

# AWIS NEWSLETTER

**Mission Statement:** The Association for Women in Science, Inc. (AWIS) is a non-profit organization dedicated to the achievement of equity and full participation of women in all areas of science and technology

## Logout Meet our Corporate Sponsors

By Janice Payne



Canji, Inc. has generously supported AWIS fundraising efforts for several years. Most recently they were a Platinum level sponsor of the year 2000 AWIS scholarship program. Many thanks to Canji for their ongoing support.

Canji, a leading gene therapy company, employs approximately 55 scientists in labs that are located on John Hopkins Court in the Torrey Pines area. The company was founded in 1990 and became a wholly owned subsidiary of Schering-Plough Corporation in 1996.

Researchers at Canji are actively involved in developing cancer therapeutics based on the tumor suppressor genes p53 and retinoblastoma (RB). Mutations or loss of the p53 or RB gene can lead to malignancies, and replacement of these genes in cancer patients allows the patient's own system to suppress tumor formation.

Canji has also developed a recombinant adenoviral vector delivery system that has proved to be an efficient reproducible method of gene transfer. Their p53 adenovirus gene product, which demonstrated tumor suppression in preclinical studies, is currently in Phase III clinical trials for treatment of ovarian cancer.

For information about career opportunities at Canji, call 858-597-0177.

## AWIS Event for January

By Susan Carroll

Join us on Wed, Jan 10 for our first event of 2001. We will be meeting at the San Diego Supercomputer Center (SDSC) on the UCSD campus; a short presentation on the function of the SDSC will be followed by a tour of the facility. Parking on campus is available for \$3.00. Please join us from 6 to 6:30pm for refreshments, with the program starting at 6:30pm.

## Women in Bioscience Conference Scheduled for May 2001

By Barbara Armstrong

The AWIS Women in Bioscience Conference committee is hard at work planning the conference scheduled for May 5<sup>th</sup> 2001 at the Salk Institute. The theme of this year's conference is: "Taking the Lead." Rita Colwell and Fran Heller will be the plenary speakers with the remainder of the day devoted to many exciting workshops:

### The Personal/Professional Development:

- Saving & Managing Money
- Appropriate Responses to Inappropriate Situations
- Strategy for Balance
- How to be a Mentor

### The Career Advancement:

- Your "Stay or Leave" Equation
- Negotiation Skills
- Managing Your Boss
- Advancing without a Ph.D.

### The Art of Leadership:

- Entrepreneurship
- The Big Picture
- Leadership in Academia vs. Industry
- How to be a Boss

### New Trends in Biosciences

- Bioinformatics
- Biotechnology Past, Present, and Future
- Ethical Issues in Biosciences
- Interfacing your Science Degree

### Registration information

AWIS members will receive information about registration in the mail or, check the website ([awis.npaci.edu/WIB](http://awis.npaci.edu/WIB)) for information as it becomes available. Online registration will begin Feb. 15, 2001.

### Updates and information by e-mail (free.)

Subscribe to the AWIS e-mail list and receive information about the conference, job opportunities, and AWIS events (between newsletters.) To subscribe to the AWIS e-mail list, please send email to [sdawis@san.rr.com](mailto:sdawis@san.rr.com). Include in the subject line: "Subscribe to AWIS e-mail." In the body, include your full name, address, and phone number.

## AWIS Members on the Move....

**Isabel Corcos, PhD** has joined Elitra Pharmaceuticals. She will hold the position of Research Scientist in assay development and antimicrobial and antifungal screening. She will be setting up a mammalian tissue culture lab, and profiling any hits from the antimicrobial and antifungal screening.

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**San Diego Chapter Welcomes the Following New Members:**

Meredith Kreul	Kforce.com Scientific
Vasumati Pestonjamas	UCSD, VA Medical Center
Christina CN Wu	UCSD

**AWIS SD Chapter Raises over \$1,300 for "Making Strides against Breast Cancer" Fundraiser.**

By Marcelle Vogel

On Oct.22, several AWIS members and friends participated in this annual event, a 5K walk through Balboa Park. We contributed over \$1,300 toward the \$600,000 raised for breast cancer research and grants. Special recognition to Sharon Wampler, who raised over \$1,000! Next year we hope to have 50 walkers.

