WEEK OF JANUARY 25, 2010

BioCentury Part II

ESSENTIAL SURVEILLANCE FOR BIOTECH & PHARMA

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BioBusiness for the week ended January 22

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Using BioCentury Part II

BioCentury Part II is a comprehensive compendium of business news for management and investors in bioscience companies. It is organized into three departments: Company News, Clinical News and Financial News.

The index on this page lists all the companies covered this week. The news items in each department are organized alphabetically by company. When more than one company is listed, the biotech company is shown first. Each brief is labeled with one or more applicable business categories from the following list:

ADMET; Agbio/Environmental; Antibodies; Autoimmune; Bioinformatics; Biomanufacturing; Biopharmaceuticals; Biosimilars; Cancer; Cardiovascular; Chemistry; Combinatorial biology; Computational chemistry/biology; Dental; Dermatology; Diagnostic; Drug delivery; Endocrine; Finance; Functional genomics; Gastrointestinal; Gene/Cell therapy; Generics; Genitourinary; Genomics; Hematology; Hepatic; High throughput screening; Infectious; Inflammation; Metabolic; Microarrays; Microfluidics; Musculoskeletal; Neurology; Nutraceuticals; Ophthalmic; Other; Pharmaceuticals; Pharmacogenetics; Proteomics; Pulmonary; Renal; Supply/Service; Transplant; Veterinary

COMPANY NEWS/Deals, Sales & Marketing, Other News, Management Tracks

DEALS

AC Immune S.A., Lausanne, Switzerland
Lomonosov Moscow State University, Moscow, Russia
Business: Neurology

The university granted AC Immune exclusive rights to develop and commercialize ACI-518. The Ampakine that is a positive modulator of AMPA 1 glutamate receptor (GRIA1; GLUR1) is in preclinical testing to treat Alzheimer's disease. Further terms were not disclosed.

Affomix Corp., Branford, Conn.
City of Hope National Medical Center, Duarte Calif.
Business: Antibodies

Affomix will use its Y2Hexpress and Phage ESCape technologies to develop antibodies for City of Hope. The hospital will use the antibodies with next-generation sequencers to develop proteomic profiles of cancers, including renal and prostate, for use in its laboratories. Financial terms were not disclosed.

Alcon Inc. (NYSE:ACL), Hunenberg, Switzerland
Nestle S.A. (SIX:NESN), Vevey, Switzerland
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Business: Ophthalmic

An independent committee of directors for Alcon formally rejected a takeover proposal from Novartis and called the offer "grossly inadequate." Novartis, which already owns 25% of Alcon, exercised an option this month to acquire a further 52% of Alcon from Nestle for $180 per share. It then proposed to buy out the remaining 23% of Alcon in a stock deal valued at about $151.43 per share.

The Alcon committee reiterated that the merger requires the approval of Alcon's independent directors and that Swiss law requires interested directors to abstain from merger votes. Novartis could not be reached for comment (*see BioCentury, Jan. 11*).

Altea Therapeutics Corp., Atlanta, Ga.
KAI Pharmaceuticals Inc., South San Francisco, Calif.
Business: Drug delivery

The companies will use Altea's PassPort Transdermal Delivery System to co-develop three undisclosed protein kinase C (PKC) inhibitors from KAI to treat pain, hyperparathyroidism and a potential third indication. The companies will develop the compounds through Phase 1 trials, after which KAI has the option to receive worldwide rights to develop and commercialize resulting compounds. If KAI

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Regulatory,
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Genmab (CSE:GEN)/GlaxoSmithKline (LSE: GSK; NYSE:GSK)
Genzyme NASDAQ:GENZ)
Gilead (NASDAQ:GILD)/Roche (SIX:ROG; OTCQX:RHHBY)
GlaxoSmithKline (LSE:GSK; NYSE:GSK)
Helsinn/Eisai (Tokyo:4523; Osaka:4523)
NicOx (Euronext:COX)
Novartis (NYSE:NVS; SIX:NOVN)
Novo Nordisk (CSE:NVO; NYSE:NVO)
Rigel (NASDAQ:RIGL)/Merck KGaA (Xetra: MRK)
Roche (SIX:ROG; OTCQX:RHHBY)
SkyePharma (LSE:SKP)/Kyorin (Tokyo:4569)/ Mundipharma/Abbott (NYSE:ABT)
Somaxon (NASDAQ:SOMX)
UCB (Euronext:UCB)/Otsuka (Tokyo:4768)

Clinical Results (Page B12)

Aeolus (OTCBB:AOLS)/Arca (NASDAQ: ABIO)/Endo (NASDAQ:ENDP)
Aterovax
Biogen Idec (NASDAQ:BIIB)/Elan (NYSE:ELN)
Biotie (HSE:BTH1V)/Roche (SIX:ROG; OTCQX:RHHBY)
Galapagos (Euronext:GLPG; Pink:GLPYY)
Inspire (NASDAQ:ISPH)/Allergan (NYSE: AGN)/Santen (Tokyo:4536; Osaka:4536)
Lexicon (NASDAQ:LXRX)
Merck (NYSE:MRK)
Mitsubishi (Tokyo:4508; Osaka:4508)/Novartis (NYSE:NVS; SIX:NOVN)
Onyx (NASDAQ:ONXX)/Bayer (Xetra:BAY)
PCI (OSE:PCIB)
Qiagen (Xetra:QIA; NASDAQ:QGEN)
Roche (SIX:ROG; OTCQX:RHHBY)
Symphony Evolution
Teva (NASDAQ:TEVA)/Merck KGaA (Xetra: MRK)

Preclinical Results (Page B16)

Access (OTCBB:ACCP)
Critical Outcome (TSX-V:COT; Pink:COTQF)
Merck (NYSE:MRK)
Symphony Evolution

Clinical Status (Page B16)

BioNumerik
BTG (LSE:BGC)
Cempra
Circassia
CytoDyn (OTCBB:CYDY)
Durect (NASDAQ:DRRX)/Nycomed
Genzyme (NASDAQ:GENZ)/PTC Therap
GlaxoSmithKline (LSE:GSK; NYSE:GSK)
Idera (NASDAQ:IDRA)/Merck KGaA (Xetra: MRK)
Intl Medica Fdn
MorphoSys (Xetra:MOR)
Pharmasset (NASDAQ:VRUS)
Sunesis (NASDAQ:SNSS)

FINANCIAL NEWS

Completed Offerings (Page B18)

Achillion (NASDAQ:ACHN)
AMAG (NASDAQ:AMAG)
BioCurex (OTCBB:BOCX)
Cortex (OTCBB:CORX)
Curis (NASDAQ:CRIS)
Cyclacel (NASDAQ:CYCC)
Elevation Pharma
EnteroMedics (NASDAQ:ETRM)
Geron (NASDAQ:GERN)
GlobeImmune
InterMune (NASDAQ:ITMN)
Kolltan
Liquidia Tech
Novita
Ohr (OTCBB:OHRP)
ProChon
Rosetta (NASDAQ:ROSG)

Proposed Offerings (Page B19)

Nutri Pharma (OSE:NUT)
Sinovac (NASDAQ:SVA)

Amended Offerings (Page B19)

Ironwood Pharma

Other Financial News (Page B20)

Athersys (NASDAQ:ATHX)
Diamyd (SSE:DIAM B)
EntreMed (NASDAQ:ENMD)
EpiCept (NASDAQ:EPCTD; SSE:EPCT)
Luna (NASDAQ:LUNA)
Repros (NASDAQ:RPRX)
Synta (NASDAQ:SNTA)
Targeted Genetics (Pink:TGEN)

Deals,
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exercises its option, Altea will receive undisclosed upfront payments and would be eligible for milestones and royalties. KAI's lead product is KAI-9803, an isozyme-selective delta PKC inhibitor in Phase IIb testing to reduce myocardial injury in heart attack patients.

Amerifit Brands Inc., Cromwell, Conn.
Martek Biosciences Corp. (NASDAQ:MATK), Columbia, Md.
Business: Other

Martek agreed to acquire consumer products company Amerifit from investment firm Charterhouse Group for $200 million in cash. Canaccord Adams Inc. advised Martek on the deal, which is expected to close by April 30.

Axxam S.p.A., Milan, Italy
Juvenile Diabetes Research Foundation International (JDRF), New York, N.Y.
American National Multiple Sclerosis Society, New York, N.Y.
Business: Autoimmune, Endocrine

JDRF and the society's not-for-profit technology transfer subsidiary Fast Forward LLC will contribute an undisclosed sum to fund Axxam's discovery and development of new treatments for multiple sclerosis and Type I diabetes. Axxam will use the funds to screen its chemical library to identify compounds that target potassium channel Kv1.3 (KCNA3). Further details were not disclosed.

BioAtla LLC, San Diego, Calif.
Halozyme Therapeutics Inc. (NASDAQ:HALO), San Diego, Calif.
Business: Cancer, Dermatology, Inflammation

The companies will use BioAtla's gene synthesis and high throughput expression screening technology to discover and develop biologics for cancer, aesthetic dermatology and inflammation. Halozyme will have exclusive, worldwide rights to the biologics developed from the three-year deal. Further details were not disclosed.

BioForm Medical Inc. (NASDAQ:BFRM), San Mateo, Calif.
Merz GmbH & Co. KGaA, Frankfurt, Germany
Business: Dermatology

Merz began its previously announced tender offer to acquire all outstanding shares of BioForm for $5.45 per share. The tender offer expires at midnight on Feb. 12 (*see BioCentury, Jan. 11*).

bioMerieux S.A. (Euronext:BIM), Marcy l'Etoile, France
Meikang Biotech (Shanghai) Co. Ltd., Shanghai, China
Business: Diagnostic

bioMerieux acquired manufacturing company Meikang Biotech for an undisclosed sum. Meikang, which has a production facility in Shanghai, manufactures rapid tests for cardiovascular disease, cancer and infectious disease. bioMerieux said the deal will give it a base in China, where the biotech expects the most growth in the *in vitro* diagnostics business over the next 10 years.

Bionor Immuno AS, Skien, Norway
Nutri Pharma ASA (OSE:NUT), Oslo, Norway
Business: Infectious

Nutraceuticals company Nutri Pharma acquired 97.4% of the outstanding shares of infectious disease company Bionor in a stock deal. The deal closing is contingent upon Nutri Pharma raising at least NOK50 million ($8.9 million) and Bionor's creditor reducing the company's debt to NOK20 million ($3.6 million) from NOK 43.6 million ($7.8 million). Nutri Pharma has proposed to raise up to NOK100 million ($17.6 million) in a private placement, which closes on Jan. 29. Nutri Pharma has until March 31 to decide whether to close the deal.

Nutri Pharma said the deal will allow it to expand into infectious disease. Bionor's lead candidate is Vacc-4x, a therapeutic peptide composed of four modified synthetic peptides that correspond to a conserved domain of the HIV p24 protein. Vacc-4x is in Phase IIb testing to treat HIV/AIDS, with data expected in October.

Biovel Lifesciences Pvt. Ltd., Bangalore, India
Ranbaxy Laboratories Ltd. (NSE:RANBAXY; BSE:500359), Gurgaon, India
Business: Infectious, Biosimilars

Ranbaxy will acquire Biovel for an undisclosed sum. Biovel develops and markets biogenerics and biopharmaceuticals, including Typhoid Vi antigen vaccine against typhoid and Hib conjugate vaccine against *Haemophilus influenzae*, which are approved in India. Ranbaxy said the deal gives it an entry into vaccine and biotherapeutics manufacturing. Further terms were not disclosed. Daiichi Sankyo Co. Ltd. (Tokyo:4568; Osaka:4568, Tokyo, Japan) is a majority shareholder in Ranbaxy.

Biovitrum AB (SSE:BVT), Stockholm, Sweden
Swedish Orphan International AB, Stockholm, Sweden
Business: Cancer, Metabolic

Biovitrum completed its previously announced acquisition of Swedish Orphan for SEK3.5 billion ($496.7 million) (*see BioCentury, Nov. 9, 2009*).

Can-Fite BioPharma Ltd. (Tel Aviv:CFBI), Petah Tikva, Israel
Morningside Group (Holdings) Ltd., Hong Kong, China
Business: Infectious

The parties signed a memorandum of understanding to create a JV to develop Can-Fite's CF102 to treat Liver diseases in China, Hong Kong, Macau and Taiwan. The JV will receive an exclusive license to IP covering the nucleoside adenosine A3 receptor agonist in those markets. Morningside will provide up to $7.5 million in funding for preclinical and clinical development of the compound up through Phase II. Can-Fite will have full access to the data and the right to use it for regulatory purposes in other countries. CF102 is in Phase I/II testing to treat chronic hepatitis C virus (HCV) genotype 1 infection. Further terms were not disclosed.

Celera Corp. (NASDAQ:CRA), Alameda, Calif.
University of California, San Francisco, Calif.
Business: Diagnostic

The university received non-exclusive rights to Celera's IP covering the use of kinesin family member 6 (KIF6) in California for three years. The university will use the IP to develop a test to detect the 719Arg KIF6 gene polymorphism, which is associated with an increased risk of cardiac events that can be minimized with statins. Financial terms were not disclosed. Celera's Berkeley HeartLab Inc. subsidiary co-markets its KIF6 test with Proven Diagnostics, the service lab of Geisinger Health System (Danville, Pa.) (*see BioCentury, Nov. 9, 2009*).

