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Georgia Bio Newsletter Credits

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We are entering 2016 following an exciting year for our industry and our association. If you joined us at our Awards Dinner in January, the evidence of the industry’s impact in 2015 was evident from the large number of worthy winners. Congratulations to all those winners for their accomplishments!

We kicked off the year with our first trip to San Francisco for the JP Morgan Healthcare Conference week and welcomed over 600 attendees to the state bio association’s reception. Thank you to Kilpatrick Townsend for making meeting suites available to our members during the week as well.

We are halfway through the legislative session and I encourage members to review the Legislative Watch, our weekly update for the Georgia Bio membership on the legislative session of the Georgia General Assembly.

I would like to extend my personal thanks to Ed Schutter, CEO of Arbor Pharmaceuticals for his extraordinary leadership as our chairman for the past two years. With Ed’s guidance, we increased our industry reach and enhanced programs for all members. His focus on the value of membership is carrying us into 2016, with Jay Yadav now taking on the role of board chair. Jay has challenged us to continue with the value focus and to serve as the authoritative voice for our industry, informing our members and tackling the issues that are most important to you.

Georgia Bio is committed to helping our member companies bring products to market that are improving and saving lives. We rely on your help to accomplish this goal, and hope that you will take full advantage of your member benefits and be actively involved with the association in 2016. Feel free to call or email me to discuss your needs and find solutions through our vast network.

Stay tuned to additional events, news, and activities by following us at: www.gabio.org or connecting with us on Twitter, LinkedIn, and Facebook.

Thank you,

Russell Allen
President & CEO

Save the date for Georgia's premier life sciences event.

Cobb Galleria | Atlanta, GA
Ennaid Therapeutics Prioritizes Zika Virus Drug Development in Wake of Crisis

Ennaid Therapeutics, located in Alpharetta, GA, is developing therapeutic cures to help the millions of people worldwide infected with the mosquito-borne disease, Zika Virus, now named a global public health emergency by the World Health Organization and the CDC. The global health community is urging caution and care in response to Zika's explosive spread and is calling for rapidly stepped-up efforts by researchers to find therapeutics and vaccines for those who contract it.

For years, Ennaid Therapeutics has been committed to developing cures for mosquito-borne diseases, including Dengue, Chikungunya and Zika viruses – and is now advancing its work on Zika to address the urgent global need.

Zika Virus
Zika is linked to microcephalic birth defects and possible eye damage in babies. The virus, which is transmitted by the Aedes species mosquito, has infected 1 million Brazilians and 50+ people in the United States. An estimated 4 million infections are expected in the Americas in 2016. Zika's risk to pregnant women is a top priority, according to the CDC.

"Zika virus, which is now our focus, has been in our ten-product pipeline for years, and we will continue developing cures for the growing numbers of Dengue, West Nile and Chikungunya sufferers, among other mosquito-borne diseases," says Darnisha Harrison, Ennaid Therapeutics' CEO.

Please see the link below of Discovery Channel's "Innovations with Ed Begley, Jr.", in which Ennaid Therapeutics will be featured: http://www.prweb.com/releases/2015/10/prweb13028491.htm.

Ennaid Therapeutics' Science

- Our peptide fusion inhibitors show significant inhibition against many viruses in the Flaviviridae family, such as Dengue and possibly Zika; both Dengue and Zika are carried by the Aedes species mosquito, and both are of the flavivirus genus
- Our peptide's stem mimics the stem of many Flaviviridae viruses, thus inhibiting viral infections
- Zika stem is a very close match to our peptide's stem; feasibility studies are underway
- Already-planned development studies will determine our peptide's inhibition against Zika virus in vivo, as well as safety in pregnancy
- Our fast-track development strategy will then allow Ennaid Therapeutics to immediately begin clinical trials, as funding is secured
- Currently there are safe and effective commercialized peptide fusion inhibitors, such as Enfuvirtide (brand name Fuzeon)

Ennaid Therapeutics
Founded in 2012, Ennaid Therapeutics is developing a proprietary platform technology of flavivirus fusion inhibitors that show significant inhibition against flavivirus infectivity, such as Dengue. Its rapid development plan has the potential to safely and quickly bring a Zika virus therapeutic cure to market in record time.