Please make a point to join us for 2001 for this worthwhile cause - fall date to be announced.

**AWIS Events Committee Schedule of Events for 2001**

By Marcelle Vogel

Jan - Tour of the Supercomputer Center, UCSD Campus  
 Feb - How to Write a Business Plan  
 Mar - Wine Tasting at the Wine Bank  
 April - The Changing Role of Forensics as seen by the FBI  
 May - WIB Conference

Posting Jobs in the AWIS newsletter: Contact Elaine Weidenhammer at eweiden@nanogen.com, or AWIS voicemail: 619-687-5580, or AWIS PO Box: 178096, San Diego, CA 92177-8096 for the details. Deadline for inclusion in the next AWIS newsletter is February 2, 2001. If submitting by snail mail, include the words ATTN: Elaine Weidenhammer on the bottom left corner of the envelope.

**IMPORTANT INFORMATION ABOUT**



**San Diego Chapter**

**Voice Mail:** (619) 687-5580  
**Website:** <http://awis.npaci.edu>  
**E-mail:** [sdawis@san.rr.com](mailto:sdawis@san.rr.com)  
**Mail:** AWIS, San Diego Chapter  
 PO Box 178096  
 San Diego, CA 92177-8096

**National Chapter**

**Telephone:** (202) 326-8940  
**Web Site:** <http://awis.org>  
**E-mail:** [awis@awis.org](mailto:awis@awis.org)  
**Mail:** AWIS National  
 1200 New York Avenue, NW, Suite 650  
 Washington, DC 20005

**Moving? Address Change?**

Please notify us of your new address so you won't miss our mailings! E-mail **Susan Jennings** at: [sdawis@san.rr.com](mailto:sdawis@san.rr.com), phone the AWIS voicemail: (619) 687-5580, or mail changes to AWIS - San Diego, PO Box 178096, 92177-8096.

**About the AWIS Newsletter**

The AWIS Newsletter is published bimonthly and provides AWIS members and supporters with information on chapter activities, career developments, and issues related to women in science. The newsletter is free to AWIS members. Subscription rate for non-members is \$20 a year.

**Jan./Feb. Newsletter staff:**

Janice Payne	Tobey Tam	Susan Brown
Cathy Manner	Barbara Armstrong	Christine Haws

Send news items, comments, and subscription requests to Barbara Armstrong via e-mail: [baawis@nethere.com](mailto:baawis@nethere.com); or AWIS, PO Box 178096, San Diego, CA 92177-8096. If you would like your article included in the next issue, the deadline for inclusion is February 2, 2001.

**IMPORTANT CONTACTS**

<u>Committee</u>	<u>Contact</u>	
Events	Marcelle Vogel	<a href="mailto:marcelle@biospace.com">marcelle@biospace.com</a>
Membership	Susan Jennings	<a href="mailto:sdawis@san.rr.com">sdawis@san.rr.com</a>
Newsletter	Barbara Armstrong	<a href="mailto:baawis@nethere.com">baawis@nethere.com</a>
Outreach	Anna-Maria Hays	<a href="mailto:haysam@scripps.edu">haysam@scripps.edu</a>
Publicity	Elaine Weidenhammer	<a href="mailto:eweiden@nanogen.com">eweiden@nanogen.com</a>

**AWIS Board**

	<u>E-mail address</u>
Dr. Sharon Wampler	<a href="mailto:Sharon_Wampler@yahoo.com">Sharon_Wampler@yahoo.com</a>
Dr. Elaine Weidenhammer	<a href="mailto:eweiden@nanogen.com">eweiden@nanogen.com</a>
Linette Edison	<a href="mailto:linette.edison@advancedtissue.com">linette.edison@advancedtissue.com</a>
Cathleen Pena Davies	<a href="mailto:cdavies@mcc.miracosta.cc.ca.us">cdavies@mcc.miracosta.cc.ca.us</a>
Dr. Kim Barrett	<a href="mailto:kbarrett@ucsd.edu">kbarrett@ucsd.edu</a>