Celgene Corp. (NASDAQ:CELG), Summit, N.J.
Gloucester Pharmaceuticals Inc., Cambridge, Mass.
Business: Cancer

Celgene completed its previously announced acquisition of Gloucester for $340 million in cash. Former Gloucester shareholders are eligible for up to $300 million in milestones *(see BioCentury, Dec. 14, 2009)*.

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Deals,
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Cellectis S.A. (Euronext:ALCLS), Romainville, France
Bayer AG (Xetra:BAY), Leverkusen, Germany
Business: Functional genomics

Bayer's Bayer Healthcare unit received a worldwide license to Cellectis' WO9011354 patent family covering homologous recombination for introducing new features into a genome. The deal includes the use of technology from Institut Pasteur (Paris, France) covering the use of homologous recombination to obtain and use certain transgenic animals for research. Cellectis has exclusive rights to the Institute's technology under an earlier deal. Further terms were not disclosed.

Chiasma Inc., Jerusalem, Israel
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Business: Drug delivery

Novartis received an option to license exclusive, worldwide rights to develop and commercialize Chiasma's Transient Permeability Enhancer (TPE) technology for oral delivery of macromolecules and poorly absorbed small molecules. In exchange for the option, Novartis made an undisclosed equity investment in Chiasma through its MPM Bio IV NVS fund. Novartis can exercise the option after a one-year feasibility program to evaluate TPE with the pharma's products, including an undisclosed marketed drug. If the option is exercised, Novartis expects to use the technology with the marketed drug, and Chiasma will receive an undisclosed option exercise fee and would be eligible for milestones and profit sharing.

Chiasma's lead product, an undisclosed peptide that uses the TPE technology, will start Phase I testing for an undisclosed indication this quarter, with results expected in 2Q10.

CryoLife Inc. (NYSE:CRY), Kennesaw, Ga.
Medafor Inc., Minneapolis, Minn.
Business: Hematology

CryoLife took an 8% stake in partner Medafor through the purchase of 1.6 million shares at about $2 per share and proposed to acquire the hematology company for $2 per share in cash, plus stock. CryoLife said that it believes it is now Medafor's largest single shareholder. CryoLife has exclusive rights to distribute Medafor's HemoStase MPH polysaccharide hemostatic technology in the U.S. to control surgical bleeding under a 2008 deal. In a letter to the Medafor Board, CryoLife Chairman, President and CEO Steven Anderson said he does not believe that Medafor has the resources to maximize the potential of HemoStase on its own.

Medafor has twice rejected previous offers from CryoLife, citing significant undervaluation. The first offer did not include a price and the second was for $25 million in CryoLife stock.

CrystalGenomics Inc. (KOSDAQ:083790), Seoul, South Korea
AstraZeneca plc (LSE:AZN; NYSE:AZN), London, U.K.
Business: Infectious

CrystalGenomics will use its structure-based drug discovery technologies to identify compounds against an undisclosed antibacterial target from AstraZeneca. The pharma will own rights to IP developed under the deal and is responsible for development and commercialization. CrystalGenomics will receive two years of research funding and is eligible for undisclosed milestones and royalties. Further terms were not disclosed.

Dako A/S, Glostrup, Denmark
AstraZeneca plc (LSE:AZN; NYSE:AZN), London, U.K.
Business: Pharmacogenetics

AstraZeneca and Dako partnered to develop companion diagnostics for multiple undisclosed AstraZeneca oncology projects, including biologics and small molecules, in various stages of discovery and development. The diagnostics would help determine the most appropriate treatment for cancer patients. Further terms were not disclosed.

Depomed Inc. (NASDAQ:DEPO), Menlo Park, Calif.
Covidien plc (NYSE:COV), Loughlinstown, Ireland
Business: Drug delivery

Depomed received a $500,000 milestone payment from Covidien under a 2008 deal that granted Covidien's Mallinckrodt Inc. subsidiary non-exclusive, worldwide rights to Depomed's AcuForm gastric retentive formulation technology. Covidien is using the technology to develop and commercialize four acetaminophen/opioid analgesic combination products. The milestone was triggered by development of the second formulation. This is the second milestone received by Depomed, which is eligible for $63 million in remaining milestones, plus royalties *(see BioCentury, Oct. 26, 2009)*.

Evotec AG (Xetra:EVT), Hamburg, Germany
CHDI Foundation Inc., New York, N.Y.
Business: Neurology

Evotec and CHDI extended through 2012 a 2006 deal under which Evotec is providing CHDI with medicinal chemistry, assay development, screening and library synthesis services for use in CHDI's discovery programs. Evotec is eligible for an additional $37.5 million in research funding. The deal was previously extended by two years to 2010 in 2008. CHDI is a not-for-profit organization focused on Huntington's disease (*see BioCentury, Aug. 21, 2006 & Feb. 18, 2008*).

Fresenius SE (Xetra:FRE), Bad Homburg, Germany
Bayer AG (Xetra:BAY), Leverkusen, Germany
Business: Pharmaceuticals

Fresenius' Fresenius Kabi Deutschland GmbH subsidiary and Bayer's Bayer Schering Pharma AG subsidiary extended a 2009 deal that granted Bayer a license to develop and commercialize Fresenius' HESylation technology. The extension triggered an undisclosed payment to Fresenius, which is eligible for milestones and royalties under the deal. The Fresenius technology couples hydroxyethyl starch (HES) to existing drugs. Further details were not disclosed *(see BioCentury, May 25, 2009)*.

Galapagos N.V. (Euronext:GLPG; Pink:GLPYY), Mechelen, Belgium
Johnson & Johnson (NYSE:JNJ), New Brunswick, N.J.
Merck & Co. Inc. (NYSE:MRK), Whitehouse Station, N.J.
Business: Cancer, Endocrine, Cardiovascular

Galapagos' BioFocus service division received a €1.6 million ($2.3 million) milestone payment from Johnson & Johnson's Janssen Pharmaceutica N.V. subsidiary under a January 2008 deal to discover and validate new cancer targets. The payment was triggered by BioFocus' development of advanced cellular assays and identification and validation of new cancer targets. BioFocus is eligible for up to an additional €4.5 million ($6.5 million) in milestones *(see BioCentury, Jan. 7, 2008)*.

Separately, Galapagos will receive a €3.6 million ($5.2 million) milestone payment from Merck under an amended 2009 deal to use Galapagos' SilenceSelect gene knock-down technology to discover compounds to treat diabetes, obesity and atherosclerosis. The payment was triggered by an undisclosed event. This is first milestone received under the deal. Galapagos is eligible for over €400 million ($574.9 million) in total milestones (*see BioCentury, Jan. 12, 2009 & Oct. 19, 2009*).

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GenVec Inc. (NASDAQ:GNVC), Gaithersburg, Md.
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Business: Other

GenVec granted Novartis exclusive, worldwide rights to GenVec's preclinical hearing loss and balance disorders program. The program uses GenVec's adenovector technology to deliver atonal homolog 1 (ATOH1; HATH1) to the inner ear. GenVec will receive $5 million up front and is eligible for up to $206.6 million in milestones, plus royalties. Novartis also purchased 1.9 million shares of GenVec stock for $2 million, or $1.07 per share, a 39% discount to GenVec's close of $1.74 on Jan. 15, the day before the deal was announced. GenVec also will receive research funding for a program to develop additional adenovectors for hearing loss.

Hard to Treat Diseases Inc. (Pink:HTDS), Clearwater, Fla.
Business: Infectious

Hard to Treat Diseases said it will postpone its previously announced merger discussions with an undisclosed European company due to public rumors and naked short selling by investors. Hard to Treat's Mellow Hope Bio Chem China division markets MEVAC-Hib Haemophilus influenza type B vaccine under a June deal with Yunnan Walvax Biotech Co. Ltd. (China). At Sept. 30, 2009, Hard to Treat Diseases had $343,798 in cash and a three-month net loss of $541 for 3Q09. The previous quarter the company reported a three-month net profit of $33,046 (*see BioCentury, Nov. 9, 2009*).

Healthpoint Ltd., Fort Worth, Texas
Intercytex Group plc, Manchester, U.K.
Business: Dermatology

Healthpoint acquired Cyzact (ICX-PRO) and ICX-SKN from Intercytex. Cyzact is a second-generation allogeneic human dermal fibroblast in fibrin-based gel matrix which missed the primary endpoint in a Phase III trial to treat venous leg ulcers in 2009. ICX-SKN is an allogeneic human dermal fibroblasts set in a human collagen matrix that has completed a Phase I trial to treat acute wounds via skin graft. Further terms were not disclosed. In 2009, Intercytex refocused and reduced headcount and said it planned to divest all of its assets *(see BioCentury, April 6, 2009 & Dec. 7, 2009)*.

Immunomedics Inc. (NASDAQ:IMMU), Morris Plains, N.J.
Nycomed, Zurich, Switzerland
Business: Autoimmune

Immunomedics received a $5 million milestone payment from Nycomed under a 2008 deal granting Nycomed exclusive, worldwide rights to develop subcutaneous veltuzumab for non-cancer indications. The payment was triggered by achievement of an undisclosed clinical milestone for the humanized antibody targeting CD20 to treat immune thrombocytopenia purpura (ITP). This is the first milestone under the deal. Immunomedics is eligible for up to $580 million in total milestones, plus escalating, double-digit royalties (*see BioCentury, July 21, 2008*).

Inspiration Biopharmaceuticals Inc., Laguna Niguel, Calif.
Ipsen Group (Euronext:IPN), Paris, France
Business: Hematology

The companies announced a deal that gives Ipsen the ability to acquire Inspiration in undisclosed increments triggered by milestones for hemophilia products from both companies. Ipsen will make an upfront investment of $85 million, giving it a 20% stake in Inspiration. Ipsen also will receive $50 million in notes that convert into a further 9% stake.

Inspiration received exclusive, worldwide rights to Ipsen's OBI-1, a recombinant porcine Factor VIII that is expected to start Phase III testing this year to treat patients with acquired hemophilia and hemophilia A who have developed an inhibitory immune reaction to human Factor VIII. Inspiration is eligible for up to $174 million in milestone payments for development of OBI-1 and Inspiration's IB1001, a recombinant Factor IX product expected to begin Phase III testing this year for the acute and preventative treatment of bleeding in patients with hemophilia B.

For each milestone payment, Ipsen would receive a note that is convertible into Inspiration equity. If all milestones are met and all notes are converted, Ipsen would have a 47% stake in Inspiration. Ipsen can acquire full ownership of Inspiration upon completion of undisclosed milestones through 2019. Ipsen is eligible for a 27.5% royalty on sales of OBI-1. Ipsen also is entitled to one seat on Inspiration's board.

Inspiration's hemophilia pipeline also includes a recombinant Factor VIII product for hemophilia A and a recombinant Factor VIIa product for hemophilia A and B, which is expected to begin clinical testing next year. The deal is expected to close this quarter.

Inspiration investor Celtic Pharmaceutical Holdings L.P. (Hamilton, Bermuda), which had a low double-digit equity stake in the company and a "direct interest" in IB1001, said it exchanged those interests for a new class of preferred shares constituting an undisclosed minority stake.

International Vitamin Corp., Freehold, N.J.
Inverness Medical Innovations Inc. (NYSE:IMA), Waltham, Mass.
Business: Nutraceuticals

Inverness sold its Inverness Medical Nutritionals and IVC Industries vitamin and nutritional supplement business to International Vitamin Corporation for $63.4 million in cash. Inverness markets diagnostics for cardiovascular disease, oncology, women's health and infectious disease, including its Clearview Complete HIV 1/2 test that detects HIV-1 and HIV-2 antibodies in human whole blood, serum and plasma.

Intrinsic Bioprobes Inc., Tempe, Ariz.
Johnson & Johnson (NYSE:JNJ), New Brunswick, N.J.
Business: Diagnostic

Johnson & Johnson's Ortho-Clinical Diagnostics Inc. subsidiary received exclusive rights to two diabetes biomarkers from Intrinsic. The biomarkers are modified forms of blood-circulating proteins, which Intrinsic said are linked to the presence of pre-diabetes and Type II diabetes. Further terms were not disclosed.

Inverness Medical Innovations Inc. (NYSE:IMA), Waltham, Mass.
Miraculins Inc. (TSX-V:MOM), Winnipeg, Manitoba
Mount Sinai Hospital, Toronto, Ontario
Business: Diagnostic

Miraculins and Inverness partnered to develop and commercialize Miraculins' preeclampsia biomarker technology to detect preeclampsia, intrauterine growth and other pregnancy-related diseases. Inverness will develop and evaluate tests for the biomarkers and will receive an exclusive option to commercialize biomarkers of interest. Miraculins will retain commercialization rights to pursue complementary strategies for the biomarkers and will receive from Inverness rights to IP related to the biomarker endoglin (CD105; ENG). Inverness has rights to use endoglin to develop diagnostics for preeclampsia under a July 2008 deal with the hospital.

If Inverness exercises its option to commercialize the biomarkers, Miraculins will receive an undisclosed upfront fee and would be eligible for additional fees, milestones and royalties. The hospital, which licensed Miraculins rights to the preeclampsia biomarkers in 2008, also would receive 250,000 shares of Miraculins' stock upon Inverness' decision to exercise the option.

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Kinaxo Biotechnologies GmbH, Martinsried, Germany
Roche (SIX:ROG; OTCQX:RHHBY), Basel, Switzerland
Business: Chemistry

Kinaxo will use its PhosphoScout phosphoproteomics technology to support development of undisclosed programs from Roche's Roche Diagnostics division. PhosphoScout identifies regulated protein phosphorylation sites in response to treatment and monitors these sites to facilitate the analysis of the phosphoproteome in patient samples, animal models and cell culture. Further terms were not disclosed.