Darnisha Harrison, Ennaid Therapeutics CEO
Formerly a Microbiologist and Chemist, Ms. Harrison is a nationally recognized pharmaceutical entrepreneur by Newsweek magazine. With 22 years' experience in the life sciences, she is a member of the American Association for the Advancement of Science and the New York Academy of Sciences. She received a Bachelor of Science in Microbiology and a Minor in Chemistry from LSU.

For more information contact:
Gigi Gilbert, Public Relations, Phone: +404-309-7034, Email: Gigi@ennaidthera.com, www.ennaidthera.com
Drug Resistance – New Implications for Fungal Infections

Article Source: Centers for Disease Control and Prevention

According to the Centers for Disease Control and Prevention (CDC), anyone can get a fungal infection – including people who are otherwise healthy. Fungi are common in the environment (in soil, plants, trees, indoor surfaces, and on human skin) and people breathe in or come in contact with fungal spores every day. Normally people will not get sick; however, fungal infections do occur. Some are fairly common and non-life threatening, such as skin, nail, or vaginal yeast infections. Others can be severe, particularly in people with weak immune systems. Fungal infections of the lungs like Valley Fever or histoplasmosis also happen in people who live in or visit certain areas.

Fungal disease poses a notable threat to public health. Per the World Health Organization (WHO), vulnerable populations such as cancer patients, transplant recipients, neonates, and patients in intensive care units are more severely affected. WHO reports that candidiasis (infection caused by Candida) is the most common fungal infection worldwide, and invasive Candida infections have high sickness and mortality rates. Geographic variability exists among patients with candidiasis in terms of rates, drug resistance, antifungal treatment use, and antifungal medicine availability.

Changes in drug efficacy, or the ability of a drug to achieve the desired effect, has recently had an impact in treating different infections. Just as antibiotics can cure bacterial infections, antifungal medications can sometimes save lives by curing dangerous fungal infections. And just as some bacterial infections have become resistant to antibiotics, some fungi no longer respond to the antifungal medicines designed to eradicate them. This emerging phenomenon is known as antifungal resistance, and it’s especially concerning for invasive infections.

Antifungal drug resistance in candidiasis further burdens patients and healthcare systems. In some locations, WHO estimates that half of all fungal infections have become resistant to standard treatment regimens. WHO also states that resistance to the newest class of antifungal agents, the echinocandins, is emerging in some countries. Echinocandins, which function by disrupting the fungal cell wall, are the most commonly prescribed antifungal medicines for serious Candida glabrata, opportunistic infections of the blood stream. In 2005, CDC estimated that one Candida bloodstream infection can result in 3-13 additional days of hospitalization and $6,000-$29,000 in added healthcare costs in the United States.

Currently, laboratories detect echinocandin resistance by special susceptibility testing which requires intense resources, is expensive, and takes more than 24 hours to conduct. CDC scientists recently developed a set of DNA probes that can rapidly detect mutations in Candida glabrata genes indicating echinocandin resistance. Such information could assist physicians in selecting the most effective treatments for patients with these dangerous infections. CDC’s patented invention offers early detection, adaptability for different volumes or throughputs being processed, and a cost-effective, easy to interpret test.

Please contact CDC’s Technology Transfer Office (TTO) at 404.639.1330 or TTO@cdc.gov to learn more about CDC and technologies available for licensing. CDC offers diagnostics, vaccine candidates, environmental health advances, occupational safety and health inventions, biological materials for testing, software, medical devices, research tools (e.g. cell lines), and more. Specialty areas include: infectious, respiratory, gastrointestinal, sexually transmitted, tropical, zoonotic, and veterinary diseases. CDC welcomes new partners for research collaborations including antifungal and antibiotic resistance research.
IEC 60601-1 is a lengthy, complex electrical safety standard. Over the years, revisions have addressed innovations in technology, changes in techniques and safety concerns that have emerged with time. Amendment 1 mainly clarifies the 3rd Edition’s original intent by addressing approximately 100 issues outstanding from the first release. It takes into account new industry understandings and addresses issues such as risk management, essential performance, protection for operators and patients, battery use, mobile integration, radiation, temperature and electrical and mechanical safety.