**Advisors**

Bylaws	Denise Hickey	<a href="mailto:dhickey@collateralthx.com">dhickey@collateralthx.com</a>
Treasurer	Meslissa Cunningham	<a href="mailto:melissa@gen-probe.com">melissa@gen-probe.com</a>
Website	Sharon Cherf	<a href="mailto:scherf@qualcomm.com">scherf@qualcomm.com</a>

## Job Posting

We're **NEUROCRINE BIOSCIENCES, INC.**, a leading biopharmaceutical company committed to the discovery and development of novel therapeutics and innovative treatments to treat diseases and disorders of the central nervous system (CNS) and immune systems. With five products in clinical development, our significant cash position, and a broad research pipeline of potential next generation products, we bring hope to patients, as well as value to our shareholders. Discover what our rapid development can do for your career.

Please forward resume to: Neurocrine Biosciences, Inc., Attn: Human Resources, 10555 Science Center Dr., San Diego, CA 92121; Fax: (858) 623-3397; E-mail: hr@neurocrine.com. Please indicate position of interest and reference AWIS on your resume or cover letter. EOE. To learn more about Neurocrine Biosciences, please visit our website at [www.neurocrine.com](http://www.neurocrine.com).

### CLINICAL RESEARCH ASSOCIATES

**Responsibilities:** We are seeking experienced Sr. CRAs for a growing clinical research department. Under general supervision these candidates will be responsible for independent management of multiple clinical trials (all phases). This position is responsible for monitoring the activities of the CROs to their assigned projects to assure compliance with GCP and ICH guidelines. Additional duties include; assisting senior staff with budget negotiations and clinical trial agreements, preparing confidentiality agreements, assisting with quality and validity of clinical trial data, interaction with other departments within the company, may represent the department at clinical project meetings, will provide clinical project managers with ongoing study status reports and assisting in preparation and submission of documents for regulatory filing.

**Qualifications:** Four-year degree in a biological or physical science or a nursing degree preferred. Minimum 4 years experience in a pharmaceutical industry. Must have excellent organization skills, be a team player, function independently and be able to interact comfortably with company personnel as well as CROs and investigational sites. Experience with managing a CRO is preferred. Must be willing to travel at least 30% within the United States and internationally.

### ASSOCIATE DIRECTOR, CLINICAL OPERATIONS

**Responsibilities:** Manage the operational activities to support the planning, initiation, conduct, and closeout phases for multiple clinical studies and multiple therapeutic areas. Candidate will also ensure that these activities are conducted in compliance with FDA regulations and ICH guidelines, and are in adherence with corporate and departmental Standard Operating Procedures (SOP). Manage, coordinate, expedite and monitor tasks, timelines, budgets, and resources to achieve program objectives in a timely fashion. May also select and manage CROs, develop monitoring plans, department SOPs, Clinical Trials Materials Plans, and study budgets. Track patient enrollment and study timelines, and recruit investigators. Responsible for Case Report Form design, protocol design and review, and CIB preparation. Train and supervise multiple CRAs or contract monitors. Provide periodic study progress reports to senior management.

**Qualifications:** Requires a B.S. degree or equivalent, with a minimum of eight years pharmaceutical or biotechnology industry experience in Clinical Research/Operations. Previous experience as a Clinical Project Manager is required.

### REGULATORY AFFAIRS MANAGER

**Responsibilities:** Responsible for leading, coordinating and organizing regulatory submissions, amendments, supplements, and routine reports for several drugs in clinical development up to

phase III. The position is also responsible for developing and maintaining excellent relationships with regulatory agencies, internal customers and other third parties. Provides advice to project teams regarding the development and implementation of strategies for drug development and registration that ensure to market timeliness and success. Recommends specific registration and material presentation strategies. Provides recommendations to CMC, non-clinical and clinical documents to ensure compliance with regulations.