LeukoDx L.P., Towson, Md.
Trillium Diagnostics LLC, Brewer, Maine
Business: Diagnostic

The companies signed a memorandum of understanding under which LeukoDx will receive exclusive, worldwide rights to Trillium's patent and technology covering the quantification of Fc gamma receptor I (CD64; FCGR1) for point of care. LeukoDx will combine the technology with its compact flow cytometry technology to develop diagnostics. LeukoDx will focus first on neonatal sepsis and then expand into sepsis detection in pediatric and general populations. Trillium will receive an equity stake in LeukoDx, and is eligible for royalties. Further terms were not disclosed.

Maxygen Inc. (NASDAQ:MAXY), Redwood City, Calif.
Astellas Pharma Inc. (Tokyo:4503), Tokyo, Japan
Business: Autoimmune

Perseid Therapeutics LLC, a JV between Maxygen and Astellas, received a $5 million milestone payment from Astellas under an amended 2008 deal to co-develop CTLA4-Ig fusion proteins to treat rheumatoid arthritis and other autoimmune diseases. The payment was triggered by an undisclosed preclinical event. The deal was amended last year when Maxygen moved almost all of its protein therapeutics assets into the JV, including the CTLA4-Ig program (*see BioCentury, Sept. 22, 2008 & July 6, 2009*).

MDRNA Inc. (NASDAQ:MRNA), Bothell, Wash.
Business: Drug delivery

MDRNA partnered with an undisclosed international pharmaceutical company to evaluate systemic delivery of siRNA using MDRNA's DiLA2 liposome technology in animal models. Further details were not disclosed.

MedGenesis Therapeutix Inc., Victoria, B.C.
Amgen Inc. (NASDAQ:AMGN), Thousand Oaks, Calif.
Biovail Corp. (TSX:BVF; NYSE:BVF), Mississauga, Ontario
Business: Neurology

Amgen granted MedGenesis exclusive, worldwide rights to glial cell-derived neurotrophic factor (GDNF) protein. Amgen received a high single-digit percentage stake in MedGenesis and an undisclosed upfront payment. Amgen also is eligible for milestones and royalties.

At the same time, MedGenesis entered into a deal with Biovail to co-develop and commercialize GDNF for Parkinson's disease and other undisclosed CNS indications. Biovail will focus on commercialization in the U.S., Europe, and Japan. MedGenesis will receive an undisclosed upfront payment and is eligible for milestones. The companies will share profits 50/50.

Biovail also received a license to use MedGenesis' Convection Enhanced Delivery (CED) technology with GDNF for CNS indications. The technology uses an indwelling, long-term catheter to deliver therapeutics to the brain.

MorphoSys AG (Xetra:MOR), Martinsried, Germany
Wacker Chemie AG (Xetra:WCH), Munich, Germany
Business: Antibodies

The companies added the production of antigen material to a 2008 deal giving MorphoSys non-exclusive, worldwide rights to use Wacker's Esetec prokaryotic antibody secretion technology. The earlier license was limited to the production of antibody fragments. In return, Wacker will receive an additional undisclosed yearly license fee *(see BioCentury, Dec. 8, 2008)*.

Priaxon AG, Munich, Germany
Boehringer Ingelheim GmbH, Ingelheim, Germany
Business: Cancer

Boehringer and Priaxon partnered to discover and develop small molecule antagonists of mdm2 p53 binding protein homolog (MDM2) for cancer. The companies will jointly identify and advance candidates into preclinical development, after which Boehringer will lead development and commercialization. Priaxon will receive undisclosed upfront payments and research funding, and will be eligible for up to €86 million ($123.6 million) in milestones, plus royalties. MDM2 antagonists inhibit the binding of MDM2 to p53. Further terms were not disclosed.

Qiagen N.V. (Xetra:QIA; NASDAQ:QGEN), Venlo, The Netherlands
WuXi PharmaTech Inc. (NYSE:WX), Shanghai, China
Business: Diagnostic

WuXi's WuXi AppTec Inc. subsidiary partnered with Qiagen to develop biomarkers, assay panels, personalized healthcare diagnostics and other products. The companies also will co-promote the other's services to their respective customers. Further details were not disclosed.

RXi Pharmaceuticals Corp. (NASDAQ:RXII), Worcester, Mass.
University of Massachusetts Medical School, Worcester, Mass.
Business: Ophthalmic

RXi and the university will explore the application of RXi's sd-rxRNA compounds for ocular diseases such as age-related macular degeneration (AMD). The parties will use preclinical models of ocular disease to evaluate the delivery and silencing activity of the self-delivering rxRNA compounds. RXi will own resulting IP. Financial terms were not disclosed. sd-rxRNA uses RNAi delivery technology from Advirna LLC (Boulder, Colo.).

Sirnaomics Inc., Gaithersburg, Md.
University of Maryland School of Medicine, Baltimore, Md.
Business: Dermatology, Ophthalmic

The university granted Sirnaomics exclusive rights to U.S. Patent Application 60/173,576 covering the use of histidine-lysine polymer (HKP) for siRNA therapeutics for wound healing and ocular diseases. The parties collaborated on the discovery of Sirnanomics' Cutasil (STP705), which is in preclinical testing for wound healing. Further terms were not disclosed.

ValiRx plc (LSE:VAL), London, U.K.
Vivamer Ltd., Cambridge, U.K.
Business: Cancer, Drug delivery

The companies formed a JV to use Vivamer's Cell Penetrating Polymer technology to develop a drug delivery system for ValiRx's GeneICE compounds. ValiRx's lead GeneICE compound, VAL 201, is a src kinase inhibitor in preclinical testing to treat cancer, with Phase I testing expected to start this year. The JV will be headquartered in London, England. The ownership of the JV was not disclosed.

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Deals,
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ViroPharma Inc. (NASDAQ:VPHM), Exton, Pa.
Sanquin Blood Supply Foundation, Amsterdam, the Netherlands
Business: Cardiovascular

The parties added new territories to a 2004 deal granting ViroPharma rights to market Cinryze to treat hereditary angioedema (HAE). ViroPharma will have worldwide rights, excluding 11 territories where Sanquin will retain rights, including the U.K., France, Ireland, Egypt, Iran, Israel, the Benelux region and other territories where Sanquin has "existing relationships" or where Sanquin markets Cetor, a complement 1 (C1) esterase inhibitor for the prophylaxis and acute treatment of angioedema. ViroPharma also acquired rights to market Cetor in territories where Cinryze does not secure approval. ViroPharma will supply €1 million ($1.5 million) in annual research funding to Sanquin for five years, increase the minimum purchase requirements and provide Sanquin with a €5 million ($7.2 million) loan to fund capacity expansions. Sanquin will repay the loan by Jan. 1, 2015, through a discount to ViroPharma on the unit purchase price of Cinryze. Cinryze, a C1 esterase inhibitor, is currently approved to prevent HAE in the U.S. The original deal was between Sanquin and Lev Pharmaceuticals Inc., which ViroPharma acquired in 2008 *(see BioCentury, Oct. 27, 2008)*.

SALES & MARKETING

Alcon Inc. (NYSE:ACL), Hunenberg, Switzerland
Sirion Therapeutics Inc., Tampa, Fla.
Business: Ophthalmic

Alcon will acquire exclusive, U.S. rights to two approved ophthalmic drugs from Sirion: Zirgan ganciclovir ophthalmic gel and Durezol difluprednate. Zirgan was approved in the U.S. in September to treat acute herpetic keratitis. Alcon expects the antiviral gel that targets viral DNA to be available in the U.S. this year. Durezol, a topical ophthalmic emulsion containing difluprednate, is marketed to treat postoperative ocular inflammation and pain.

Alcon also will receive exclusive, worldwide rights, excluding Latin America, to develop and commercialize Zyclorin cyclosporine. The topical ophthalmic immunomodulator and immunosuppressive agent is in preclinical testing for ocular surface diseases, including dry eye. JPMorgan advised Sirion on the deal, which is expected to close this quarter. Financial terms were not disclosed.

Sirion would not comment on its future plans.

Ambry Genetics, Aliso Viejo, Calif.
Business: Genomics

Ambry launched its StemArray karyotyping system to detect genomic abnormalities in human embryonic stem cells (hESC) and induced pluripotent stem (iPS) cells. The price of a four-sample pack is $562.50 per sample, or $2250.

Enzo Biochem Inc. (NYSE:ENZ), Farmingdale, N.Y.
Business: Diagnostic

Enzo's Enzo Clinical Labs division launched its H1N1 PCR test in New York City, New Jersey and Pennsylvania to detect swine influenza A (H1N1). Further details were not disclosed.

Genomic Health Inc. (NASDAQ:GHDX), Redwood City, Calif.
Business: Diagnostic

Genomic Health launched its Oncotype DX colon cancer test worldwide. The 12-gene diagnostic test predicts individual recurrence risk in stage II colon cancer patients following surgery. The test is priced at $3,200.

Illumina Inc. (NASDAQ:ILMN), San Diego, Calif.
Business: Genomics

Illumina launched its Genome Analyzer IIe sequencing system. The DNA sequencing system, which can generate 200 million paired-end reads and 20 gigabases of data per run, is priced at $250,000.

Interleukin Genetics Inc. (NYSE-A:ILI), Waltham, Mass.
Labec Pharma S.L., Madrid, Spain
Business: Diagnostic

Labec will start selling Interleukin's Cardio Health genetic test in Spain and Portugal by the end of January. The test is based on interleukin-1 (IL01) gene variations. Samples will be processed at Interleukin's U.S. CLIA-certified laboratory. Interleukin also is eligible for royalties and processing fees. Labec has exclusive rights to market the diagnostic in these territories under a 2009 deal *(see BioCentury, April 13, 2009)*.

Lantheus Medical Imaging Inc., North Billerica, Mass.
Business: Diagnostic

Lantheus launched Ablavar gadofosveset in the U.S. to evaluate aortoiliac occlusive disease (AIOD) in adults with known or suspected peripheral vascular disease (PVD). Lantheus acquired U.S., Canadian and Australian rights to the injectable gadolinium magnetic resonance imaging (MRI) contrast agent from Epix Pharmaceuticals Inc. (Pink:EPIX, Lexington, Mass.) last year. The list price of a single 10 mL vial of Ablavar is $121.85, and a single 15 mL vial is $182.37. Vials are sold in packs of 10 *(see BioCentury, April 13, 2009)*.

OraSure Technologies Inc. (NASDAQ:OSUR), Bethlehem, Pa.
Roche (SIX:ROG; OTCQX:RHHBY), Basel, Switzerland
Business: Diagnostic

OraSure and Roche's Roche Diagnostics division will co-commercialize oral fluid assays to detect commonly abused drugs worldwide. The assays, which are being jointly developed under a January deal between the companies, use Roche's KIMS technology in combination with OraSure's Intercept oral specimen collection device. The assays are designed to run on clinical chemistry automated analyzers. Financial terms were not disclosed.

Zogenix Inc., San Diego, Calif.
Astellas Pharma Inc. (Tokyo:4503), Tokyo, Japan
Business: Neurology

Zogenix and Astellas launched Sumavel DosePro sumatriptan in the U.S. for the acute treatment of migraine attacks with or without aura and for the acute treatment of cluster headache episodes. The wholesale acquisition cost (WAC) for the sumatriptan delivered subcutaneously via the DosePro needle-free system is $83 per 0.5 mL dose. Each 0.5 mL dose contains 6 mg sumatriptan. Astellas' Astellas Pharma U.S. Inc. unit co-promotes Sumavel DosePro with Zogenix in the U.S. Zogenix acquired Sumavel DosePro from Aradigm Corp. (OTCBB: ARDM, Hayward, Calif.) in 2006.

OTHER NEWS

Affimed Therapeutics AG, Heidelberg, Germany
Business: Cancer, Antibodies

Affimed spun out its antibody discovery business into a subsidiary called AbCheck s.r.o. AbCheck is located in Plzen, Czech Republic, and Volker Lang, formerly CBO at Affimed, serves as managing director. The spin out will continue Affimed's antibody discovery activities and provide its antibody discovery technology and services to other biotech and pharma companies.

Affimed will focus on development of its TandAb tetravalent

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antibody candidates including AFM13, which will begin Phase I trials to treat Hodgkin's lymphoma in 1H10. AFM13, a bispecific, tetravalent human antibody against CD30 and CD16, has Orphan Drug designation for the indication.

Alnylam Pharmaceuticals Inc. (NASDAQ:ALNY), Cambridge, Mass.
Business: Chemistry

The German Patent Office upheld a patent in Alnylam's Kreutzer-Limmer I patent series (DE 10066235), which covers siRNAs with a length between 15 and 49 nucleotides expressed through a vector. Alnylam said the patent was challenged by Pfizer Inc. (NYSE:PFE, New York, N.Y.), sanofi-aventis Group (Euronext:SAN; NYSE:SNY, Paris, France) and Silence Therapeutics plc (LSE:SLN, London, U.K.). Further details were not disclosed.

Benitec Ltd. (ASX:BLT), Hawthorne East, Australia
Business: Other, Infectious

Benitec said the U.S. Patent and Trademark Office (USPTO) found four of Benitec's claims for U.S. Patent No. 6,573,099 to be free and allowable. The ruling is the result of Benitec's appeal of a November 2008 Final Office Action, which rejected the patent. The other claims remain objected. Benitec said it will submit a reply by March 7.

