR) and matrix-assisted laser desorption ionization time-of-flight mass spectrometry (MALDI-TOF MS). The two techniques together confirmed the formation of prepolymers of high purity and narrow mass distribution (PD < 1.02). The ^{1}H NMR spectra for PEGDM shows the expected peaks, but the lack of additional peaks suggests that unreacted methacrylate anhydride, methacrylic acid by-product, and triethylamine all have been quantitatively removed (Figure 2). MALDI-TOF MS is a powerful technique from which the molecular mass, molecular

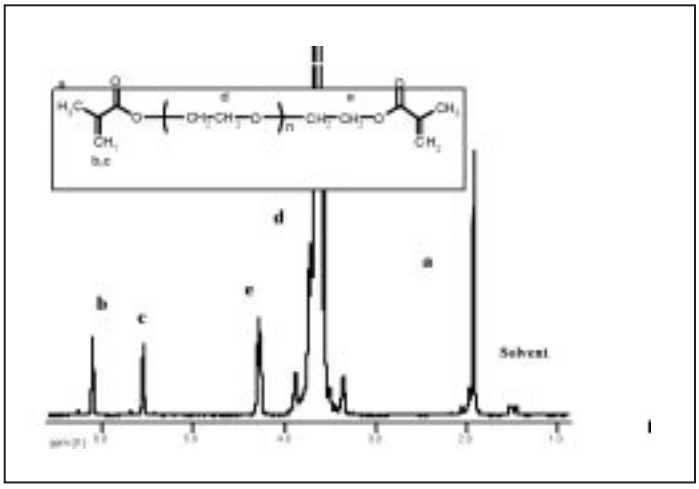


Figure 2. *^{1}H NMR of 3k-PEGDM (left), and MALDI-TOF MS of a series of PEGDMs. Insert shows the MALDI-TOF MS of 1k PEGDM (right).*

mass distribution, and endgroup functionalities can be determined. Since MALDI detects all species within a discrete molecular mass range, it can be used to determine the amount of PEGDM versus the amount of other impurities, such as PEGs with only one hydroxyl reacted (PEG mono-methacrylate) and unreacted PEG in a mixture. The MALDI-TOF MS spectra of PEGDMs prepared from different molecular mass PEGs are shown in Figure 2. Intrinsic to MALDI analysis, the relative signal intensities decrease and the breadth of the peak appears to increase as the molecular mass increases. Each molecular mass can be clearly distinguished with all oligomers displaying the expected molecular mass distribution. The degree of conversion is quantitatively assessed for each product. The MALDI-TOF MS spectrum of 1k-PEGDM (Figure 2) clearly illustrates both the high degree of methacrylate conversion and narrow polydispersity. Upon a closer examination, three sets of peaks are observed. The main series corresponds to Na+ cationized PEGDM. The two minors sets correspond to H+ and K+ cationized PEGDM.

Bovine chondrocytes, seeded in PEGDM and PEGUDM

hydrogels, are used as preliminary assessment for determining the biocompatibility of these materials. Live cells are distinguished by their intracellular esterase activity and are enzymatically activated the fluorescent calcein (green). The dead stain Ethidium homodimer-1 only enters cells with damaged membranes and attaches to nucleic acids within dead cells to produce red fluorescence. The cell viability is thus