**Qualifications:** BS in scientific field or equivalent. 3 plus years industrial FDA regulatory experience in small molecules or biologics is required. Experience in regulatory filings up to phase II required; up to phase III preferred. International regulatory experience is a plus.

### DRUG SAFETY MANAGER

#### Regulatory Affairs

**Responsibilities:** Responsible for implementing a product safety surveillance program. Develops guidelines and ensures the timely processing of adverse event reports. Assures compliance to the company guidelines, and FDA, ICH and local country regulations for adverse event reporting to regulatory agencies. Interfaces with clinical, QA and regulatory agencies. Responsibilities may include, but are not limited to, preparation of IND safety reports, development of SAE narratives, review of product-related documents and management of safety handling processes. Acts as the primary drug safety system expert. Investigates, proposes, designs, implements, ensures integrity of, and maintains a product safety database system.

**Qualifications:** BS/MS/RN/PharmD in related scientific field or equivalent. Three plus years experience in drug safety is required. Regulatory submission experience in ICH & FDA reporting is required. Some database exposure for data capture and report generation is preferred. Experience in procedure generation, implementation and coordination with CROs is preferred.

### MEDICAL WRITERS

#### Regulatory Affairs

**Responsibilities:** Write, rewrite, or edit pre-clinical and clinical, statistical, efficacy and/or safety study reports, investigator's brochures, protocols and materials for publications or presentations. Manage medical writing projects as well as review and provide feedback on documents prepared by internal personnel and independent consultants. Department liaison to project teams.

**Qualifications:** BS/BA degree in a health care, biological sciences, or communications field, 4 years of medical writing experience, and 2 years of direct pharmaceutical industry experience preparing clinical documents for submission to regulatory authorities such as IND, NDA or P/BLA filings. Requires knowledge of GCP, CFR 21 and ICH regulations. Requires strong analytical skills. The ability to interpret complex scientific and medical data clearly, and translate to a final product is a must. Strong written and oral communication skills are a must. Background in neurology, cancer and/or diabetes fields is a plus.

### REGULATORY DOCUMENTATION COORDINATOR

**Responsibilities:** Responsible for creating, formatting, tracking, and making changes to numerous regulatory documents submitted to the FDA. Creates electronic document standards and templates for documentation to be included in regulatory submissions, to assist in the preparation of regulatory documentation for the Regulatory Affairs department, and to assist with electronic publishing.

**Qualifications:** HS or equivalent and 3 years of documentation production experience in a biologic or drug clinical development

environment is required. Excellent computer skills in word processing (MS Word) are required, and proficient skills in spreadsheet (Excel) are a plus. Ability to work independently, under timelines and across multiple departments is required. Experience in Core Dossier or a comparable system is a plus.

#### **RESEARCH ASSOCIATE Pharmacology**

**Responsibilities:** We are seeking a motivated individual to join the Screening group at Neurocrine. Specific duties will include participating in High Throughput Screens and ongoing small molecule screening operations. This will include optimization and robotic validation of assays, execution of HTS screens, and data analysis. The candidate will be involved in the day-to-day operation of the screening laboratory and work in close conjunction with both chemists and biologists as part of discovery teams. The types of assays carried out may include but are not limited to SPA, fluorescence polarization, filtration radioligand binding, and whole-cell second messenger assays. In addition, the candidate will be responsible for the presentation of data related to project teams on a routine basis.

**Qualifications:** The successful candidate will have a Bachelors or Masters degree in Pharmacology, Biochemistry or equivalent. At least 2 years of experience in a research laboratory with employment in the pharmaceutical industry preferred. Experience with membrane receptors and transporters would be beneficial. Excellent oral and written communication skills are essential. Familiarity with computer software programs such as Word, Excel, and data analysis packages such as Prism or equivalent helpful.