The reexamination proceeding was originally requested by Nucleonics Inc. as part of a lawsuit between the two companies. Nucleonics dissolved in 2009. The '099 patent covers the use of DNA constructs to silence genes by inducing double-stranded RNA in cells (*see BioCentury, May 18, 2009*).

Boston Scientific Corp. (NYSE:BSX), Natick, Mass.
Johnson & Johnson (NYSE:JNJ), New Brunswick, N.J.
Business: Cardiovascular

The U.S. District Court for the District of Delaware granted Boston Scientific's motion for summary judgment finding that Johnson & Johnson's U.S. Patent Nos. 7,217,286; 7,223,286; 7,229,473; and 7,300,662, covering coatings for drug-eluting stents are invalid due for nonenablement, lack of written description and indefiniteness. In 2007, JNJ filed suit claiming Boston Scientific's Promus everolimus-eluting coronary stents infringed on the four patents. Boston Scientific has rights to distribute Promus under a 2006 agreement with Abbott Laboratories (NYSE:ABT, Abbott Park, Ill.), which markets it independently as Xience V. JNJ said it would appeal the decision.

ChinaBio LLC, Shanghai, China
Business: Other

ChinaBio formed ChinaBio Accelerator (Shanghai) Co. Ltd. to support U.S. biotech companies in establishing operations in China. ChinaBio said the subsidiary will provide U.S. biotech companies access to financial, technical and support resources. ChinaBio founder and CEO Greg Scott will serve as President of ChinaBio Accelerator.

ConjuChem Biotechnologies Inc. (TSX:CJB), Montreal, Quebec
Business: Endocrine

ConjuChem established a Special Committee of independent board members to explore strategic alternatives, including the sale of the company or its assets. ConjuChem's PC-DAC: Exendin-4 (CJC-1134-PC) is in Phase II testing for Type II diabetes. PD-DAC is an exendin-4 created through preformed conjugate-drug affinity complex (PC-DAC) technology. In 2009, ConjuChem reduced headcount to focus on its preclinical PC-Insulin long-acting basal insulin and securing a partner for PC-DAC. At the end of its fiscal 3Q09 on July 31, 2009, ConjuChem had C$4.3 million (US$4 million) in cash and a nine-month net loss of C$13.3 million (US$12.3 million) (*see BioCentury, March 23, 2009*).

deCode genetics Inc., Reykjavik, Iceland
Business: Cardiovascular, Diagnostic, Genomics

deCode genetics made good on plans to sell its Islenk Erfdagreining subsidiary — the custodian of deCode's IP — to Saga Investments LLC, facilitating the re-emergence of the gene discovery company. The new private company will be called deCode genetics ehf (Reykjavik, Iceland). The parent company, which has been in Chapter 11 bankruptcy since November, changed its name to DGI Resolution Inc. and expects to be liquidated (*see BioCentury Nov. 23, 2009 & Dec. 7, 2009*).

Earl Collier will become CEO of deCode, while Kari Stefansson will be executive chairman and president of research. Collier was previously EVP at Genzyme Corp. (NASDAQ:GENZ, Cambridge, Mass.) and Stefansson was president and CEO of deCode genetics Inc.

iThemba Pharmaceuticals Ltd., Modderfontein, South Africa
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK), London, U.K.
BIO Ventures for Global Health, Washington, D.C.
Emory University, Atlanta, Ga.
Business: Infectious

GlaxoSmithKline CEO Andrew Witty updated the pharma's strategy on increasing access to medicines and vaccines in the developing world and announced the creation of an "Open Lab" for independent researchers focused on neglected tropical diseases. In a speech given to the Council on Foreign Relations, Witty said GSK will provide an initial $8 million seed investment to establish the lab, which will be located at the pharma's research center in Tres Cantos, Spain. GSK also will provide free public access to data for 13,500 potential malaria compounds.

Witty also announced that iThemba and not-for-profit Emory Institute for Drug Discovery (EIDD) signed a memorandum of understanding to join the patent pool for tropical diseases started by GSK. iThemba is discovering and developing therapeutics for diseases of poverty, including HIV, tuberculosis, malaria and their associated co-infections. The EIDD was established last year to conduct early-stage discovery and preclinical testing for small molecule therapeutics for commercially neglected diseases. Witty said not-for-profit BIO Ventures for Global Health will assume governance of the pool, which already includes participation from Alnylam Pharmaceuticals Inc. (NASDAQ:ALNY, Cambridge, Mass.) (*see BioCentury, April 6, 2009 & July 13, 2009*).

Johnson & Johnson (NYSE:JNJ), New Brunswick, N.J.
Business: Pharmaceuticals

The U.S. Department of Justice filed suit against Johnson & Johnson in the U.S. District Court for the District of Massachusetts, alleging the pharma offered kickbacks to Omnicare Inc. to increase sales of its drugs, including antipsychotic Risperdal risperidone. In its complaint, DOJ alleges J&J offered kickbacks in the form of rebates and illegal payments to the nursing home pharmacy, but allegedly referred to the rebates as "grants" and "educational funding." The DOJ alleges that these payments resulted in Omnicare's annual purchases of J&J drugs increasing to over $280 million in 2004 from about $100 million in 1999. The suit is seeking damages, restitution and civil penalties under the False Claims Act and joins two whistleblower suits filed in the same court.

In November, Omnicare paid $98 million to the U.S. and multiple states to settle its role in the alleged kickback scheme.

LifeCycle Pharma A/S (CSE:LCP), Horsholm, Denmark
Business: Transplant

LifeCycle will restructure and reduce headcount by about 30 (46%)

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to 35 to focus on late stage development, while adding 10 employees this half in late stage and business development. The cuts will come from chemistry, manufacturing and administration. LifeCycle's LCP-Tacro, tacrolimus delivered using MeltDose technology, is in Phase III testing to prevent organ transplant rejection in renal transplant recipients.

In August, the company reduced headcount to centralize all administrative functions at its Horsholm headquarters. At Sept. 30, 2009, LifeCycle had DKK392.1 million ($76.9 million) in cash and a nine-month operating loss of DKK219.3 million ($43 million) (*see BioCentury, Aug. 24, 2009*).

Medicure Inc. (TSX:MPH), Winnipeg, Manitoba
Business: Cardiovascular

Medicure retained Bloom Burton & Co. to assist in the evaluation of financial and fundraising alternatives. The biotech also retained Beal Advisors LLC to assist in the partnership, license or sale of Medicure's Aggrastat tirofiban. The non-peptide glycoprotein GPIIb/IIIa (CD41/CD61) antagonist is marketed in the U.S. to treat acute coronary syndrome (ACS). Medicure said it has received expressions of interest from third parties about Aggrastat and/or an investment in the biotech.

At the end of Medicure's fiscal 1Q10 on Aug. 31, 2009, Medicure had C$938,467 (US$847,811) in cash, a three-month net loss of C$1.9 million (US$1.7 million) and Aggrastat sales of C$940,960 (US$850,063). For FY09 on May 31, 2009, Medicure had a 12-month operating loss of C$7 million (US$6.4 million) and annual Aggrastat sales of C$4.8 million (US$4.4 million).

MediGene AG (Xetra:MDG), Martinsried, Germany
Business: Cancer, Autoimmune, Infectious

MediGene adopted a shareholder rights plan to guard against an unsolicited takeover. The plan would be effective if any party acquires more than 20% of the company's outstanding shares, unless the acquisition is a "permitted bid." MediGene said it is not aware of any current or potential takeover bids. The plan is subject to shareholder approval at an annual meeting to be held Feb. 12.

Roche (SIX:ROG; OTCQX:RHHBY), Basel, Switzerland
Business: Drug delivery, Cancer

Roche will invest CHF190 million ($185.1 million) in two of its production facilities to support manufacturing of an infusion-free delivery device for self-administering biological cancer medicines. Roche plans to use the device to deliver a subcutaneous formulation of cancer drug Herceptin trastuzumab. The subcutaneous formulation uses Enhanze recombinant human hyaluronidase (rHuPH20) drug delivery technology from Halozyme Therapeutics Inc. (NASDAQ:HALO, San Diego, Calif.), which granted Roche rights to the technology in 2006.

The production facilities are located in Mannheim, Germany, and Kaiseraugst, Switzerland. Subcutaneous Herceptin is in a Phase III trial comparing it to IV Herceptin in HER2-positive breast cancer patients. The IV formulation of the humanized mAb against epidermal growth factor (EGF) receptor 2 (HER2) is already marketed in the indication by Roche's Genentech Inc. unit in the U.S. and by Roche elsewhere (*see BioCentury, Dec. 11, 2006*).

MANAGEMENT TRACKS

Boards of Directors

DiagnoCure Inc. (TSX:CUR), Quebec City, Quebec
Business: Diagnostic
Appointed: Co-founder and CMO Yves Fradet, also a director, as chairman; he replaces Alan Rheaume, who resigned for personal reasons

Elevation Pharmaceuticals Inc., San Diego, Calif.
Business: Pulmonary
Appointed: Brent Ahrens, general partner at Canaan Partners; Jan Leschly, chairman and partner at Care Capital; and Heather Preston, managing director at TPG Biotech

Liquidia Technologies Inc., Research Triangle Park, N.C.
Business: Infectious, Drug delivery
Appointed: Stephen Bloch, general partner at Canaan Partners; and Isaac Cheng of Morningside Technology Advisory LLC

Navigenics Inc., Foster City, Calif.
Business: Diagnostic
Promoted: Vance Vanier to president and CEO, from CMO

Management

Antares Pharma Inc. (NYSE-A:AIS), Ewing, N.J.
Business: Drug delivery
Hired: Pavan Handa as SVP of business development, formerly VP and head of business development and alliance management at Noven Pharmaceuticals Inc.

China Aoxing Pharmaceutical Co. Inc. (OTCBB:CAXG), Shijiazhuang, China
Business: Neurology
Promoted: Hui Shao to CFO from VP of finance

Constellation Pharmaceuticals Inc., Cambridge, Mass.
Business: Cancer
Hired: Garen Bohlin as EVP, formerly COO of Sirtris Pharmaceuticals Inc.

IRX Therapeutics Inc., New York, N.Y.
Business: Cancer, Infectious
Hired: Neil Berinstein as CSO, formerly assistant VP and global program leader at the Sanofi Pasteur S.A. unit of sanofi-aventis Group; he replaces founder John Hadden, who will remain a director

LifeCycle Pharma A/S (CSE:LCP), Horsholm, Denmark
Business: Metabolic, Transplant, Drug delivery
Hired: Tim Melkus as SVP of development operations, formerly SVP of business development and operations at IDM Pharma Inc.

Sirtex Medical Ltd. (ASX:SRX), Sydney, Australia
Business: Cancer, Hepatic
Hired: Michael Mangano as president of Sirtex's U.S. sales and marketing operation, Sirtex Medical Inc., formerly director of international distributor management at Boston Scientific Corp.

T-Ray Science Inc. (TSX-V:THZ), Vancouver, B.C.
Business: Diagnostic
Hired: Tom Walker as SVP of business development, formerly president and CEO of Rapid Laboratory Microsystems Inc.

CLINICAL NEWS

Clinical activities and selected announcements for the week ended January 22.

REGULATORY

Abaxis Inc. (NASDAQ:ABAX), Union City, Calif.
Product: C-Reactive Protein assay
Business: Inflammation

FDA granted 510(k) clearance for Abaxis' C-Reactive Protein (CRP) assay to detect inflammation or infection. Abaxis said the assay, which is used in conjunction with the Piccolo Xpress point-of-care blood test, can be used by rheumatologists to detect rheumatoid arthritis. The company plans to launch the assay this quarter.

Abbott Laboratories (NYSE:ABT), Abbott Park, Ill.
Product: Meridia sibutramine
Business: Endocrine

EMEA's CHMP recommended the suspension of marketing for anti-obesity sibutramine from Abbott after a safety review indicated an increased risk of cardiovascular events. CHMP said physicians in Europe should not issue any new prescriptions for sibutramine, which is marketed in Europe as Reductil, Reduxade and Zelium.

In the U.S., FDA concluded its own safety review of sibutramine and requested the label include a new contraindication stating that sibutramine is not to be used in patients with a history of cardiovascular disease. The serotonin, norepinephrine and dopamine reuptake inhibitor will remain on the market in the U.S., where Abbott markets it as Meridia. Both agencies began their reviews last year after preliminary data from the long-term SCOUT study suggested the sibutramine was associated with an increased risk of serious cardiovascular events *(see BioCentury, Dec. 7, 2009)*.

Acorda Therapeutics Inc. (NASDAQ:ACOR), Hawthorne, N.Y.
Biogen Idec Inc. (NASDAQ:BIIB), Cambridge, Mass.
Elan Corp. plc (NYSE:ELN), Dublin, Ireland
Product: Ampyra dalfampridine (Fampridine-SR, Fampridine-PR)
Business: Autoimmune

FDA approved an NDA from Acorda for Ampyra dalfampridine (formerly Fampridine-SR) to improve walking ability in patients with multiple sclerosis. The NDA was approved with a risk evaluation and mitigation strategy (REMS) concerning the risk of seizures associated with use of higher than recommended doses of Ampyra. The company plans to launch the sustained-release formulation of 4-aminopyridine in March. Acorda, which has worldwide rights to Ampyra from Elan, granted Biogen Idec exclusive ex-U.S. rights to develop and commercialize the product *(see BioCentury, July 6, 2009)*.

This month, Biogen Idec submitted an MAA to EMEA for the product as Fampridine-PR. Biogen Idec also submitted an NDS in Canada, where the product is called Fampridine-SR *(see BioCentury, Jan. 18)*.

