

# Office of Biotechnology Newsletter

<http://www.aecom.yu.edu/home/biotechnology/>

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We are pleased to send you this inaugural issue of a new newsletter produced by Einstein's Office of Biotechnology. Its purpose is to inform you about an important resource at the College of Medicine that may be extremely useful to you in your research efforts.

The Office of Biotechnology manages the intellectual property assets of the Albert Einstein College of Medicine. It is charged with taking the results of Einstein research and channeling them to benefit the public through the development of new drugs and other medical advances, all of course, in accordance with academic principles and ethical standards.

Among the Office's responsibilities are: providing staff to the Patent Committee; managing the College's patent portfolio; managing all aspects of technology transfer, including licensing Einstein technologies to commercial partners; negotiating industry-sponsored research agreements; and negotiating and processing material transfer agreements and confidential disclosure agreements.

The Office consults regularly with the Biotechnology Subcommittee of Einstein's Board of Overseers. This subcommittee consists of current and former Board members, Jay Goldberg and Fred Tepperman, who bring their extensive experience in venture capital and corporate finance.

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## STATISTICAL SNAPSHOTS:

|  |                         |
|--|-------------------------|
| Invention Disclosures Received (2005):                             | 41                      |
| Significant Licenses/Options Concluded (2004 and 2005):            | 21                      |
| New Companies Created based on Einstein Technologies (since 2004): | 5                       |
| Active Licenses:   | 70                      |
| License Income (projected FY2006):                                 | >\$5 Million            |
| Industry Sponsored Research Agreements:                            | 30                      |
| Industry Sponsored Research Income:                                | ~\$1.7 million per year |
| Material Transfer Agreements:                                      | >400 per year           |

## TECHNOLOGY SPOTLIGHT

### DR. VERN SCHRAMM'S TECHNOLOGY STEADILY ADVANCES THROUGH CLINIC ATTRACTS BIG PHARMA SUBLICENSES

BioCryst Pharmaceuticals, Inc. announced exclusive agreements with Roche and MundiPharma International Holdings, Ltd., to develop and commercialize compounds developed by Dr. Vern Schramm, Chairman of Biochemistry at Einstein, in collaboration with scientists at Industrial Research Ltd. of New Zealand. In November 2005, Roche obtained exclusive rights to BioCryst's Phase I compound BCX-4208 for treating autoimmune diseases and acute rejection in transplantation. In February 2006, MundiPharma licensed exclusive rights to BioCryst's anti-cancer drug, Fodosine™ for development in Europe, Asia, Australia, Japan, New Zealand and China. BioCryst retained rights in North America and other markets.

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### DR. VERN SCHRAMM'S TECHNOLOGY STEADILY ADVANCES THROUGH CLINIC ATTRACTS BIG PHARMA SUBLICENSES

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In June 2000, the Office of Biotechnology negotiated a license with BioCryst to inhibitors of human purine nucleoside phosphorylase (PNP) developed by Dr. Schramm and his IRL collaborators. The PNP enzyme is crucial for the survival and proliferation of T-cells, since it maintains the cells' DNA synthesis. By blocking PNP activity, Dr. Schramm's PNP inhibitors have the potential for treating conditions in which T-cells run amok, including several types of cancer and autoimmune diseases such as psoriasis and rheumatoid arthritis.

Since execution of the license, BioCryst has developed BCX-4208 for autoimmune indications and Fodosine™ for treating T-cell leukemia and other cancers. Before sublicensing the compounds, BioCryst had taken BCX-4208 into a Phase-1b clinical trial to evaluate the safety, tolerability, and pharmacokinetics of the drug in healthy volunteers. Fodosine™ is currently in Phase I or I/II clinical trials for T-cell leukemia, cutaneous T-cell lymphoma (CTCL), and B-cell acute lymphoblastic leukemia (B-ALL), as well as a Phase II trial for chronic lymphocytic leukemia (CLL). The FDA has granted Orphan Drug status to Fodosine™ in several indications and fast track status for using Fodosine™ in the treatment of relapsed or refractory T-cell leukemia.