#### **POSTDOCTORAL SCIENTIST Molecular Biology**

**Responsibilities:** This Postdoctoral Fellow will study novel G-protein coupled receptors in the CNS. The focus of this effort will be to characterize them and their role in neurological diseases with the goal of developing these receptors as future drug targets. The research will include the identification of ligands and interacting proteins, characterization of signaling pathways, and the use of a variety of disease model systems as well as transgenics and knockout mice to characterize the biology of these receptors.

**Qualifications:** Knowledge of molecular biology, biochemistry and pharmacology of G-protein coupled receptors is essential. The successful post-doctoral scientist should be able and willing to work within a multidisciplinary environment and interact with key scientists from medicinal chemistry to in vivo biology. Excellent oral and written skills are a must and a strong publication record is desired.

#### **POSTDOCTORAL SCIENTIST Pharmacology**

**Responsibilities:** To study the Corticotropin-releasing factor (CRF) system and the effects of selective receptor antagonists. The major effort will be in the identification of novel non-peptide receptor antagonists both for use as therapeutics in a wide variety of stress-related disorders as well as in the generation of unique tools with which to further probe this complex system.

**Qualifications:** Interested candidates should possess a Ph.D. in Pharmacology, Neuroscience or Biochemistry and have a solid background in the function and regulation of G-protein coupled receptors. Although prior experience with peptide receptors and specifically the CRF system is not absolutely required, a genuine interest and experience in vitro methodologies in the study of GPCRs is crucial. The successful post-doctoral scientist should be able and willing to work within a multidisciplinary environment and interact with key scientists from medicinal chemistry to in vivo biology. Excellent oral and written skills are a must and a strong publication record is desired. Candidates in current molecular pharmacology and cellular/biochemistry programs with a focus on cell surface receptors are encouraged to apply.

#### **POSTDOCTORAL SCIENTIST Neuroscience**

**Responsibilities:** Will conduct research into the function of excitatory amino acid transporters (EAATs) in relation to motor-neuron survival under pathological conditions in vitro. Neurocrine has an ongoing drug discovery program for the development of novel therapeutics which modulate glutamate transport by targeting EAATs, aimed at the treatment of amyotrophic lateral sclerosis (ALS) and other neurodegenerative conditions. The successful candidate will join this multidisciplinary team.

**Qualifications:** In addition to a Ph.D. in a Neuroscience-related area, the candidate should have experience in molecular/cellular biology and in primary neuronal or organotypic culture techniques. Experience in transporter physiology/pharmacology would also be beneficial. The successful post-doctoral scientist should be able and willing to work within a multidisciplinary environment and interact with key scientists from medicinal chemistry to in vivo biology. Excellent oral and written skills are a must and a strong publication record is desired.

#### **RESEARCH ASSOCIATE: Molecular Biology**

**Responsibilities:** This candidate will be responsible for performing all gene cloning and expression techniques as well as mammalian cell culture.

**Qualifications:** B.S. in molecular biology or related field with 2-4 years of experience. Must have knowledge of DNA and RNA purification, RT-PCR, DNA cloning and sequencing, RACE, Southern and Northern blots, cDNA library screening, Western blot analysis, and cell culture techniques. Additional experience in receptor binding assays would be helpful. Good communication and organization skills, ability to multi-task, and attention to detail are absolutely required.

#### **DEVELOPMENT: BIO-ANALYTICAL SCIENTIST**

##### **Pre-Clinical Development Department**

**Responsibilities:** Candidate will develop and validate analytical methods for quantitative determination of drug and metabolites in biological matrices, performing sample analysis in support of pharmacokinetics studies and lead compound screenings. Some project management responsibilities shall also be expected.

**Qualifications:** PhD or MS degree, with at least 2 years bio-analytical development experience in pharmaceutical industry; experience in trace analysis of organic compounds from complex biological matrices using LC/MS/MS and HPLC with UV, fluorescent detection. Familiarity with modern sample preparation techniques and GLP/GMP regulations is highly desirable.