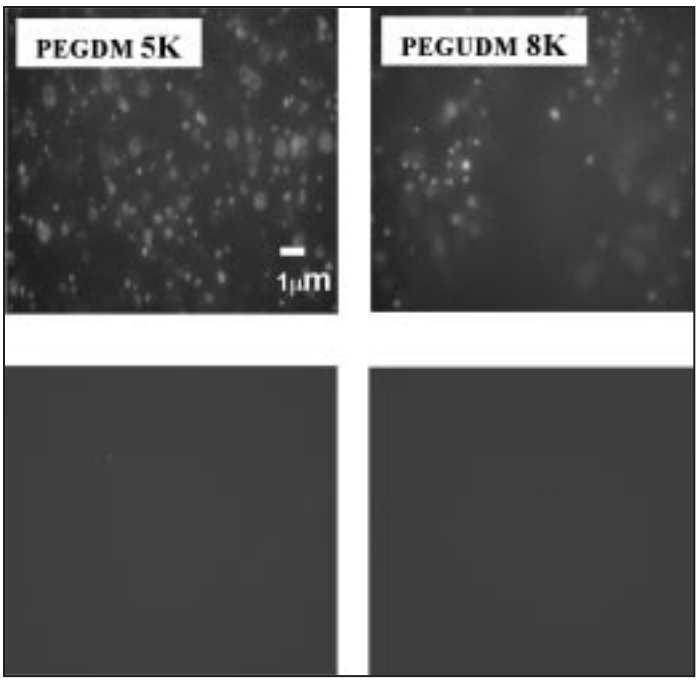


Figure 3. *Live/dead stain (top and bottom, respectively) of PEGDM and PEGUDM hydrogels containing bovine chondrocytes. The cell density is 100 000 cell/mL.*

measured through these physical biochemical properties. Figure 3 shows the live/dead cell stain for PEGDM and PEGUDM. Live and dead cell stains show that cells are completely (or nearly completely) viable in both types of hydrogels after two weeks.

The PEGDM hydrogel structure and mechanical properties were determined using small-angle neutron scattering (SANS) and uniaxial compression tests, respectively. Figure 4 shows the two-dimensional SANS patterns for the 4k-PEGDM solutions and gels obtained at the 2m detector distance. A marked difference is evident as the solutions photo-crosslink to form hydrogels. At high PEGDM mass fractions, a ring develops in the scattering pattern indicating the presence of a well-defined structural length scale (correlation length ξ). Both the gel structure and shear modulus depend on the PEGDM molecular mass as well as the oligomer mass fraction. For PEGDM of all molecular masses, the shear modulus increased as ξ_{gel} decreased. These observations are consistent with the theory of rubber elasticity. The effect of molecular mass is less apparent for lower mass fraction hydrogels (10 percent). For the 30-percent hydrogels, the expected trend of increased shear modulus with decreased molecular mass is observed. Hydrogels prepared from these dimethacrylates can provide a basis for understanding the effect of material structures and properties influence on cell response. For more information on this topic, contact the author at slgibson@nist.gov (NIST Polymers Division) and see "Synthesis and Characterization of PEG

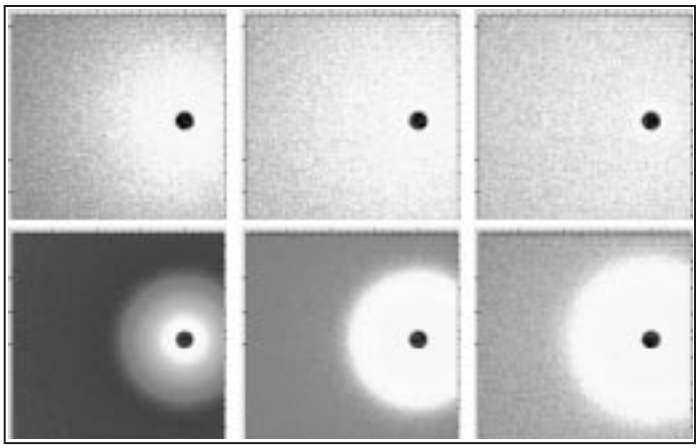


Figure 4. *Two-dimensional scattering patterns of 4k-PEGDM solutions (top row) and corresponding hydrogels (bottom row) at various PEGDM mass fractions (10 percent, 20 percent, and 30 percent from left to right).*

Dimethacrylates and Their Hydrogels," which can be accessed at http://polymers.nist.gov/uploads/lin-gibson0204.pdf.

Financial support was provided from NIDCR/NIST Interagency Agreement Y1-DE-1021-03. Technical support was provided by Mr. S. Bencherif, Dr. J. A. Cooper, and Dr. R.L. Jones.

