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BIOWORLD® TODAY

FRIDAY
AUGUST 10, 2007

THE DAILY BIOTECHNOLOGY NEWSPAPER

VOLUME 18, NO. 155
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Alnylam Gets $38.6 Million Grant For RNAi Antivirals

By Trista Morrison
Staff Writer

Alnylam Pharmaceuticals Inc. gained additional government funding for its biodefense program with a $38.6 million grant from the U.S. Defense Threat Reduction Agency (DTRA) for the development of an RNAi drug to treat viral hemorrhagic fevers.

Viruses in general are an "attractive option" for treatment with RNAi, because the drugs can target "aspects of the viral genome that are highly conserved and required for viral replication" yet are not characteristic of endogenous genes, said Alnylam's Chief Operating Officer Barry Greene.

Under the contract, Alnylam will research the silencing of host targets believed to be involved in viral pathogenesis and disease progression, with the goal of developing a

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Nereus' Series D-2 Round Adds $45M To Advance Cancer Drugs

By Jennifer Boggs
Staff Writer

Nereus Pharmaceuticals Inc. secured funding to move its lead oncology candidates into Phase II programs with a $45 million Series D-2 financing round.

Funds will be drawn down in two tranches, based on milestone achievements. That arrangement is similar to the company's first Series D round, which brought in $24.3 million in December 2004, with an additional $18.3 million added upon the completion of company goals, including the filing of investigational new drug applications for lead programs NPI-0052 and NPI-2358.

The recent round will be used to complete ongoing safety studies for those compounds and, "hopefully, allow us to begin our Phase II programs sometime next year," said Kobi Sethna, president and CEO of San Diego-based

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NEWCO NEWS

PB Biosciences Start-Up Stakes Claim In Antibiotics

By Trista Morrison
Staff Writer

Pacific Beach Biosciences Inc., an anti-infectives player founded last year with seed money from Paramount Biosciences LLC, licensed a novel antibiotic called zabofloxacin from Dong Wha Pharmaceutical Ind. Co. Ltd.

The deal calls for San Diego-based PB Biosciences to pay Seoul, Korea-based Dong Wha an undisclosed up-front payment and up to $56.5 million in development and commercialization milestones, as well as royalties. In exchange, PB Biosciences gets exclusive rights to zabofloxacin outside Japan, Korea, China, Taiwan, Singa-

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Financings Roundup

Adnexus Closes $15.5M Series C To Advance Its Anticancer Drug

By Donna Young
Staff Writer

Adnexus Therapeutics will use the proceeds from $15.5 million garnered in Series C financing to help fund further clinical development activities of its anticancer drug Angiocept (CT-322), a product that inhibits activation of vascular endothelial growth factor receptor-2 (VEGFR-2).

The financing was led by new investor HBM BioVentures Ltd., a global health care investment firm. Existing venture investors Atlas Venture, Flagship Ventures, Polaris Venture Partners and Venrock also participated in the financing.

Angiocept is part of a new class of protein therapeutics known as adnectins, which are based on human fibronectin. The product currently is being tested in the U.S. in a Phase I clinical trial in adult patients with advanced solid tumors or

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AHC Media LLC

Alnylam

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broad-spectrum RNAi therapeutic that potentially could be used to treat multiple viruses responsible for viral hemorrhagic fevers. Drug candidates developed by Alnylam will undergo in vitro and in vivo testing at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). The 33-month contract fully supports all research activities through Phase I clinical trials.

Viral hemorrhagic fevers include illnesses caused by Ebola virus, Marburg virus, Omsk hemorrhagic fever virus, Lassa virus and several others. All are RNA viruses carried by animal or insect hosts. Infections usually result in vascular damage, bleeding and organ failure, and there are no established treatments or cures for most cases.

Last month, the DTRA selected a grant application from Peregrine Pharmaceuticals Inc. seeking $44.5 million to investigate bavituximab and other antiphosphotidylserine antibodies as potential therapies for hemorrhagic fever virus infections. The contract is now in final negotiations. The DTRA also has awarded hemorrhagic fever virus grants to AVI BioPharma Inc. for the development of antisense therapeutics and to Protiva Biotherapeutics Inc. for treatments based on Stable Nucleic Acid Lipid Particle (SNALP) technology.