#### **SCIENTIST (ANALYTICAL DEVELOPMENT)**

##### **Pharmaceutical Development**

**Responsibilities:** Principal duties of this position involve routine physical characterization of potential clinical drug candidates. Must have experience in applying and developing methods to conduct studies designed to solve problems in the area of physical chemical characterization as applied to small molecule drug candidates.

**Qualifications:** MS or Ph.D. in Chemistry, Pharmaceutical Chemistry, Pharmaceutics, or related field, with 5+ years of relevant analytical and/or preformulation experience. A demonstrated knowledge of the following methodology is preferred: analytical HPLC, GC, chiral purity, logP/pKa determinations, solution- and solid-state testing and stability, and equilibrium solubility. Familiarity with USP and other regulatory requirements for drug development a plus.

(Job posting continued on page 5.)

**SENIOR RESEARCH ASSOCIATE****Preclinical Development/Toxicology**

**Responsibilities:** Responsible for the development, validation and implementation of in vitro systems for assessment of general and mechanistic toxicity. In vitro systems include, but are not limited to, one or more of the following: primary cell cultures such as isolated hepatocytes, perfused organ systems, in-vitro tissue slices, studies with established cell lines, and/or microsomal preparations. The candidate will also be responsible for the performance of study-related procedures, protocol compliance, and data analysis, interpretation and reporting.

**Qualifications:** Requires a MS in toxicology, pharmacology, physiology, cell biology, animal sciences or related fields and one year experience in industrial preclinical drug development, or a BS with 3-5 years experience. Requires proficiency in technical procedures conducting toxicological studies in in-vitro models. Experience in working with rodents is also necessary, including handling, clinical observations, dosing, surgical procedures and necropsy. Experience with analytical instrumentation, including HPLC and LC/MS highly desirable. Proficiency with data documentation and acquisition systems required. Must be a team player, self-starter, and have the ability to work in the fast paced environment of preclinical development of novel compounds.

**PROGRAM MANAGER Development**

**Responsibilities:** Responsible for planning and coordinating multiple projects from the point of drug candidate selection through to licensing the drug worldwide. Specific responsibilities include managing project teams, coordinating, and expediting tasks, monitoring timelines, budgets, and resources to achieve project objectives. The Program Manager will present project proposals/plans, issues and recommendations to senior management committees.

**Qualifications:** The position requires a scientific degree with 5 years in pharmaceutical development and 2 years in project management. Must have a strong understanding of drug development and project management systems and software. Requires a motivated self-starter with excellent communication and influencing skills and the ability to handle multiple tasks simultaneously. Familiarity with drug development budgeting/expense tracking is a plus.

**SENIOR CONTRACT ADMINISTRATOR Finance**

**Responsibilities:** We're seeking a highly organized, hands-on professional with excellent analytical skills to, review, adjust, negotiate, and administer contracts with outside service providers, as well as track contractual obligations for internal clients. Specifically, the position will be responsible for facilitating and managing the contract process for clinical trial, transfer, research, pre-clinical, manufacturing, and consulting agreements. The Administrator will also abstract and summarize licensing and collaborative agreements regarding payment/milestone events, act as primary contact with Legal, Finance and operational departments, ensure company compliance, and advise and assist in the development of standard and non-standard contract terms and conditions.

**Qualifications:** BS/BA degree in science, finance or business with 3 years experience in pharmaceutical and/or the CRO industry preparing, negotiating and administering contracts. Thorough knowledge of budget preparation and accounting skills and advanced knowledge of MS Word, Excel, and Access is essential. You must also have strong organizational and facilitation skills to synthesize data from multiple sources and individuals, the ability to work independently and take direction from and interface with various levels of management, the ability to analyze proposals and

budget documents, and excellent communication and interpersonal skills.



Have a happy and  
prosperous New Year!