Implant Pathology Special Interest Group

By Janson E. Emmanual

Where Cooperation Begins With Communication

Implant pathology is the evaluation and recapitulation of host responses to biomaterials and devices. The Implant Pathology Special Interest Group (IP-SIG) has organized workshops (Histology Analysis of Tissue Surrounding Biomaterials, 2001), symposia (Clinical Relevance of Animal Models, 2002), tutorials (Histotechnology: Evaluating the Tissue Response to Biomaterials, 2001) and sessions (Implant pathology, at every annual meeting). In an effort to increase service from the Society to the biomaterials industry, Elaine Duncan, SIG Representative, has negotiated the presentation of a tutorial by three IP-SIG members to the Medical Device and Manufacturing (MD&M) conference in Minneapolis in October 2004. Chaired by H. Winet, PhD, the IP-SIG chair, the tutorial will feature presentations by Audrey Tsao, MD, and Carmelita Frondoza, PhD. The conference presents a variety of topics from business decisions to cleanliness issues for biomedical devices and addresses a range of biomaterials subjects, including materials failure analysis and medical device testing. Attending companies are involved with bioengineering and biomedical devices.

One goal of the IP-SIG is to increase the understanding of tissue interactions with medical devices from the molecular to the functioning implanted device level. Another goal is to encourage a greater participation of clinicians in reporting their experiences with the *in vivo* performance of medical devices. A more thorough understanding of the behavior of implanted devices is necessary before new materials and devices that will perform better during critical phases of wound healing can be confidently designed. Commencing with adsorption, the fight for the implant surface begins at surgery and continues until a biofilm, a fibrous capsule, a foreign body reaction layer, an immunological response complex, or any combination of these coatings seals the host-device interface. Understanding the events surrounding this process, and the process itself, is key for the design of successful biomaterials and devices. Bioengineers, materials and biomaterials scientists, and industry scientists must cooperate to achieve this success. Cooperation begins with communication. Elaine Duncan is thanked for initiating a communication effort that will serve the goals of the Society as well.

To become a member of the Implant Pathology SIG, please contact Tim Muench at tmuench@NAMSA.com.

Make a Pledge to the C. William Hall Scholarship Fund

By Lynne Jones and the Finance Committee

During the past year, the Finance Committee has initiated a project to review solicitation and allocation of donations from members and sponsors. Novel funding mechanisms have been explored and a poll has been taken of the membership to define and prioritize the types of projects that should be supported in this manner. However, before any new initiatives are begun, existing initiatives should be emphasized.

Are members aware that a scholarship was established in memory of C. William Hall, the first President of the Society For Biomaterials? It seems few do. This scholarship was established to support a junior or senior undergraduate pursuing a bachelor's degree in bioengineering or a related discipline with a focus on biomaterials. Money has slowly accumulated in this fund, but a level to sustain scholarships has not yet been reached.

Why have a scholarship fund? Of course, it is preaching to the choir to state that members of the Society must support efforts to increase awareness of the field of biomaterials and to encourage the entry of undergraduates into this field. But, more needs to be done than just talk about it. Action must follow words!

If members would like a way to demonstrate that they support the training of undergraduate students in the field of biomaterials, they are strongly encouraged to donate to the C. William Hall Scholarship Fund. All donations are tax deductible. For information on how to make a donation to the scholarship fund, please contact Dan Lemyre at the Society For Biomaterials office (dlemyre@ahint.com). What a great way for members to show their support of the future of biomaterials and the future of the Society!

New Standard to Help Diagnose Heart Attacks

Diagnosing heart attacks will become a more precise science thanks to the first of a new series of clinical standards just issued by the National Institute of Standards and Technology (NIST). Standard Reference Material (SRM) 2921 (human cardiac troponin complex) will help manufacturers develop and calibrate assays that measure specific protein concentrations in patient blood samples to determine whether a heart attack has occurred.

The SRM is a solution containing certified concentrations of three related proteins, including cardiac troponin I purified from human heart tissue from cadavers. Users can calibrate their assays by analyzing the SRM and comparing the results to the NIST-certified value for troponin I. The standard is expected to help reduce variations in clinical test results from as much as 50-fold on the same sample to just twofold. "It's a big first step toward getting the system under control," says Michael Welch, leader of the NIST development team.

Computer model of the complex crystal structure of the human protein cardiac troponin.Graphic Courtesy of Protein Data Bank.