Auxilium Pharmaceuticals Inc. (NASDAQ:AUXL), Malvern, Pa.
BioSpecifics Technologies Corp. (NASDAQ:BSTC), Lynbrook, N.Y.
Product: Xiaflex collagenase clostridium histolyticum (Cordase) (PF-5076985) (formerly AA4500)
Business: Musculoskeletal

EMEA accepted for filing an MAA from Pfizer Inc. (NYSE:PFE, New York, N.Y.) for Xiaflex collagenase clostridium histolyticum to treat Dupuytren's contracture, a condition that affects the joints in the hand. The acceptance triggers a $15 million milestone payment to Auxilium, which granted Pfizer rights in the EU. Auxilium has worldwide rights from BioSpecifics, which will receive a $1.2 million portion of Auxilium's milestone payment. The injectable form of collagenase is also under FDA review.

Biogen Idec Inc. (NASDAQ:BIIB), Cambridge, Mass.
Elan Corp. plc (NYSE:ELN), Dublin, Ireland
Product: Tysabri natalizumab
Business: Autoimmune

EMEA's CHMP recommended updating the label of autoimmune drug Tysabri natalizumab from Biogen Idec and Elan to warn of an increased risk of developing progressive multifocal leukoencephalopathy after two years of treatment. The committee said the benefits of Tysabri continue to outweigh its risks. CHMP said that as of Jan. 20, the total number of worldwide reported cases of PML was 31, up from 23 in October 2009, when CHMP began its review of the drug. The companies market the humanized mAb against integrin alpha(4) to treat multiple sclerosis in the EU and to treat MS and Crohn's disease in the U.S.

Cypress Bioscience Inc. (NASDAQ:CYPB), San Diego, Calif.
Forest Laboratories Inc. (NYSE:FRX), New York, N.Y.
Laboratoires Pierre Fabre S.A., Castres, France
Product: Savella (Impulsor) milnacipran
Business: Musculoskeletal

Consumer advocacy group Public Citizen sent a letter to FDA calling for the removal of fibromyalgia drug Savella milnacipran from the market due to "highly questionable clinical efficacy" and safety concerns, including hypertension, increased heart rate, and increased suicidal ideation. The agency declined to comment. Last month, EMEA's CHMP confirmed a negative opinion of an MAA for the product due to what it found to be marginal effects and a lack of data on long-term effects in a European population *(see BioCentury, Dec. 7, 2009)*.

Forest and Cypress co-market Savella in the U.S. Cypress licensed the rights for the norepinephrine and serotonin reuptake inhibitor (NSRI) in the U.S. and Canada from Pierre Fabre, which markets it as Impulsor in Europe to treat major depressive disorder and generalized anxiety disorder *(see BioCentury, Aug. 6, 2001 & Jan. 12, 2004)*.

Genmab A/S (CSE:GEN), Copenhagen, Denmark
GlaxoSmithKline plc (LSE:GSK; NYSE:GSK), London, U.K.
Product: Arzerra ofatumumab (HuMax-CD20)
Business: Cancer

EMEA's CHMP issued a positive opinion recommending conditional approval of an MAA for Arzerra ofatumumab from GlaxoSmithKline to treat chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab. As part of the conditional approval, GSK is required to submit further data, including clinical data on the long term use of Arzerra in the population and comparative clinical data for Arzerra in the fludarabine-refractory, bulky lymphadenopathy population (patients ineligible for alemtuzumab). GSK has exclusive, worldwide rights from Genmab to co-develop and commercialize the mAb against CD20, which already has accelerated approval in the U.S. for the indication *(see BioCentury, Nov. 2, 2009)*. Genzyme Corp. (NASDAQ:GENZ, Cambridge, Mass.) markets Campath alemtuzumab.

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Genzyme Corp. (NASDAQ:GENZ), Cambridge, Mass.
Product: Lumizyme alglucosidase alfa (Myozyme)
Business: Metabolic

FDA accepted a BLA from Genzyme for Lumizyme alglucosidase alfa produced at the 4,000L bioreactor scale to treat Pompe's disease. The agency designated the BLA as a Class 2 complete response, with a PDUFA date of June 17. In November 2009, FDA issued a complete response letter for Lumizyme produced at the 2,000L scale due to deficiencies observed at Genzyme's manufacturing plant in Allston, Mass. In the U.S., 160L alglucosidase alfa is known as Myozyme; all production volumes are called Myozyme elsewhere *(see BioCentury, Nov. 23, 2009)*.

Gilead Sciences Inc. (NASDAQ:GILD), Foster City, Calif.
Roche (SIX:ROG; OTCQX:RHHBY), Basel, Switzerland
Product: Tamiflu IV
Business: Infectious

EMEA's CHMP issued a positive opinion recommending compassionate use of IV Tamiflu oseltamivir from Roche to treat critically ill patients with suspected or confirmed pandemic or seasonal influenza, who cannot take authorized oral or nasal antivirals. Roche already markets an oral formulation of Tamiflu to treat and prevent influenza infection. Roche has rights to both formulations of the neuraminidase inhibitor from Gilead.

GlaxoSmithKline plc (LSE:GSK; NYSE:GSK), London, U.K.
Product: Arepanrix
Business: Infectious

EMEA's CHMP issued a positive opinion recommending conditional approval of an MAA for Arepanrix adjuvanted swine influenza A (H1N1) vaccine from GSK to prevent influenza in an officially declared pandemic situation. The recommendation for the vaccine containing H1N1 antigen plus GSK's AS03 adjuvant was made under an emergency procedure, which fast tracks evaluation of new vaccines developed during a pandemic.

Product: Tyverb lapatinib (Tykerb)
Business: Cancer

The U.K.'s NICE said it would delay a final appraisal determination (FAD) for breast cancer drug Tyverb lapatinib from GlaxoSmithKline in order for its independent advisory committee to reconsider which comparator to use. Last October, the U.K.'s NICE issued a preliminary appraisal recommending against the use of Tyverb lapatinib in previously treated patients with advanced or metastatic breast cancer whose tumors overexpress HER2 based on data comparing capecitabine with or without Tyverb *(see BioCentury, Oct. 26, 2009)*. NICE requested the committee consider whether Herceptin trastuzumab, a humanized mAb against HER2 from Roche (SIX:ROG; OTCQX:RHHBY, Basel, Switzerland), might be the most appropriate comparator. The next appraisal meeting will be held on Feb. 16. The HER1 and HER2 receptor kinase inhibitor, which is marketed as Tykerb in the U.S., has conditional approval from the EC for the indication.

Helsinn Healthcare S.A., Pazzallo, Switzerland
Eisai Co. Ltd. (Tokyo:4523; Osaka:4523), Tokyo, Japan
Product: Aloxi (Onicit, Paloxi) palonosetron
Business: Gastrointestinal

Japan approved Aloxi palonosetron to prevent chemotherapy-induced nausea and vomiting (CINV) in patients with cancer. Taiho Pharmaceutical Co. Ltd., a subsidiary of Otsuka Pharmaceutical Co. Ltd. (Tokyo:4768, Tokyo, Japan), has Japanese rights for the serotonin (5-HT3) receptor antagonist from Helsinn. Eisai markets palonosetron in the U.S. as Aloxi under a deal with Helsinn, while various partners market the product elsewhere as Onicit and Paloxi.

NicOx S.A. (Euronext:COX), Sophia-Antipolis, France
Product: Naproxcinod (HCT 3012)
Business: Autoimmune

EMEA accepted for filing an MAA from NicOx for naproxcinod to relieve the signs and symptoms of primary osteoarthritis. The application was submitted under the centralized procedure. The cyclooxygenase (COX)-inhibiting nitric oxide donator (CINOD) that releases naproxen and nitric oxide is also under FDA review. The PDUFA date is July 4.

Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Product: Afinitor everolimus (Certican) (RAD001)
Business: Cancer

Japan's Ministry of Health, Labor and Welfare (MHLW) approved Afinitor everolimus from Novartis to treat advanced kidney cancer. The company expects to launch the oral mTOR protein inhibitor, which is already marketed in the U.S. and EU, in Japan in April.

Product: Exforge amlodipine/valsartan
Business: Cardiovascular

Japan's Ministry of Health, Labor and Welfare (MHLW) approved Exforge valsartan/amlodipine from Novartis to treat high blood pressure. The company expects to launch the combination of calcium channel blocker amlodipine and angiotensin receptor blocker valsartan, which is already marketed in the U.S. and EU, in Japan in April.

Product: Equa vildagliptin (Galvus)
Business: Endocrine

Japan's Ministry of Health, Labor and Welfare (MHLW) approved Equa vildagliptin from Novartis as monotherapy or in combination with sulfonylurea to treat Type II diabetes. The company expects to launch the dipeptidyl peptidase-4 (DPP-4) inhibitor, which is marketed in the EU as Galvus, in Japan in April.

Novo Nordisk A/S (CSE:NVO; NYSE:NVO), Bagsvaerd, Denmark
Product: Victoza liraglutide (NN2211)
Business: Endocrine

Japan's Ministry of Health, Labor and Welfare (MHLW) approved Victoza liraglutide from Novo Nordisk to treat Type II diabetes. The company plans to launch the once-daily, long-acting analog of glucagon-like peptide-1 (GLP-1) this half. Victoza already is marketed in Europe and is under review in the U.S. and China.

Rigel Pharmaceuticals Inc. (NASDAQ:RIGL), South San Francisco, Calif.
Merck KGaA (Xetra:MRK), Darmstadt, Germany
Product: AS703569 (formerly R763)
Business: Cancer

EMEA's Committee for Orphan Medicinal Products (COMP) issued a positive opinion to grant Orphan Drug designation to Merck's AS7030569 to treat acute myelogenous leukemia (AML). AS703569 is in Phase I testing to treat solid tumors and hematological malignancies. Merck has worldwide rights to the aurora kinase inhibitor from Rigel.

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Roche (SIX:ROG; OTCQX:RHHBY), Basel, Switzerland
Product: RoActemra tocilizumab (Actemra) (RG1569)
Business: Autoimmune

The Scottish Medicines Consortium recommended use of Roche's RoActemra tocilizumab on the National Health Service (NHS) in Scotland to treat moderate to severe active rheumatoid arthritis in combination with methotrexate in adults whose disease has not responded adequately to, or who are intolerant of, previous therapy with one or more DMARDs or TNF alpha antagonists. The humanized mAb against IL-6 is approved for RA in the EU, Australia, Brazil, India, Japan and Switzerland, as well as the U.S., where it is called Actemra. Roche's Chugai Pharmaceutical Co. Ltd (Tokyo:4519, Tokyo, Japan) subsidiary co-developed the product and markets it in Japan.

SkyePharma plc (LSE:SKP), London, U.K.
Kyorin Pharmaceutical Co. Ltd. (Tokyo:4569), Tokyo, Japan
Mundipharma International Ltd., Cambridge, U.K.
Abbott Laboratories (NYSE:ABT), Abbott Park, Ill.
Product: Flutiform fluticasone/formoterol
Business: Inflammation

FDA issued a complete response letter for an NDA from SkyePharma for Flutiform to treat persistent asthma in patients ages 12 and older. The company said FDA raised a number of issues that would involve additional clinical work, including additional data on dosing. SkyePharma said in September that it is unlikely Flutiform will be approved in the U.S. before 2H11.

Abbott has U.S. rights to the combination of formoterol and fluticasone delivered via a metered-dose hydrofluoroalkane (HFA) inhaler. SkyePharma said it plans to submit an MAA for the product this quarter in Europe, where Mundipharma has rights. Kyorin has rights in Japan.

Somaxon Pharmaceuticals Inc. (NASDAQ:SOMX), San Diego, Calif.
Product: Silenor doxepin
Business: Neurology

Somaxon resubmitted an NDA to FDA for Silenor doxepin to treat insomnia. Somaxon said that at a meeting with FDA on Wednesday, the agency indicated it would consider the NDA a Class 1 resubmission, with a two-month review. The company expects a PDUFA date of March 21. Doxepin has received two complete response letters, the latest of which came last month.

The application was submitted under section 505(b)(2) of the Food, Drug and Cosmetic Act, which allows sponsors to reference data on safety and efficacy from the scientific literature or from previously approved products. Doxepin, a serotonin and noradrenaline reuptake inhibitor, is marketed as a generic to treat depression and anxiety.

UCB Group (Euronext:UCB), Brussels, Belgium
Otsuka Pharmaceutical Co. Ltd. (Tokyo:4768), Tokyo, Japan
Product: Cimzia certolizumab pegol
Business: Autoimmune

The U.K.'s NICE issued a final appraisal determination recommending Cimzia certolizumab pegol from UCB Group to treat rheumatoid arthritis only if UCB provides the first 12 weeks of treatment for free to all patients as part of a patient access scheme. The patient access scheme was not included in an October preliminary appraisal, in which NICE recommended against Cimzia for the indication and requested further clarification on the clinical and cost effectiveness of Cimzia relative to other tumor necrosis factor (TNF) alpha inhibitors *(see BioCentury, Oct. 26, 2009)*.The pegylated humanized antibody fragment against TNF alpha is approved in the EU for use in combination with methotrexate to treat moderate to severe, active RA in adult patients inadequately responsive to DMARD therapy. Cimzia is partnered with Otsuka in Japan.