In exchange for the exclusive worldwide rights that it granted

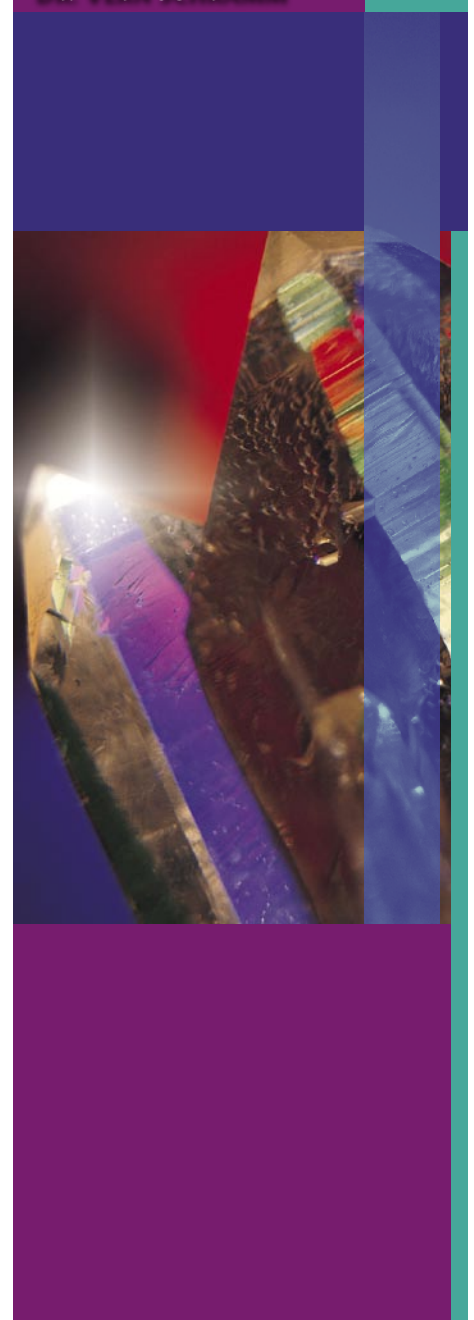
to Roche, BioCryst received an upfront fee of \$25 million. Future payments to BioCryst based on milestones could reach an additional \$530 million, plus royalties based on product sales. This transaction was the fifth largest biotech-pharma deal in the world for 2005.

Although smaller in scope and economics, the license agreement between BioCryst and Mundipharma has the potential to generate \$190 million plus royalties on product sales. Mundipharma agreed to pay BioCryst a \$10 million upfront license fee as well as an additional \$10 million for further research on Fodosine™ and another \$15 million for development efforts in Europe. If specific milestones are met, payments of up to an additional \$155 million could be forthcoming to BioCryst, plus royalties on product sales.

In accord with the original license agreement Einstein and IRL will receive a percentage of the upfront payments to BioCryst. Additionally, Einstein and IRL will continue to capture percentages of future milestone payments to BioCryst as well as royalties on product sales should either Fodosine™ or BCX-4208 reach the market. Distributions from Einstein's share of the sublicense income will be made to Dr. Schramm and Dr. Schramm's research in accord with Einstein's Patent Policy.



**DR. VERN SCHRAMM**



# MATERIAL TRANSFER AGREEMENTS

## What is a Material Transfer Agreement?

A Material Transfer Agreement (MTA) is a contract governing the exchange of biological and non-biological materials for research purposes among the scientific community, including academic institutions, other not-for-profits, and industry. (Software is an example of a non-biological material that may be exchanged using an MTA.)

An MTA is a legal contract between the owner of the material (Provider) and a party requesting permission to obtain and use the material for research purposes (Recipient). MTAs typically cover the transfer of a variety of materials, including cell lines, DNA clones, antibodies, animal models and reagents. The Office of Biotechnology processes over 400 MTAs in a typical year.

## Why is an MTA important?

MTAs are important because they protect the rights of both parties. They address issues such as:

- Ownership of the original materials and modifications or derivatives made by recipients
- Limits on use of the material by recipient and the recipient's liability
- Publication rights and rights to inventions arising out of research with the material

## Is processing an MTA a complicated and lengthy procedure?

Not always. Einstein, like many

other U.S. academic institutions, is a signatory to the Uniform Biological Material Transfer Agreement (UBMTA). The UBMTA is a standard form recommended by the NIH. Use of the UBMTA greatly facilitates the exchange of materials among academics, since the agreement may be executed without further negotiation between the parties.