NIST already produces more than 60 SRMs for the clinical diagnostics community, but this is the first designed to help measure concentrations of large, protein-based health status markers. Troponin I is difficult to measure because it can exist in low concentrations and in different chemical forms, sometimes attached to other related proteins. NIST is developing additional standards and methods for measuring other health status indicators of this type, including hormones used to assess thyroid function, and other markers for heart attack risk such as homocysteine and C-reactive protein.

SRM 2921 is intended to help U.S. makers of *in vitro* diagnostic (IVD) medical devices sell their products in Europe. A European Union directive requires that such devices be calibrated with standards that are traceable to internationally recognized certified reference materials or procedures. SRM 2921 has been nominated for inclusion on the international list of higher order reference materials. The list currently contains about 150 entries for 96 health status markers; NIST SRMs provide traceability for 72 of these.

Uncertainty in Clinical Tests Raises Health Care Costs

Small measurement uncertainties in clinical laboratory tests can add large amounts to health care costs, according to a newly released study commissioned by the National Institute of Standards and Technology (NIST).

The study, conducted by RTI International, Research Triangle Park, N.C., and the Mayo Clinic, Rochester, Minn., estimates that calibration errors in measurements of calcium levels in blood may add between $60 million and $199 million to U.S. health care costs annually. High calcium levels can be a symptom of diseases such as cancer and thyroid disorders.

Accurate measurements are critical because calcium levels in healthy people fall within a narrow range, between 8.9 to 10.1 milligrams (mg) per deciliter (dL). Through interviews with laboratory managers and equipment manufacturers, researchers estimated that results for up to 15 percent of calcium laboratory tests contain calibration errors of between 0.1 mg and 0.5 mg per dL. This means some results that fall in the center of the normal range, say 9.7 mg/dL, may in fact be for patient samples with elevated calcium, defined as 10.2 mg/dL and above. At the same time, patients with measured values above the threshold, but who actually have normal calcium levels, may receive unnecessary follow-up procedures such as hormone measurements and chest X-rays.

The study analyzed data for more than 89,000 patients receiving serum calcium tests at the Mayo Clinic from 1998 to 1999. It found that calibration errors added between $8 and $89 per patient to the health care costs of approximately 3.55 million patients.

Major sources of calibration error include differences in analysis methods used by different laboratory instruments, lot-to-lot variations in calibration materials, and lack of traceability between secondary reference materials and primary standards such as Standard Reference Materials produced by NIST.

The full text of the report is available at www.nist.gov/director/prog-ofc/report04-1.pdf.

Controlling Biomolecules With Magnetic "Tweezers"

An array of magnetic traps designed for manipulating individual biomolecules and measuring the ultrasmall forces that affect their behavior has been demonstrated by scientists at the National Institute of Standards and Technology (NIST).

Described in a recent issue of *Applied Physics Letters*, the chip-scale microfluidic device works in conjunction with a magnetic force microscope. It is intended to serve as magnetic "tweezers" that can stretch, twist, and uncoil individual biomolecules such as strands of DNA. The device should help scientists study folding patterns and other biochemical details important in medical, forensic, and other research areas.

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NIST post doctoral researcher Elizabeth Mirowski inserts a magnetic tip into a holder for a magnetic force microscope. The tip will be used to manipulate magnetic microparticles attached to biomolecules as part of a project to study folding patterns and other biochemical details.

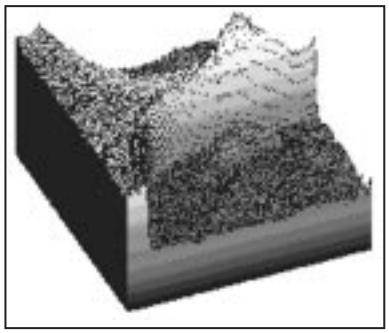
The new NIST device works like drawing toys that use a magnetized stylus to pick up and drag magnetic particles. Magnetic particles 2 to 3 micrometers across are suspended in a fluid and injected into the device. The surface of a thin membrane enclosing the fluid is dotted with an array of thin film pads made of a nickel-iron alloy. When a magnetic field is applied, each particle is attracted to the closest nickel-iron "trap."