CLINICAL RESULTS

Aeolus Pharmaceuticals Inc. (OTCBB:AOLS), Laguna Niguel, Calif.
Arca biopharma Inc. (NASDAQ:ABIO), Broomfield, Colo.
Endo Pharmaceuticals Holdings Inc. (NASDAQ:ENDP), Chadds Ford, Pa.
Product: Gencaro bucindolol
Business: Cardiovascular
Molecular target: Adrenergic receptor beta (ADRB)
Description: Non-selective beta blocker and mild vasodilator
Indication: Treat congestive heart failure (CHF)
Endpoint: All-cause mortality; progression of heart failure, cardiovascular mortality, mortality or cardiac transplantation, heart failure hospitalization, myocardial infarction, change in need for co-therapy, quality of life and left ventricular ejection fraction
Status: Additional Phase III data
Milestone: NA

A genetic sub-study of 1,040 patients in the double-blind, North American Phase III BEST trial showed that carriers of wild-type adrenergic receptor alpha 2c (ADRA2C) had mild reductions in norepinephrine in response to Gencaro, while carriers of ADRA2C polymorphisms had significantly greater reductions in norepinephrine, which Arca said compromised the clinical efficacy of the compound (50 vs. 153 pg/mL, p=0.01). Furthermore, Gencaro produced no evidence of a favorable survival benefit in patients with ADRA2C polymorphisms vs. placebo (p=0.80), but produced a 30% reduction in mortality in patients with wild-type ADRA2C vs. placebo (p=0.025). Data were published in *Circulation: Heart Failure*.

Last May, Arca received a complete response letter for an NDA seeking approval in the broad heart failure population with additional labeling information about genotypes likely to respond to treatment. In the letter, FDA sought additional data about the position 389 arginine polymorphism. The companies previously reported that Gencaro missed the primary endpoint of a significant reduction in mortality vs. placebo in the BEST trial in 2,708 patients *(see BioCentury, April 6, 2009)*. Arca has rights to the compound from CPEC LLC, a company jointly owned by Aeolus and Endo.

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BioCentury Part II

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Aterovax S.A., Paris, France
Product: SPLA2 activity test
Business: Diagnostic
Molecular target: Secretory phospholipase A2 (PLA2G2A) (sPLA2)
Description: Test for secretory phospholipase A2 (sPLA2) activity in blood plasma
Indication: Determine risk of secondary cardiovascular events in patients with acute coronary syndrome (ACS)
Endpoint: Clinical utility of circulating sPLA2 levels for identifying patients at high risk for myocardial necrosis
Status: Pivotal trial data
Milestone: Submit CE Mark (2010); submit 510 (k) (2010)

An analysis of sPLA2 activity in serum samples from 419 patients with non-ST-segment elevation (NSTE) at baseline, but with chest pain or other clinical features indicative of ACS, showed that median sPLA2 activity as measured by Aterovax's sPLA2 activity test was significantly higher in patients with a final diagnosis of NSTE-ACS compared to patients with a final diagnosis of another cardiac disease, such as congestive heart failure or angina, or non-cardiac diseases ($p<0.001$ for both). Additionally, patients with sPLA2 activity or mass in the highest quartile at baseline had a significantly higher incidence of both cardiac death and myocardial infarction vs. patients with sPLA2 activity or mass in the lowest quartile at baseline (37.5% vs. 13.4 %, $p=0.0001$ for cardiac death; 33.6% vs. 16%, $p=0.0047$ for MI). Data were presented at the French Cardiology Society meeting in Paris.

Biogen Idec Inc. (NASDAQ:BIIB), Cambridge, Mass.
Elan Corp. plc (NYSE:ELN), Dublin, Ireland
Product: Tysabri natalizumab
Business: Autoimmune
Molecular target: Integrin alpha(4) (VLA-4) (CD49D)
Description: Humanized mAb against integrin alpha(4)
Indication: Treat multiple sclerosis
Endpoint: NA
Status: Post-marketing study data
Milestone: NA

As of Jan. 12, Biogen Idec said that there have been 31 confirmed cases of progressive multifocal leukoencephalopathy (PML) in patients receiving Tysabri monotherapy for MS since the drug was relaunched in the U.S. and its first international approval in 2006. At Sept. 30, 2009, Biogen Idec reported that 60,700 patients had been treated with Tysabri in the post-marketing setting. Last September, FDA reported 13 confirmed cases of PML in patients receiving Tysabri monotherapy for MS as of Sept. 8, and that the risk for developing PML appears to increase with the number of Tysabri infusions received *(see BioCentury, Sept. 28, 2009)*.

The companies originally withdrew the drug in February 2005 because its use was associated with PML. Tysabri's label contains a boxed warning that alerts prescribers of the increased risk of PML that could lead to death or severe disability. Elan and Biogen Idec market Tysabri to treat MS in the EU and to treat MS and Crohn's disease in the U.S.

Biotie Therapies Corp. (HSE:BTH1V), Turku, Finland
Roche (SIX:ROG; OTCQX:RHHBY), Basel, Switzerland
Product: VAP-1 antibody (BTT-1023)
Business: Autoimmune
Molecular target: Vascular adhesion protein-1 (VAP-1) (SSAO)
Description: Human monoclonal antibody against vascular adhesion protein-1 (VAP-1)
Indication: Treat rheumatoid arthritis (RA)
Endpoint: Safety; pharmacokinetics
Status: Pilot trial data
Milestone: NA

Top-line data from a double-blind, placebo-controlled, European pilot trial (BTT12-CD015) in 24 patients with an inadequate response to methotrexate showed that repeated doses of 1, 2, 4 and 8 mg/kg IV BTT-1023 plus methotrexate were well tolerated with no serious adverse events reported. Biotie said that several patients receiving higher doses of BTT-1023 achieved a 50% or greater improvement in signs and symptoms of RA as measured by American College of Rheumatology (ACR50) response during treatment.

Roche has an option to license exclusive rights to the compound outside of Japan, Taiwan, Singapore, New Zealand and Australia *(see BioCentury, Jan. 3, 2005)*. The option expires upon completion of Phase I testing. Biotie said it expects a decision from the pharma this half.

Galapagos N.V. (Euronext:GLPG; Pink:GLPYY), Mechelen, Belgium
Product: GLPG0187
Business: Cancer
Molecular target: NA
Description: Integrin receptor antagonist
Indication: Treat bone metastases in cancer patients
Endpoint: Safety, pharmacokinetics and biomarkers
Status: Phase I data
Milestone: Start Phase I (2010)

In a double-blind, placebo-controlled, Belgian Phase I trial in 27 healthy volunteers, both subcutaneous and oral GLPG0187 displayed favorable safety profiles with no adverse events or changes in vital signs. Subjects received 17.5-315 mg subcutaneous GLPG0187 or 50-1,200 mg oral GLPG0187. The company plans to start a second Phase I trial evaluating GLPG0187 in cancer patients later this year.

Inspire Pharmaceuticals Inc. (NASDAQ:ISPH), Durham, N.C.
Allergan Inc. (NYSE:AGN), Irvine, Calif.
Santen Pharmaceutical Co. Ltd. (Tokyo:4536; Osaka:4536), Osaka, Japan
Product: Prolacria diquafosol tetrasodium (INS365)
Business: Ophthalmic
Molecular target: P2Y(2) receptor
Description: Uridine 5'-triphosphate (UTP) natural P2Y2 ligand
Indication: Treat dry eye
Endpoint: Clearing of fluorescein staining in the central region of the cornea; ≥2 unit reduction in staining score
Status: Phase III data
Milestone: NA

Top-line data from a North American Phase III (Trial 03-113) trial in 490 patients with a fluorescein staining score of 3 at baseline showed that Prolacria given 4 times daily missed the primary endpoint of a significantly greater proportion of patients that achieved clearing of fluorescein staining, a staining score of 0, in the central region of the cornea at week 6 vs. placebo ($p=0.526$). Prolacria also missed the secondary endpoint of a significantly greater proportion of patients achieving a ≥2 unit reduction in staining scores at week 6 vs. placebo ($p=0.368$). Inspire, which has an SPA from FDA for the trial, is co-developing Prolacria with Allergan. Santen has rights to Prolacria in Japan and 9 other Asian countries.

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Lexicon Pharmaceuticals Inc. (NASDAQ:LXRX), The Woodlands, Texas
Product: LX4211
Business: Endocrine
Molecular target: Sodium-glucose cotransporter 2 (SGLT2)
Description: Sodium-glucose cotransporter type 2 (SGLT2) inhibitor
Indication: Treat Type II diabetes
Endpoint: Change from baseline in 24-hour urinary glucose excretion to week 4; glucose tolerance, fasting plasma glucose (FPG), plasma fructosamine, homeostasis model assessment (HOMA) and 2-hour postprandial glucose levels
Status: Phase II data
Milestone: NA

Top-line data from a double-blind, U.S. Phase II trial in 36 patients showed that both 150 and 300 mg oral once-daily LX4211 met the primary endpoint of significantly increasing 24-hour urinary glucose excretion from baseline to week 4 vs. placebo ($p<0.001$ for both). Both doses of LX4211 also met all secondary endpoints vs. placebo, including significant improvements in glucose tolerance ($p<0.001$ for both) and significantly greater reductions in FPG from baseline to week 4 (53.4 and 65.9 mg/dL vs. 15.1 mg/dL, $p=0.001$ and $p<0.001$, respectively). Additionally, 42% of patients receiving 300 mg LX4211 achieved an FPG of <105 mg/dL at week 4 vs. undisclosed for placebo ($p=0.037$). Low- and high-dose LX4211 also significantly reduced HbA1c by 1.15% and 1.25%, respectively, from baseline to week 4 vs. 0.49% for placebo ($p=0.036$ and $p=0.017$, respectively). LX4211 displayed a favorable safety profile with no dose-limiting toxicities.

Merck & Co. Inc. (NYSE:MRK), Whitehouse Station, N.J.
Product: Vicriviroc
Business: Infectious
Molecular target: CC chemokine receptor 5 (CCR5) (CD195)
Description: CCR5 receptor antagonist
Indication: Treat HIV infection in treatment-experienced patients
Endpoint: Proportion of patients with undetectable plasma HIV-1 RNA (<50 copies/mL) at week 48; mean change from baseline in plasma HIV-1 RNA and proportion of patients with <400 copies/mL of plasma HIV-1 RNA
Status: Phase III data
Milestone: NA

Merck disclosed in an investor update that 30 mg once-daily vicriviroc missed the primary endpoint of a significantly greater proportion of patients with undetectable plasma HIV-1 RNA levels (<50 copies/mL) vs. placebo in the double-blind Phase III VICTOR-E3 and VICTOR-E4 trials evaluating the compound in treatment-experienced HIV patients. The company said that ongoing Phase II studies of vicriviroc in treatment-naïve HIV patients will continue unchanged, but that it will not submit an NDA for vicriviroc in treatment-experienced HIV patients at this time. Data will be presented at the Retroviruses and Opportunistic Infections meeting in San Francisco in February.

Mitsubishi Tanabe Pharma Corp. (Tokyo:4508; Osaka:4508), Osaka, Japan
Novartis AG (NYSE:NVS; SIX:NOVN), Basel, Switzerland
Product: Fingolimod (FTY720)
Business: Autoimmune
Molecular target: Sphingosine 1-phosphate (S1P) receptor
Description: Sphingosine 1-phosphate (S1P) receptor agonist
Indication: Treat relapsing-remitting multiple sclerosis (RRMS)
Endpoint: Annualized relapse rate; proportion of relapse-free patients treated for up to 12 months, safety and burden of disease and inflammatory activist as measured by MRI lesion parameters in patients treated for up to 12 months
Status: Additional Phase III data
Milestone: NA

Additional data from the double-blind, international Phase III TRANSFORMS trial in 1,292 patients showed that both 0.5 and 1.25 mg oral fingolimod significantly reduced the number of new or enlarged T2 lesions and gadolinium-enhanced T2 lesions vs. Avonex interferon beta-1a at 1 year. Data were published in the *New England Journal of Medicine*. Top-line data from the study previously showed that fingolimod met the primary endpoint of significantly reducing the annualized relapse rate at 1 year vs. Avonex *(see BioCentury, Dec. 15, 2008)*. Last month, Novartis submitted regulatory applications to FDA and EMEA for 0.5 mg fingolimod to treat MS. Novartis licensed fingolimod from Mitsubishi Tanabe. Avonex is marketed by Biogen Idec Inc. (NASDAQ:BIIB, Cambridge, Mass.).

Indication: Treat relapsing-remitting multiple sclerosis (RRMS)
Endpoint: Annualized relapse rate up to 24 months; reduction in disability progression measured by an increase in baseline in Expanded Disability Status Scale (EDSS) score, safety, proportion of patients with confirmed disability progression, frequency of relapses and effect on burden of disease (by MRI)
Status: Additional Phase III data
Milestone: NA

Additional data from the double-blind, international Phase III FREEDOMS trial in 1,272 patients showed that both 0.5 and 1.25 mg oral fingolimod significantly reduced the number of new or enlarged T2 lesions and gadolinium-enhanced lesions vs. placebo at 2 years ($p<0.001$ for all). Data were published in the *New England Journal of Medicine*. The partners previously reported that fingolimod met the primary endpoint of significantly reducing annualized MS relapse rate vs. placebo at 2 years *(see BioCentury, Oct. 5, 2009)*. Last month, Novartis submitted regulatory applications to FDA and EMEA for 0.5 mg fingolimod to treat MS. Novartis licensed fingolimod from Mitsubishi Tanabe.