Implementing the new and revised requirements of 60601-1 Edition 3.1 can be challenging, given the size and complexity of the standard itself. Also complicating the matter is the fact that there are global variations in adopting, transitioning, and enforcing the revised standard. Knowing the specific requirements of Edition 3.1, as well as where your target markets are in the process of transitioning can play a valuable role in designing new products. Conducting a gap analysis for products already in compliance with previous editions of the standard, as well as an audit on process requirements, can also help.

Enlisting the help of an experienced, knowledgeable third party, like Intertek, can help you navigate the requirements. In our lab in Duluth, GA, we have experts who can help manufacturers determine which standards and requirements apply to their product. A trusted partner can also conduct design reviews, assess risk management, and examine usability and software processes to determine their suitability to the 3rd Edition series.

For more information download the white paper Transitioning to IEC 60601-1 Edition 3.1: Guidance for Global Implementation or email us at iCenter@intertek.com.
Preclinical Trials with T3 Labs Generate Critical Improvements to St. Jude Medical’s CardioMEMS HF System

By: Jeff White, Chief Operating Officer, T3 Labs

For arguably the most important stage in the medical product development lifecycle, St. Jude Medical and Atlanta’s T3 Labs conducted the necessary preclinical trials for the first wireless device implanted in the pulmonary artery to monitor pulmonary artery pressures. The goals for the CardioMEMS HF sensor are to reduce heart failure readmissions and improve quality of life for the 1.4 million Americans suffering from NYHA class III heart failure.

In the case of any innovative medical device, especially for a highly complex, first-of-its-type FDA Class III device (one that is “life supporting, life-sustaining or important in preventing impairment of human health”), the regulatory development requirements are necessarily stringent and the stakes are high for all concerned: the patients whose lives stand to benefit, the innovators themselves, the investors and even the regional medtech innovation ecosystem that can blossom quickly under the right conditions.

During preclinical research, St. Jude and T3 Labs refined the system’s sensor from being attached to the right ventricular septum with an anchor coil to being placed in the distal pulmonary artery passively anchored by wire loops. The new attachment site made the sensor easier to use during the implant procedure and provided improvements in long-term safety.

“Our experience with T3 Labs for the CardioMEMS device created new knowledge and refinements to the device that resulted in a product that was highly mature at the time we started our clinical trials in humans,” said Jason White, St. Jude Medical senior director of product development.

T3’s facilities include seven state-of-the-art procedure areas, including three operating rooms on par with the top hospitals in the country and a robust suite of advanced medical imaging capabilities.

“The T3 Labs team possesses high levels of capability with vascular procedures and state-of-the-art equipment and facilities providing solid, real world operating conditions,” White says. “The testing team operates in the same clinical setting in which cardiologists currently use the CardioMEMS HF system. This is a critical step in understanding how your product is going to perform in use. It is a step in the process that should get a lot of attention.”

The results:

- After filing the IDE (Investigational Device Exemption) with FDA that included data collected from T3 Labs, CardioMEMS received its letter of approval to begin clinical trials in humans.

- After submitting its premarket approval application to the FDA, CardioMEMS received its letter of approval to begin commercial distribution on May 28, 2014.
- The CardioMEMS HF sensor(1) is the first-of-its-kind implantable wireless device implanted in the pulmonary artery to monitor pulmonary artery pressures.

- Following a six-year, $100 million development process, St. Jude Medical completed its acquisition of CardioMEMS for a total of $435 million.

Given the success of the CardioMEMS program and the potential for pressure monitoring in other applications, St. Jude Medical and T3 Labs are now collaborating on the “next gen” products currently in the concept stage.

Read the full case study of T3 Labs’ preclinical work with St. Jude Medical’s CardioMEMS HF system here.