So far, the research team has demonstrated that the traps attract individual particles and the microscope tip can gently drag particles with piconewton forces. One piconewton is about a trillionth the force required to hold an apple against Earth's gravity. The next step is to attach particles to both ends of biomolecules such as DNA. The trapping stations then can be used to hold one end of a molecule while the microscope tip gently pulls on the other end. By applying magnetic fields in different directions the researchers hope to ultimately rotate the magnetic particles to produce complex single molecule motions for genomic studies.

Method Produces Uniform, Self-Assembled Nanocells

Nanotechnology is about making improved products by building them from components hundreds of times smaller than a human blood cell. But how does one put things together at such a tiny scale? One way is to create the right conditions so they assemble themselves.

For example, a new method for producing uniform, self-assembled nanocells has been developed by researchers at the National Institute of Standards and Technology (NIST). Reported in the March 10 issue of the *Journal of the American Chemical Society*, the method may have applications as an improved method for encapsulating drug therapies. A patent application has been filed.



The peaks on this three-dimensional plot indicate a high concentration of liposomes forming in a microchannel.

Current bulk methods for producing nanocells called liposomes—a type of artificial cell—produce particles in a wide range of sizes. The sizes must be sorted and filtered before being used for drug delivery, since dosage depends critically on size.

The new NIST method uses micrometer-size channels etched into a device to produce self-assembled liposomes of specific sizes from as large as about 240 nanometers (nm) to as small as about 100 nm. A stream of natural fats (lipids) dissolved in alcohol is directed at an intersection of two channels that looks like a micro version of a four-way stop. A water-based liquid containing medicines or other substances is sent toward the lipid stream from two opposing directions. Rather than mixing with the water, the lipids surround it, forming self-assembled nanocells.

Controlling flow rates in the microchannels produces nanocells of specific sizes. Faster flows produce smaller cells. Medicine-filled liposomes made in nanosizes should allow for more accurate drug delivery. In particular, liposomes have been studied for years as a way to concentrate the effectiveness of cancer chemotherapy while minimizing harmful side effects.

Abbott Laboratories, Abbott Park, Ill., and **Spinal Concepts** Inc. announced that the companies have entered into an agreement for Abbott to acquire Spinal Concepts, a medical device company. Spinal Concepts currently markets a broad range of devices, including spinal fixation products used in the treatment of spinal disorders, diseases, and injuries. Under the terms of the agreement, Abbott will acquire all of the stock of Spinal Concepts, a privately held company, for approximately $170 million in cash plus additional milestone payments of up to $40 million if agreed upon targets are met.

Access Pharmaceuticals Inc., Dallas, disclosed that it has entered into a research collaboration with a major U.S. drug delivery company to assess the Nanoparticle Aggregate Technology. The Nanoparticle Aggregate Technology is being developed primarily for the controlled release of water-soluble proteins. Access Pharmaceuticals has demonstrated that these proteins can be incorporated into the aggregate in a simple cost-effective manufacturing process using aqueous solutions at room temperature and that release of the protein from the nanoparticle aggregate can be tailored to meet the desired profile, allowing delivery at a substantial reduction of the "burst release" of the protein, lasting from several days up to a projected six-month period.

A major milestone in industrial biotechnology has been achieved with the first commercial shipment of **bioethanol**. Unlike conventional ethanol, bioethanol is made not from grain, but from cellulosic biomass such as wheat straw, sugarcane bagasse, and corn stovers and stalks left over after harvesting. This green alternative fuel, compatible with current automobile engines, could significantly reduce greenhouse gas emissions. The commercial production breakthrough reported by a Canadian biotech company, **Iogen** Corp., involved using recombinant DNA-produced enzymes to break apart cellulose—the tough substance that gives plants their rigidity—to produce sugars. The sugars produced in such a biorefinery process are used to make greener versions of ethanol and plastics.

Dow AgroSciences LLC, Indianapolis, has signed a cooperative agreement with the U.S. Department of Agriculture-Agricultural Research Service (USDA-ARS) laboratory in Laramie, Wyo., to develop a plant-made vaccine to protect against West Nile virus. Plant-made vaccines are highly robust, which may result in needle-free delivery techniques such as through food, water, or inhaled mist. In addition, an attractive safety aspect of using plant-made vaccines is that there is less chance of contamination with extraneous disease agents during use.