Exchange of materials to and from industry is managed on a case-by-case basis. The single most significant delay in finalizing incoming MTAs from industry is negotiating acceptable terms. In many cases, industry MTAs include terms that conflict with Einstein policy, NIH guidelines, and legal obligations required of federally funded institutions. Most negotiations center on two concerns: a company's desire to own the inventions as well as the data arising from research using company materials, and the company's desire to control or unduly delay publications.

## Who should be contacted about MTAs?

All MTAs must be reviewed by the Office of Biotechnology and should be directed to:

Kevin Schadick  
Belfer 302  
Ext. 3357  
Email: [schadick@acom.yu.edu](mailto:schadick@acom.yu.edu)

**Incoming MTAs:** Incoming MTAs involve situations in which Einstein requests materials from a nonprofit or commercial entity.

All incoming MTAs require signatures from the scientist requesting the material and a College official. Incoming MTAs seeking material from academic and not-for-profit institutions may be signed by the recipient scientist and then forwarded to Kevin Schadick for processing. MTAs seeking material from industry should be forwarded directly to Kevin Schadick. It is preferable that electronic versions of MTAs from companies be provided.

**Outgoing MTAs:** Outgoing MTAs involve situations in which Einstein provides materials to nonprofit or commercial entities that request them.

Academic and non-profit institutions that request material may be directed to download Einstein's MTA directly from the Office website <http://www.aecom.yu.edu/home/biotechnology/mta.htm>. The requestor should provide the requested information and return the MTA to Einstein signed by the recipient scientist and by an authorized representative of the recipient scientist's institution.

MTAs with industry are negotiated on a case-by-case basis. The College provides research tools to industry and negotiates a non-exclusive license that typically includes a license fee. Incomes from such licenses are treated in accordance with the Patent Policy. All requests for materials from industry should be referred to the Office of Biotechnology.

## EINSTEIN RENEWS ONCOMOUSE AND CRE-LOX AGREEMENTS

Many of Einstein's faculty use the Oncomouse and Cre-Lox technologies in the lab to advance their research. These technologies are proprietary to DuPont and Bristol-Myers Squibb ("BMS") respectively. In order to protect our faculty and allow for their continued use, the Office of Biotechnology recently renewed its licensing agreements with DuPont and BMS. Under both licenses, the terms of the agreements refer to Einstein's use of the technologies strictly for research purposes and prohibit Einstein from using the technology to generate data or information in conjunction with industry-sponsored research or collaborations with commercial third parties. Materials generated through the use of these technologies may be transferred to non-profit institutions only if these institutions have entered into a licensing agreement with DuPont or BMS or if they sign an addendum to Einstein's standard MTA. Both DuPont and BMS have their own addendums, and each will be available for download from the Office of Biotechnology website.

Einstein has additional obligations in the DuPont agreement that require faculty participation. Under the DuPont Oncomouse agreement, Einstein must submit yearly reports identifying all principal investigators conducting research with Oncomouse. Furthermore, Einstein is required to submit a list of all publications or manuscripts incorporating data generated using Oncomouse. The BMS Cre-Lox agreement entails no additional obligations.

Anyone wishing to transfer materials incorporating either Cre-Lox or Oncomouse to for-profit third parties, or wishing to do sponsored research that would generate data using these technologies, should contact the Office of Biotechnology. The Office is responsible for ensuring that Einstein complies with the terms of such agreements. In addition, please feel free to contact the Office of Biotechnology if you have any questions concerning either your obligations under the agreement or the addendum to the MTA.



### *Invention Disclosure Procedure*

- Do not hesitate to contact the Office of Biotechnology to discuss questions or concerns pertaining to inventions, disclosure forms, or upcoming public disclosures of research results.
- Always submit Invention Disclosure Forms prior to public disclosure such as presentations or publications.
- Contact the Office of Biotechnology for an Invention Disclosure Form or download one from the website.
- Be complete and accurate in filling out the Invention Disclosure Form (attach publications, manuscripts, abstracts, etc.).
- Obtain signatures from three (3) members of your department as witnesses.
- Provide the names of four (4) faculty members affiliated with Einstein who can evaluate your research.
- Return Invention Disclosure Form to the Office of Biotechnology (Belfer 302).