ProtecTeaV Hand Sanitizer with Potent Virucidal Efficacy
Launched by Camellix, LLC

By: Stephen Hsu, PhD, Professor of Oral Biology, Oral Health & Diagnostic Sciences, Dental College of Georgia, Augusta University

Current countermeasures against viral entry into the human body are often inadequate, according to published research results. For example, alcohol was initially considered to be an effective agent to inactivate viruses, but increasing scientific and clinical evidence indicates otherwise. Norovirus causes approximately 20 million illnesses and 70,000 hospitalizations per year with up to 800 deaths reported in the US. It is a nonenveloped virus (alcohol-resistant), and is therefore very difficult to eliminate unless toxic chemicals are used. In 2011, the CDC revised the guidelines for prevention of norovirus infection due to the ineffectiveness of alcohol-based hand sanitizers. In 2015, 12 cruise ships reported outbreaks of norovirus symptoms, an increase over 2014 reports. Despite a concerted effort by government agencies and public health organizations, outbreaks of norovirus are not declining; neither are sexually transmitted diseases (STDs) such as genital herpes and human papilloma virus infections. Now Zika virus becomes an STD.

The key to prevent viral entry into the human body is adequate skin and hand surface cleansing. Current CDC guidelines for norovirus prevention mainly rely on repeated 20-second hand washes with soap and water. Alcohol-based hand sanitizer should not replace soap and water. To better protect the public, there is a need to develop novel strategies to prevent viral entry into the human body.

Camellix, LLC, a Georgia company associated with Augusta University, has launched a new hand sanitizer developed from research on compounds derived from green tea. A molecule called EGCG has been studied by many investigators worldwide as a potentially effective and nontoxic approach to prevent and treat viral infections. Camellix owns the patent of lipophilic EGCG derivatives and used it in an over-the-counter ointment AverTeaX, developed by a team of university investigators. Published clinical trial data showed it possesses very high efficacy against herpes labialis (cold sores).

The ProtecTeaV sanitizer formulations were also developed by a team of scientists using lipophilic EGCG. They were tested according to international standards, in assays called TCID50 (50% Tissue Culture Infective Dose), which measure the virucidal capacity using poliovirus (PV, an alcohol-resistant nonenveloped virus). Only agents possessing a capability of reducing the infectivity of PV in this assay by >4 log_{10} (10,000 times) can be claimed as virucidal. The results demonstrate that ProtecTeaV hand sanitizer formulations reduced PV infectivity by 6 log_{10} (1 million times). In contrast, commonly used name-branded sanitizers in US and China failed to reach 4 log_{10}, and therefore are ineffective (Table 1). In addition to a virucidal
capability, lipophilic EGCG has also shown strong inhibitory activity against bacterial endospores, described in a patent application from Augusta University. The investigators believe that lipophilic EGCG could be a natural and nontoxic approach against healthcare-associated-infections (HAIs) that lead to 99,000 deaths/year. Georgia ranks among the worst in the nation on the progress of reducing HAIs.

**Table 1.** Efficacy of four hand sanitizers either with alcohol (ProtecTeaV, Purell) or without alcohol (adf) against PV-1 using TICD50 assays. Data is from three independent experiments.

<table>
<thead>
<tr>
<th>Product</th>
<th>Active ingredients</th>
<th>Mean log_{10} reduction of viral infectivity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>30 s</td>
</tr>
<tr>
<td>ProtecTeaV-</td>
<td>Ethanol (70%) with L-EGCG</td>
<td>6.65</td>
</tr>
<tr>
<td>ProtecTeaV+</td>
<td>Ethanol (70%) with L-EGCG</td>
<td>5.98</td>
</tr>
<tr>
<td>Purell</td>
<td>Ethanol (62%)</td>
<td>3.28</td>
</tr>
<tr>
<td>Adf</td>
<td>PVP-Iodine</td>
<td>2.88</td>
</tr>
</tbody>
</table>

ProtecTeaV-: without thickener agent.
ProtecTeaV+: with thickener agent.
L-EGCG: lipophilic epigallocatechin-3-gallate.
PV-1: poliovirus 1.