Alnylam also previously received grants for hemorrhagic fever virus work. In April 2006, the Cambridge, Mass.-based company signed a Cooperative Research and Development Agreement with the USAMRIID to discover RNAi therapeutics targeting viral organisms, including hemorrhagic fever viruses. Then in September, the National Institutes of Health awarded Alnylam a four-year, $23 million grant to support research on the Ebola virus. Less than month later, Congress passed the Defense Appropriations Act of 2007, which included another $1.1 million for Alnylam's RNAi biodefense projects. (See *BioWorld Today*, Sept. 29, 2006.)

In total, Greene said the Alnylam Biodefense group has been granted more than $63 million in federal contracts. He added that work on the Ebola program has achieved "some success" and preclinical data likely would be presented in the coming months.

Alnylam's antiviral work doesn't depend solely on government funding. The company's lead product, ALN-RSV01, is in Phase II for respiratory syncytial virus (RSV) infection. Alnylam also is working with Novartis AG to advance ALN-FLU01 against pandemic flu and with Biogen Idec Inc. to develop an RNAi approach to treating progressive multifocal leukoencephalopathy, a disease caused by the JC virus and linked in rare cases to the use of Biogen Idec's multiple sclerosis drug Tysabri. (See *BioWorld Today*, Feb. 22, 2006, and Sept. 22, 2006.)

Yet while ALN-RSV01 – and most other advanced RNAi drugs – are delivered directly to their target region of action, the Ebola and viral hemorrhagic fever drugs will need to be systemically delivered, Greene said, because the viruses replicate systemically.

Systemic delivery of RNAi has proven challenging, since RNAi is degraded quickly in the bloodstream. Alnylam has a partnership with Inex Pharmaceuticals Corp. for RNAi delivery using cationic liposomes, but Greene said the company also is exploring conjugates, antibodies and polymers as delivery options for its biodefense candidates.

Other companies focused on systemic delivery of RNAi include Tacere Therapeutics Inc., which encapsulates short-hairpin RNAs within an adeno-associated virus (AAV) protein coat; Intradigm Corp., which surrounds the RNAi with a ligand-targeted layered nanoparticle; and Silence Therapeutics plc, which chemically stabilizes its RNA and then delivers it within a liposome.

Alnylam also is working on systemically delivered RNAi therapeutics within its internal pipeline and plans to file an investigational new drug application this year for either hypercholesterolemia drug ALN-PCS01 or liver cancer drug ALN-VSP01.

Shares of Alnylam (NASDAQ:ALNY) rose 53 cents to close at $25.98 on Thursday. After the market closed, the company announced second-quarter earnings as well as the closing of its potential billion-dollar deal with Roche Holding AG. (See *BioWorld Today*, July 10, 2007.)

During the second quarter, Alnylam posted revenues of $9.1 million and a GAAP net loss of $12.7 million, or 34 cents per share. Cash, cash equivalents and marketable securities were $194.8 million as of June 30, although the company said it expects to have more than $435 million by the end of the year. ■

OTHER NEWS TO NOTE

• **Abraxis BioScience Inc.**, of Los Angeles, announced that it has signed a licensing agreement with **Biocon Ltd.**, of India, for the commercialization of the breast cancer drug Abraxane (paclitaxel protein-bound particles for injectable suspension) in India, Pakistan, Bangladesh, Sri Lanka, the United Arab Emirates, Saudi Arabia, Kuwait and certain other South Asian, and Persian Gulf countries. Under the agreement, Abraxis will receive royalties from Biocon based on net sales of the product in those countries. Abraxane is marketed in the U.S. under a co-promotion agreement between Abraxis and AstraZeneca Pharmaceuticals .

• **AVEO Pharmaceuticals Inc.**, of Cambridge, Mass., completed a cancer partnership with Whitehouse Station, N.J.-based **Merck & Co. Inc.** begun in 2005. The collaboration utilized AVEO's cancer models to identify and validate tumor maintenance genes as targets for small molecule cancer drugs. Merck has exercised its exclusive right to advance the compounds into preclinical development. The companies will continue to collaborate on identifying genetic profiles that correlate with drug response in order to guide cancer clinical trials. (See *BioWorld Today*, Nov. 3, 2005.)