Onyx Pharmaceuticals Inc. (NASDAQ:ONXX), Emeryville, Calif.
Bayer AG (Xetra:BAY), Leverkusen, Germany
Product: Nexavar sorafenib
Business: Cancer
Molecular target: Raf-1 (CRAF) (RAF); Vascular endothelial growth factor (VEGF) receptor
Description: Inhibitor of Raf-1 and multiple receptor tyrosine kinases
Indication: Treat hepatocellular cancer (HCC) following transarterial chemoembolization (TACE)
Endpoint: Time to progression (TTP) as assessed by a central review; overall survival (OS)
Status: Phase III data
Milestone: NA

Data from a double-blind, Asian Phase III trial in 458 patients with advanced HCC showed that 400 mg twice-daily Nexavar initiated after a median 9-10 week delay following 1 or 2 TACE procedures missed the primary endpoint of significantly increasing TTP as assessed by a central review vs. placebo. Specifically, median TTP was 5.4 months for Nexavar vs. 3.7 months for placebo ($p=0.25$). Additionally, Nexavar did not significantly improve OS vs.

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placebo (p=0.79). An exploratory analysis conducted by the study investigators showed that median TTP was 7.2 months for Nexavar vs. 5.3 months for placebo (p=0.049). Data were presented at the American Society of Clinical Oncology Gastrointestinal Cancers meeting in Orlando. Nexavar is approved in more than 80 countries to treat liver cancer without TACE and in more than 90 countries to treat advanced kidney cancer. Bayer and Onyx have a worldwide co-development agreement for Nexavar outside of Japan, where Bayer owns rights.

PCI Biotech Holding ASA (OSE:PCIB), Oslo, Norway
Product: Amphinex
Business: Cancer
Molecular target: NA
Description: Photosensitizer for photodynamic therapy
Indication: Treat cancer
Endpoint: Maximum tolerated dose (MTD); anti-tumor activity in combination with bleomycin and pharmacokinetics
Status: Interim Phase I/II data
Milestone: Additional Phase I/II data (1H10)

Interim data from 7 patients in the second dose group of a dose-escalation, U.K. Phase I/II trial showed that IV Amphinex plus bleomycin chemotherapy eliminated 100% of tumors within 2-4 weeks of treatment. No Amphinex-related serious adverse events were reported.

Qiagen N.V. (Xetra:QIA; NASDAQ:QGEN), Venlo, the Netherlands
Product: Digene HPV test (Hybrid Capture 2 High-Risk HPV DNA Test)
Business: Diagnostic
Molecular target: Human papillomavirus (HPV) DNA
Description: HPV-based cervical cancer screening test
Indication: Primary screening for cervical cancer and its precursors
Endpoint: Detection of cervical intraepithelial neoplasia grade 2 (CIN2) and CIN3 and detection of invasive cervical cancers during the first and second rounds of screening
Status: NA data
Milestone: NA

Researchers at the Center for Cancer Prevention in Turin and colleagues reported data from an Italian study in 94,370 women in which there was a significantly lower number of cases of invasive cervical cancer after the second of 2 screening rounds 2 years apart with the Digene HPV Test vs. liquid-based cytology (LBC) (7 vs. 18, p=0.028). In the first round of screening, the Digene HPV Test plus LBC detected 7 cases of invasive cervical cancer vs. 9 cases for LBC alone (p=0.62). In the second round of screening, the Digene HPV Test alone detected zero cases of invasive cervical cancer vs. 9 cases for LBC alone (p=0.004). Additionally, the detection of cervical intraepithelial neoplasia grade 2 (CIN2) in women ages 25-34 was much higher for the Digene HPV Test compared to LBC after the first round of screening, but only slightly lower after round 2, which the researchers said suggests that HPV testing in younger women results in over-diagnosis of regressive CIN2. Data were published in the *Lancet Oncology*. Qiagen markets the test to screen for cervical cancer and its precursors.

Roche (SIX:ROG; OTCQX:RHHBY), Basel, Switzerland
Product: Xelox
Business: Cancer
Molecular target: Thymidylate synthase; DNA
Description: Combination of oral Xeloda capecitabine and IV oxaliplatin
Indication: Treat stage III colon cancer following surgery
Endpoint: Disease-free survival; overall survival (OS) and safety
Status: Additional Phase III data
Milestone: NA

Additional data from the open-label, international Phase III NO16968 (XELOXA) trial in 1,886 previously untreated patients showed that Xelox led to 4- and 5-year disease-free survival rates of 68.4% and 66%, respectively, vs. 62.3% and 60% for 5-fluorouracil (5-FU) plus leucovorin (p=0.0045 for both). In a subgroup of patients ages 65 and up, Xelox led to a 3-year disease-free survival rate of 68% vs. 62% for 5-FU plus leucovorin. In a subgroup of patients ages 70 and up, Xelox led to a 3-year disease-free survival rate of 66% vs. 60% for 5-FU plus leucovorin. Data were presented at the American Society of Clinical Oncology Gastrointestinal Cancers meeting in Orlando. Roche previously reported that Xelox led to a 3-year disease-free survival rate of 70.9% vs. 66.5% for 5-FU plus leucovorin *(see BioCentury, July 27, 2009 & Oct. 5, 2009)*. Xeloda is approved as first-line monotherapy to treat metastatic breast cancer and colorectal cancer.

Symphony Evolution Inc., Rockville, Md.
Product: XL647
Business: Cancer
Molecular target: Epidermal growth factor (EGF) receptor 1 (HER1) (ErbB1); Vascular endothelial growth factor (VEGF) receptor
Description: Spectrum selective inhibitor of EGF, VEGF and HER2/neu/ErbB2 receptors
Indication: Treat non-small cell lung cancer (NSCLC)
Endpoint: Objective response rate (ORR) and safety; progression-free survival (PFS), duration of response, pharmacokinetics and pharmacodynamics
Status: Preliminary Phase II data
Milestone: NA

Preliminary data from an ongoing, open-label Phase II trial in 52 treatment-naïve patients showed that XL647 produced a 71% ORR and a 100% clinical benefit rate (CBR) in patients with activating EGFR mutations compared with a 14% ORR and a 55% CBR in patients with wild-type EGFR. In 6 patients receiving XL647 whose EGFR-mutated tumors were re-biopsied following disease progression, only 1 developed a T790M mutation, and at least 2 others went on to benefit from subsequent treatment with another EGFR inhibitor. Symphony Evolution said the mutation, which causes resistance to EGFR inhibitors, develops in about 50% of NSCLC patients with activating EGFR mutations. Data were presented at the AACR-IASLC Conference on the Molecular Origins of Lung Cancer in Coronado, Calif. Symphony Evolution has worldwide rights to XL647 from Exelixis Inc. (NASDAQ:EXEL, South San Francisco, Calif.).

Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA), Petah Tikva, Israel
Merck KGaA (Xetra:MRK), Darmstadt, Germany
Product: Cladribine tablets
Business: Autoimmune
Molecular target: DNA polymerase
Description: Purine nucleoside analog that inhibits DNA synthesis
Indication: Treat multiple sclerosis (MS)
Endpoint: Annualized clinical relapse rate at 96 weeks; reduction of lesion activity as measured by magnetic resonance imaging (MRI),

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proportion of subjects relapse-free and disability progression
Status: Additional Phase III data
Milestone: NA

Additional data from the double-blind, international Phase III CLARITY trial in 1,326 patients with relapsing-remitting MS showed that 3.5 and 5.25 mg/kg oral cladribine significantly increased relapse-free rates vs. placebo (79.7% and 78.9% vs. 60.9%, p<0.001 for both), lowered the risk of 3-month sustained progression of disability vs. placebo (p=0.02 and p=0.03, respectively) and reduced brain lesion count as measured by MRI vs. placebo (p<0.001 for both). Lymphocytopenia was observed in 21.6% and 31.5% of patients in the low- and high-dose cladribine arms, respectively, vs. 1.8% of patients in the placebo arm. Data were published in the *New England Journal of Medicine*.

Merck previously reported that both doses of cladribine met the primary endpoint of significantly reducing annualized clinical relapse rate at 96 weeks vs. placebo *(see BioCentury, Jan. 26, 2009)*. In November, FDA refused to file an NDA for cladribine tablets to treat relapsing forms of MS, but Merck did not disclose why *(see BioCentury, Dec. 7, 2009)*. Merck's Merck Serono S.A. division has rights to cladribine from Teva.

PRECLINICAL RESULTS

Access Pharmaceuticals Inc. (OTCBB:ACCP), Dallas, Texas
Product: Cobalamin-coated insulin-containing nanoparticles
Indication: Treat diabetes

In a rat model of diabetes, oral Cobalamin-coated insulin-containing nanoparticles lowered blood glucose levels by >80% of that achieved by subcutaneous insulin. Cobalamin drug delivery technology utilizes the body's natural vitamin B12 oral uptake mechanism to facilitate oral absorption of drugs.

Critical Outcome Technologies Inc. (TSX-V:COT; Pink: COTQF), London, Ontario
Product: COTI-2
Indication: Treat pancreatic cancer

In an animal model of human pancreatic cancer, oral COTI-2 plus Abraxane nab-paclitaxel produced complete tumor regressions and was significantly more "effective" than Abraxane alone at day 28. COTI-2 alone and in combination with Abraxane was well tolerated with no treatment-related deaths or toxicity observed. The oral small molecule inhibitor of protein kinase B (PKB; Akt) phosphorylation was identified using Critical Outcome Technologies' CHEMSAS computational drug design technology. Abraxis BioScience Inc. (NASDAQ:ABII, Los Angeles, Calif.) markets Abraxane.

Merck & Co. Inc. (NYSE:MRK), Whitehouse Station, N.J.
Product: Zocor simvastatin
Indication: Treat pneumococcal infection in patients with sickle cell disease

Researchers at St. Jude Children's Research Hospital and colleagues reported that Zocor simvastatin significantly delayed time to death following pneumococcal challenge vs. saline control in a mouse model of sickle cell disease (p=0.023). Additionally, Zocor significantly reduced bacterial burden in the lungs and blood of the mice vs. saline control at 24 hours post-infection (p=0.0024 and p=0.0001, respectively). Data were published in the *Journal of Clinical Investigation*. Merck markets the HMG-CoA reductase inhibitor.

Symphony Evolution Inc., Rockville, Md.
Product: XL647
Indication: Treat non-small cell lung cancer (NSCLC)

In vitro, human lung cancer cells with activating EGFR mutations treated with Tarceva erlotinib or BIBW 2992 developed the T790M mutation, while cells treated with XL647 did not. Symphony Evolution said the mutation, which causes resistance to EGFR inhibitors, develops in about 50% of NSCLC patients with activating EGFR mutations. Furthermore, lung cancer cells that developed resistance to XL647 did not develop other EGFR mutations and retained intermediate sensitivity to other EGFR inhibitors. Data were presented at the AACR-IASLC Conference on the Molecular Origins of Lung Cancer in Coronado, Calif.

Symphony Evolution has worldwide rights to XL647, a spectrum selective kinase inhibitor, from Exelixis Inc. (NASDAQ:EXEL, South San Francisco, Calif.). Tarceva is marketed by OSI Pharmaceuticals Inc. (NASDAQ:OSIP, Melville, N.Y.) and Genentech Inc., a unit of Roche (SIX:ROG; OTCQX:RHHBY, Basel, Switzerland), in the U.S. and by Roche elsewhere. BIBW 2992 is a dual EGFR/HER2 inhibitor from Boehringer Ingelheim GmbH (Ingelheim, Germany).

CLINICAL STATUS

BioNumerik Pharmaceuticals Inc., San Antonio, Texas
Product: Tavocept (BNP7787)
Business: Cancer
Molecular target: DNA
Description: Water soluble cisplatin
Indication: Treat advanced primary adenocarcinoma of the lung
Endpoint: Overall survival; safety
Status: Phase III started
Milestone: Complete Phase III enrollment (year end 2010 - early 2011)

BioNumerik began a double-blind, placebo-controlled, international Phase III trial to evaluate taxane and cisplatin chemotherapy with or without Tavocept in 475 patients. KI Pharmaceuticals Inc. (Tokyo, Japan), a JV between BioNumerik and ASKA Pharmaceutical Co. Ltd. (Tokyo:4514; Tokyo, Japan), has exclusive Japanese rights for Tavocept.

BTG plc (LSE:BGC), London, U.K.
Product: Pleneva (BGC20-0134)
Business: Autoimmune
Molecular target: NA
Description: Structured lipid immunomodulator
Indication: Treat multiple sclerosis (MS)
Endpoint: Reduction in number of new T1 gadolinium enhanced lesions on MRI at weeks 12, 16, 20 and 24; safety
Status: Phase IIa started
Milestone: NA

BTG began a double-blind, placebo-controlled, European Phase IIa trial to evaluate 5g oral Pleneva for 24 weeks in 166 patients with relapsing-remitting MS. The study will also include a 24-week, open-label extension portion.

Cempra Pharmaceuticals Inc., Chapel Hill, N.C.
Product: Taksta fusidic acid (CEM-102)
Business: Infectious
Molecular target: NA
Description: Oral antibiotic active against Gram-positive bacteria
Indication: Treat acute bacterial skin structure infections (ABSSIs)
Endpoint: Clinical success rates in the clinically evaluable and

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intent-to-treat patient populations at the test of cure visit; clinical response rate at end of treatment and test of cure visit and microbiological response
Status: Phase II/III ongoing
Milestone: Complete Phase II/III enrollment (year end 2010)

Cempra completed enrollment of 180 patients in the Phase II portion of a double-blind, U.S. Phase II/III trial evaluating Taksta given twice daily or as a loading-dose regimen, and twice-daily Zyvox linezolid for 10-14 days. Pfizer Inc. (NYSE:PFE, New York, N.Y.) markets Zyvox.