The Biotechnology Innovation Organization (BIO) recently launched a new ad focused on the value of biomedical innovation, highlighting the most compelling benefits of biomedical research – giving patients time to live fuller lives. The ad serves as a cornerstone for BIO’s new Value Campaign, which will provide an avenue for the biotechnology sector to highlight the value of biomedical innovation and includes a new “Time Is Precious” website. **VIEW THE AD HERE.** For more information on the advertisement or BIO’s Value Campaign, please visit: [http://timeisprecious.life](http://timeisprecious.life).

### Applying for SBIR/STTR Awards
**By: Kenneth Williams, Neo-Biz Solutions**

Are you the biotechnology entrepreneur interested in pursuing federal funding?

SBIR/STTR awards can assist with small technology firms & innovators’ current effort in receiving seed funding. The mission of the SBIR program is to support technological innovation by investing Federal research dollars in an effort to build a strong economy.

There are several steps to apply for funding.

*Do you want to get your share of the 30 plus billion dollars allocated by Congress every year for Research and Development?*

**First Step - Becoming Eligible for Federal Assistance**

In order to apply for federal funding you must:
- Setup your company.
- Securing an EIN from the IRS
- Obtain a DUN and Bradstreet number
- Get registered in System for Award Management
- Secure a [Grants.gov](http://Grants.gov) registration
- Get registered with eRA Commons
- Secure a Small Business Administration registration as it regards to the SBIR program

It will take you about two months to complete all these steps if there are no errors.

**Congratulations! You’re eligible. What do you do now?**

The first thing you must do is:
- Download and carefully read the SBIR/STTR SF424
Application Instructions and Package, and the Program Announcement. These are the guidelines that must be used to prepare the content of the application.

- Next you must complete the SF424 application. Please take special care when completing the application. The slightest of errors will prevent the system from accepting the application. Be sure to include:
  - Zip Code
  - User Name ID
  - Dates
  - Calendar months for Key Personnel

Just to name a few of many…

There are numerous triggers that would prevent an application from being successfully submitted.

We suspect some readers know exactly what we’re referencing. When the application is submitted, it may generate errors that will prevent it from going through. The applicant will receive emails indicating as such. The next step is deciphering the message, make corrections, and resubmit the application before the deadline. So the best route is to submit early.

Sounds like a headache? Yes, it can be, especially when all of the steps are recognized.

The remaining submission dates are April 5th and September 6th 2016 at 5PM.

Never fear, Neo-Biz is here! We have the experience of submitting successful applications for all types of Applicants, but specifically, Small Business Concerns. We understand the nuances that Applicants may encounter during the application/electronic submission process.

In short, we can guarantee an error-free submission.

NEXT TOPIC – We will address the federal regulations that a SBC will have to certify/prove prior to receiving an award (JIT) and managing the other aspects involved in receiving an award (Post-Award Grant Management). Please note the list is extensive.

Take the time to look out for our future articles to grasp the underlying need that you will undoubtedly realize is a necessity for the future of your company’s goals.

Contact Kenneth Williams for additional information at kwilliams@neo-bizsolutions.com.

RAPS Southeast Regional Career Day Educates Participants on Regulatory Careers
By: Austen Gage

After participating in the RAPS DC/Baltimore Chapter’s career day in 2014, Marcia Johnson, RAC, CBA, was inspired to create a similar event closer to home in the Atlanta area. Together with the Chair of the RAPS Atlanta Chapter, Penny Northcutt, RAC, FRAPS; Grace Powers, RAC; and several chapter volunteers, Marcia started pulling together sponsors and panelists.

On 8 October 2015, the RAPS Southeast Regional Career Day brought together those interested in regulatory careers, veterans of the field and regulatory employers. The program venue was generously provided by the Georgia Institute of Technology, where nearly sixty students and professionals gathered for several panel discussions on subjects ranging from educational qualifications to the different career paths available to those in the regulatory field.

During one panel, participants talked “about how they got into [regulatory] and what they are doing in their careers,” said Powers, who felt the students in attendance left with “a better understanding of what regulatory affairs is as a profession.”