Geron, Menlo Park, Calif., and its collaborators in nine presentations at the annual meeting of the International Society for Stem Cell Research (ISSCR) reported advancements in the differentiation of human embryonic stem cells (hESCs) to therapeutic cell types, the engraftment of these differentiated cells in animal models, and the production of cells for eventual clinical testing. A presentation of studies performed in collaboration with Dr. Susan Fisher of the University of California at San Francisco described two new hESC lines that were derived without exposure to mouse cells or mouse products. These new hESC lines, derived from embryos left over following fertility treatment and donated for research, were grown on human placental fibroblast feeders that were fully qualified through extensive pathogen testing and have the same properties as the original hESC lines. Unlike the hESC lines included in the NIH Stem Cell Registry, which will be treated as "xenografts" and for which the FDA will require testing to ensure that they are free of nonhuman pathogens, these new lines have never been exposed to cells of nonhuman origin. As a result, the chance of zoonosis of murine pathogens is essentially eliminated with these new lines.

InterMune Inc., Brisbane, Calif., announced that the company has initiated a Phase III clinical trial designed to evaluate the safety and efficacy of daily Infergen® (Interferon alfacon-1) in combination with ribavirin for the treatment of patients chronically infected with hepatitis C virus (HCV) who have failed to respond to a previous course of therapy with pegylated interferon alfa-2 plus ribavirin. These patients are referred to as HCV nonresponders. The primary endpoint of the clinical trial is the proportion of patients with sustained viral response (SVR), which is defined as the absence of detectable HCV RNA in serum 68 weeks and 72 weeks after the initiation of treatment.

Intradigm Corp., Rockville, Md., a leader in RNAi (RNA interference) therapeutics, announced achievement of prophylactic and therapeutic effects of siRNA (small interfering RNA) inhibitors of SARS-CoV in non-human primate cells. The published results show that siRNA duplexes are potent and specific inhibitors of SARS-CoV, protecting cells from both viral infection and replication. The results revealed SARS genome sequences sensitive to RNAi and also illustrated synergistic effects multiple siRNA sequences are combined. The studies show that siRNA degrades viral genomic RNA, in addition to inhibition of viral protein expression, and laid the foundation for ongoing *in vivo* efficacy and toxicity studies in a nonhuman primate model of SARS. Importantly, these results show that siRNA therapeutics for viral infections can be developed in an extremely short time frame, requiring only a genomic sequence of any new virus and appropriate delivery systems.

Nanosphere Inc. (Northbrook, Ill.) announced development of a colorimetric detection capability for its nanoparticle-based molecular detection systems that will further simplify the identification of genomic DNA, RNA, and protein targets without the need for traditional signal or target amplification. At the core of Nanosphere's technology, gold nanoparticles are attached to strands of nucleotides complementary to targets of interest, and when a target nucleic acid or protein is present, the nanoparticle probes latch on to the match and provide a strong optical signal indicating the target has been found. The unique hybridization characteristics of gold nanoparticle probes result in sharp melting curves that enable dramatically improved sensitivity and specificity, with the ability to detect specific DNA sequences in highly complex DNA samples.

Canadian drug maker **QLT**, Vancouver, has bought biotech company **Atrix Laboratories**, Fort Collins, Colo. QLT will pay $14.61 per share in cash and one share of its stock for each Atrix share. The publicly traded QLT is best known for Visudyne, a drug to treat age-related vision deterioration. Atrix has developed a proprietary drug delivery system where a liquid drug is injected under the skin and turns into a solid that slowly dissolves and releases its dosage over time.