“The attendees were also looking for advice on their resume, and the timing about job applications, and how to ‘break in’ to regulatory affairs,” according to Mary Ann Kinard of Halyard Health. “Most of the attendees were currently in the BioID master’s program [at Georgia Tech], which seems to be a didactic program to design, market and manufacture a mock medical device in the US. The practical experience of the program seems to be a lead-in
to regulatory affairs, and it was a pleasure to meet the
generation of attendees that are motivated to start a
career in regulatory affairs.”

Many of the presenters shared specific career advice and
insights on their own career paths. Marie Mathews, MS,
and LaReese Thomas, PhD, from the US Food and Drug
Administration (FDA) Atlanta District Office discussed
what FDA looks for in its recruitment process. “They
talked about how people went straight into the FDA,”
said Grace.

Following the panels, participants were able to network,
discuss specific topics in depth and meet with recruiting
employers. “We had a lot of good feedback from
students,” said Grace. “There was a lot of interaction
with the companies.”

“I think this event was very well attended and the
attendees were respectful and truly interested in learning
about the regulatory affairs career paths,” said Kinard.
“There was insightful dialogue from the attendees, and
plenty of well-formed questions about the regulatory
landscape as it pertained to the medical devices that
[Halyard] had on display... I would definitely like to be a
part of this type of event again in the future!”

Sponsors and participants for the program included the
Georgia Institute of Technology; The University of
Georgia, School of Pharmacy; Cryolife; CR Bard; Chart
Industries and Halyard Health.

Similar career day events were held in 2015 in the
Washington, DC and Chicago areas.

New UniFirst BIO Business
Solutions Cost Savings
Program: Uniform & facility
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UniFirst, a leading supplier of workwear programs for
businesses big and small since 1936, provides a range of
apparel from traditional uniforms and industrial wear to
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also offers various floorcare and restroom products.
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highest quality garments and services, complete with full
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uniform and facility service savings of 30-50%.

For more information on how you can sign up for these
member discounts and save your working capital, contact Angela King, Member Services Manager, at
angela.king@gabio.org.

Welcome to Our
2016 New Members

Brookhaven Medical, Inc.
Shibuya Consulting
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Post to the GaBio Career
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Georgia Bio encourages
member companies to
post openings to the Georgia Bio Career Center.

Learn more at http://jobs.gabio.org/home/

This job board is custom tailored for the Life Science
industry, which means we attract the most qualified
professionals in Georgia. Create an Employer Account
and post your Life Science jobs today!
Upcoming Events

The Biomarker Conference
February 18-19, 2016

The Genome Editing & Engineering Conference
February 18-19, 2016

The NGS Data Analysis and Informatics Conference
February 18-19, 2016

Small Dinner Series with Med Fusion’s Chuck Fogelgren
March 1, 2016

NCI SBIR Webinar: Funding, mentoring, & networking assistance for next generation cancer tech.
March 3, 2016

FDA and UGA host 40TH Annual International Good Manufacturing Practices Conference
March 7-10, 2016

Cancer Progress Conference
March 8-9, 2016

Pittcon 2016 Conference & Expo
March 6-10, 2016
15% GaBio Member Discount: 16GABIO15 Click here for this discount.

Forge Demo Day & Digital Health Showcase
March 22, 2016

Teacher Training: Basics of DNA Extraction and Gel Electrophoresis
March 25, 2016

Atlanta Science Festival
March 19-26, 2016

2016 Academic & Industry Intersection Conference: Georgia as a Biotechnology Capital?
April 4, 2016

Redefining Early Stage Investments
April 11, 2016

BIO Legislative Day Fly In
April 12-13, 2016

2016 Academic & Industry Intersection Conference: Georgia as a Biotechnology Capital?
April 14, 2016

2016 Georgia Logistics Summit
April 19-20, 2016

World Orphan Drug Congress USA 2016
April 20-22, 2016 | Washington, DC

Small Dinner Series with Grace Powers, Vice President of Regulatory Affairs for Brookhaven Medical
April 21, 2016

Ag Biotech Entrepreneurial Showcase 2016
May 18, 2016

2016 SEMDA Conference
May 18-19, 2016
2016 Champion Sponsors

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