Medical device and diagnostics companies executives say that their biggest challenges are aggressively growing top-line revenue, followed closely by defending their margins and filling their R&D pipelines with new products, according to a survey released by Tunnell Consulting at the Medical Design &

Continued on page 16

Angiotech Extends License Agreement With Poly-Med

Angiotech Pharmaceuticals Inc., a specialty pharmaceutical company focusing on drug-coated medical devices and biomaterials, announced that it has licensed a portfolio of biomaterial, drug delivery, and medical device technologies from Poly-Med Inc. This agreement will expand Angiotech's relationship with Poly-Med, a developer of biomaterial technologies, which it initially formalized in a June 2001 license agreement. The announced collaboration grants Angiotech exclusive rights to several of Poly-Med's key technologies, including a portfolio of absorbable and biodegradable polymers and drug delivery technologies that are potentially useful in several areas of interest to Angiotech, including tissue repair, orthopedic surgery and vascular surgery. The two companies will also collaborate on research to develop products derived from the licensed technologies and explore the application of these technologies to drug-loaded medical device and biomaterial research efforts already underway at Angiotech.

Poly-Med, Anderson, S.C., is devoted to the development of absorbable and biodegradable materials for medical applications. Poly-Med is headed by Shalaby W. Shalaby, member of the Society For Biomaterials, who established the Johnson & Johnson Polymer Technology Center, which is presently known as the Advanced Biomaterials Center. The company's research team comprises 20 experts in the fields of novel biomaterials, biomedical textiles, and drug delivery. Dr. Shalaby has been awarded more than 100 U.S. patents during his career; he has published nine books and more than 250 academic/technical articles.

"There is significant synergy in the research expertise and focus of Angiotech and Poly Med," said Dr. Shalaby. "We are confident that the strategic alignment of the two companies' complimentary skills and know-how will lead to the development of many beneficial medical products."

The licensed Poly-Med technologies, coupled with technologies Angiotech obtained via its recent acquisitions of Cohesion Technologies and STS Biopolymers, provide Angiotech a substantial portfolio of biomaterials and drug delivery vehicles that can be leveraged into a broad array of drug-device combinations. Angiotech, the innovator of the paclitaxel-coated coronary stent, is a recognized leader in the burgeoning field of drug-coated medical devices.

BioInk

(Continued from page 15)

Manufacturing East Conference and Exposition in New York. The executives ranked proactive regulatory compliance fifth, slightly behind cost improvement but ahead of enhancing productivity and far ahead of such challenges as M&A activity, technology transfer and scale-up, and some seven other categories. Moreover, the prime importance of filling the pipeline, as compared with the relatively low, seventh-place ranking of mergers and acquisitions in the survey, indicates that many industry leaders believe that their real future lies in organic growth—not in the kind of blockbuster M&A moves we have seen in the pharmaceutical industry.

Community Calendar

Materials & Processes for Medical Devices Conference & Exposition
August 23-25, 2004
Radisson Riverfront Hotel
St. Paul, Minnesota
www.asminternational.org

American Society for Bone and Mineral Research 26th Annual Meeting
October 1-5, 2004
Washington State Convention and Trade Center
Seattle, WA
(202) 367-1161
asbmr@dc.sba.com
www.asbmr.org

2004 Biennial Conference - Polymer Design for Biology: Activity and Structure
Division of Polymer Chemistry, American Chemical Society
October 3-6, 2004
Savannah, GA
www.polyacs.org

BMES 2004 Annual Fall Meeting
October 13-16, 2004
Wyndham Franklin Plaza Hotel
Philadelphia, PA
(301) 459-1999
www.bmes.org

Society For Biomaterials Symposium on Biomaterials in Regenerative Medicine
October 16-18, 2004
Wyndham Franklin Plaza Hotel
Philadelphia, PA
www.biomaterials.org

The 7th New Jersey Symposium on Biomaterials Science
October 20-22, 2004
Hyatt Regency
New Brunswick, NJ
www.njbiomaterials.org

Surfaces in Biomaterials Foundation Annual Symposium & Exhibition
October 27-29, 2004
Wyndham Baltimore Inner Harbor
Baltimore, MD
www.surfaces.org

Osteoarthritis Research Society International 2004 World Congress
December 2-5, 2004
Hyatt Regency Chicago
Chicago, IL
www.oarsi.org

The Minerals, Metals & Materials Society 134th Annual Meeting & Exhibition
Symposium on Biological Materials Science
February 13-17, 2005
Moscone Convention Center
San Francisco, CA
www.tms.org

15th Interdisciplinary Research Conference on Biomaterials
March 18-20, 2005
Shanghai, China
www.scschina.org

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