Circassia Ltd., Oxford, U.K.
Product: ToleroMune cat allergy therapy
Business: Inflammation
Molecular target: NA
Description: T-cell vaccine using ToleroMune T cell epitope desensitization technology
Indication: Treat cat allergy
Endpoint: Total rhinoconjunctivitis symptom score; symptom scores for ocular and nasal symptoms, acoustic rhinometry, cat-specific IgE antibody levels and adverse events
Status: Phase II started
Milestone: NA

Circassia began a double-blind, placebo-controlled, Canadian Phase II trial to evaluate 2 regimens of its ToleroMune in 210 patients who will be challenged with aerosolized cat dander in an environmental exposure chamber before and after treatment.

Product: ToleroMune house dust mite therapy
Business: Inflammation
Molecular target: NA
Description: T-cell vaccine against house dust mites using ToleroMune T cell epitope desensitization technology
Indication: Treat house dust mite allergy
Endpoint: Safety; house dust mite-specific IgE antibody levels
Status: Phase II started
Milestone: NA

Circassia began a double-blind, placebo-controlled, Canadian Phase II trial to evaluate 4 doses of the vaccine given monthly in 50 patients.

CytoDyn Inc. (OTCBB:CYDY), Santa Fe, N.M.
Product: Cytolin
Business: Infectious
Molecular target: CD8
Description: Murine monoclonal antibody against immune cell adhesion molecules
Indication: Treat HIV infection/AIDS
Endpoint: T cell number and effector functions in Cytolin-treated blood from HIV patients; in-vitro suppression of viral replication following Cytolin treatment of blood from HIV patients
Status: NA started
Milestone: NA

CytoDyn began an observational study to evaluate Cytolin in blood samples extracted from 10 HIV patients and 10 healthy volunteers.

Durect Corp. (NASDAQ:DRRX), Cupertino, Calif.
Nycomed, Zurich, Switzerland
Product: Posidur (Optesia) (formerly Saber-bupivacaine)
Business: Neurology
Molecular target: Sodium channel
Description: Injectable biodegradable gel for sustained-release delivery of bupivacaine
Indication: Treat post-operative pain
Endpoint: Mean pain intensity on movement AUC and mean total morphine equivalent opioid dose for supplemental analgesia
Status: Phase III started
Milestone: Complete Phase III enrollment (1H11)

Durect began the double-blind, placebo-controlled, international Phase III BESST trial to evaluate 5.0 mL Posidur vs. bupivacaine in 300 patients undergoing abdominal surgery. Nycomed partnered to develop Durect's Posidur in 2006, and has exclusive commercialization rights in the EU and certain other countries *(see BioCentury, Dec. 4, 2006)*.

Genzyme Corp. (NASDAQ:GENZ), Cambridge, Mass.
PTC Therapeutics Inc., South Plainfield, N.J.
Product: Ataluren (formerly PTC124)
Business: Musculoskeletal
Molecular target: Not available
Description: Small molecule that facilitates complete translation of proteins containing nonsense mutations
Indication: Treat Duchenne/Becker muscular dystrophy (DMD/BMD) due to nonsense mutation
Endpoint: Safety and tolerability; pharmacokinetics and pharmacodynamics
Status: Phase IIa started
Milestone: NA

PTC began an open-label, U.S. and UK Phase IIa evaluating oral ataluren given thrice daily for 48 weeks in 30 boys and young men. PTC and Genzyme are co-developing the compound.

GlaxoSmithKline plc (LSE:GSK; NYSE:GSK), London, U.K.
Product: Orvepitant (GW823296)
Business: Neurology
Molecular target: Neurokinin 1 (NK1) Substance P receptor (TACR1)
Description: Neurokinin 1 (NK1) receptor antagonist
Indication: Treat noncombat-related post-traumatic stress disorder
Endpoint: Change from baseline in Clinician Administered PTSD (CAPS) total severity score; percentage responders based on CAPS score, percentage of subjects remitting based on CAPS score, Columbia Suicidality Severity Rating Scale and Massachusetts Sexual Function Questionnaire (MSFQ)
Status: Phase II started
Milestone: Complete Phase II enrollment (05/2010)

Researchers began the double-blind, U.S. Phase II COPE trial to compare 60 mg/day oral orvepitant vs. placebo for 12 weeks in 240 patients.

Idera Pharmaceuticals Inc. (NASDAQ:IDRA), Cambridge, Mass.
Merck KGaA (Xetra:MRK), Darmstadt, Germany
Product: EMD 1201081 (IMO-2055)
Business: Cancer
Molecular target: Toll-like receptor 9 (TLR9)
Description: Second-generation synthetic immune modulatory oligonucleotide (IMO) agonist of TLR9
Indication: Treat squamous cell carcinoma of the head and neck
Endpoint: Progression-free survival; overall response, duration of response, overall survival time, safety, tumor response and time to progression

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OFFERINGS & SECURITIES TRANSACTIONS

Week ended 1/22/10. Shares after offering refers to shares outstanding. Proceeds are gross, not net. Shares offered don't include overallotments. Currency rates used in the week: NOK=0.1765

Completed Offerings

Achillion Pharmaceuticals Inc. (NASDAQ:ACHN), New Haven, Conn.
Business: Infectious
Date completed: 1/22/10
Type: Follow-on
Raised: $21.4 million
Shares: 10.3 million
Price: $2.08
Shares after offering: 37 million
Underwriters: Roth Capital Partners; Noble Financial Capital Markets; National Securities
Overallotment: 1.5 million

AMAG Pharmaceuticals Inc. (NASDAQ:AMAG), Cambridge, Mass.
Business: Hematology, Diagnostic
Date completed: 1/20/10
Type: Follow-on
Raised: $173.7 million
Shares: 3.6 million
Price: $48.25
Shares after offering: 21 million
Underwriters: Morgan Stanley; JPMorgan; Goldman Sachs; Leerink; Canaccord; Robert W. Baird
Overallotment: 540,000

BioCurex Inc. (OTCBB:BOCX), Richmond, B.C.
Business: Diagnostic
Date completed: 1/19/10
Type: Follow-on
Raised: $6 million
Units: 1.2 million
Price: $5 (unit)
Shares after offering: 157.1 million
Overallotment: 180,000 units
Note: Each unit comprises 70 shares and 70 five-year warrants to purchase warrants at $0.11.

Cortex Pharmaceuticals Inc. (OTCBB:CORX), Irvine, Calif.
Business: Neurology
Date completed: 1/15/10
Type: Private placement of convertible notes

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Clinical Status,
from previous page

Status: Phase II started
Milestone: NA

Merck began an open-label, international Phase II trial to evaluate Erbitux cetuximab with or without 0.32 mg/kg subcutaneous EMD 1201081 as second-line therapy in 104 Erbitux-naïve patients. The trial start triggers a €3 million ($4.3 million) milestone payment to Idera, which granted Merck exclusive rights to its TLR9 agonists, including EMD 1201081, to treat cancer *(see BioCentury, Dec. 18, 2007)*.

International Medica Foundation, Rochester, Minn.
Product: RotaShield
Business: Infectious
Molecular target: Not available
Description: Rotavirus vaccine
Indication: Prevent rotavirus infection in infants
Endpoint: Safety and incidence of rotavirus infection confirmed by analysis of stool sample in infants who develop diarrhea over 12 months post-vaccination; immunogenicity
Status: Completed Phase II enrollment
Milestone: Phase II data (year end 2010)

The non-profit organization completed enrollment of 998 infants in a double-blind, placebo-controlled, African Phase II trial evaluating oral RotaShield given once soon after birth and again 60 days later.

MorphoSys AG (Xetra:MOR), Martinsried, Germany
Product: MOR103
Business: Autoimmune
Molecular target: Granulocyte macrophage colony-stimulating factor (GM-CSF) receptor (CSF2RA) (GMR) (CD116)
Description: Human HuCAL antibody against human cytokine granulocyte macrophage-colony stimulating factor (GM-CSF)
Indication: Treat rheumatoid arthritis (RA)
Endpoint: Safety; pharmacokinetics, immunogenicity and improvement of clinical signs and symptoms of RA as measured by American College of Rheumatology criteria (ACR) and European League Against Rheumatism Responder Index (EULAR28)
Status: Phase Ib/IIa started
Milestone: Complete Phase Ib/IIa enrollment (1H11); Phase Ib/IIa data (1H12)

MorphoSys began a double-blind, placebo-controlled, European Phase Ib/IIa trial to evaluate 0.3, 1.0 and 1.5 mg/kg intravenous MOR103 in 135 patients.

Pharmasset Inc. (NASDAQ:VRUS), Princeton, N.J.
Product: PSI-7977
Business: Infectious
Molecular target: NA
Description: Single isomer form of PSI-7851, a nucleotide analog polymerase inhibitor
Indication: Treat hepatitis C virus (HCV) genotype 1 infection
Endpoint: Proportion of patients achieving a rapid virologic response (RVR) defined as undetectable HCV levels at 4 weeks; sustained virologic response (SVR) and safety
Status: Phase IIa started
Milestone: Interim Phase IIa data (3Q10)

Pharmasset began a double-blind, placebo-controlled, U.S. Phase IIa trial to evaluate 100 mg, 200 mg or 400 mg oral PSI-7977 given once daily in combination with ribavirin and Pegasys peginterferon alfa 2a for 4 weeks in 60 treatment-naïve patients. All patients will then receive ribavirin and Pegasys for an additional 44 weeks. Roche (SIX:ROG; OTCQX:RHHBY, Basel, Switzerland) markets Pegasys.

Sunesis Pharmaceuticals Inc. (NASDAQ:SNSS), South San Francisco, Calif.
Product: Voreloxin (formerly SNS-595)
Business: Cancer
Molecular target: Topoisomerase II (TOP2)
Description: Naphthyridine analog that intercalates DNA and inhibits topoisomerase II (TOP2)
Indication: Treat acute myelogenous leukemia (AML)
Endpoint: Safety; pharmacokinetics
Status: Completed Phase Ib/II enrollment
Milestone: NA

Sunesis completed enrollment of 110 patients in an open-label, dose-escalation Phase Ib/II trial evaluating IV voreloxin given once daily on days 1 and 4 in combination with cytarabine. The company said it has identified 90 mg/m^2 as the recommended dose for pivotal of testing of voreloxin, which has Orphan designation in the U.S.

Completed Offerings,
from previous page

Raised: $1.5 million
Investor: Samyang Optics Co. Ltd.
Note: The promissory note bears 6% interest.

Curis Inc. (NASDAQ:CRIS), Cambridge, Mass.
Business: Cancer
Date completed: 1/22/10
Type: Direct public offering
Raised: $16.3 million
Units: 6.4 million
Price: $2.52 (unit)
Shares after offering: 73 million
Placement agents: RBC Capital Markets; Rodman
Note: Each unit comprises a share and a five-year warrant to purchase 0.25 shares, with each whole warrant exercisable at $3.55.

Cyclacel Pharmaceuticals Inc. (NASDAQ:CYCC), Berkeley Heights, N.J.
Business: Cancer
Date completed: 1/21/10
Type: Direct public offering
Raised: $5.9 million
Units: 2.4 million
Price: $2.50 (unit)
Shares after offering: 31.4 million
Placement agent: Roth Capital Partners
Investors: Institutional investors
Note: Each unit comprises a share and a five-year warrant to purchase 0.3 shares, with each whole warrant exercisable at $2.85.

Elevation Pharmaceuticals Inc., San Diego, Calif.
Business: Pulmonary
Date completed: 1/21/10
Type: Venture financing
Raised: Undisclosed
Investors: Canaan Partners; TPG Ventures; Care Capital; Mesa Verde Venture Partners
Note: The company raised an undisclosed amount in the first of two tranches in a planned $30 million series A round. Elevation will receive the second tranche based on the achievement of undisclosed milestones.

EnteroMedics Inc. (NASDAQ: ETRM), St. Paul, Minn.
Business: Endocrine, Gastrointestinal
Date completed: 1/14/10
Type: Direct public offering
Raised: $4.8 million
Shares: 7.4 million
Price: $0.65
Shares after offering: 44.8 million
Placement agent: Canaccord Adams
Investors: Institutional investors

Geron Corp. (NASDAQ:GERN), Menlo Park, Calif.
Business: Cancer, Gene/Cell therapy
Date completed: 1/15/10
Type: Private placement
Raised: $10 million
Shares: 1.5 million
Price: $6.75
Shares after offering: 97.2 million
Investors: Existing investors
Note: The offering includes a call option for an additional $5 million at the same terms. Investors also received warrants to purchase 740,741 shares at $6.75. The warrants expire Oct. 31, 2010. Additionally, the company exchanged warrants held by the investors to purchase 5.6 million shares at $6.80 for 2.7 million shares. The number of shares after the offering includes the exchange.

GlobeImmune Inc., Louisville, Colo.
Business: Infectious, Cancer
Date completed: 1/19/10
Type: Venture financing
Raised: $17.5 million
Investors: Generali Financial Holding; BSI; existing investors

InterMune Inc. (NASDAQ: ITMN), Brisbane, Calif.
Business: Pulmonary, Infectious, Hepatic
Date completed: 1/20/10
Type: Follow-on
Raised: $98.7 million
Shares: 7 million
Price: $14.10
Shares after offering: 53.7 million
Underwriters: Goldman Sachs; Canaccord; JMP Securities; Leerink; Oppenheimer
Overallotment: 1.1 million

Kolltan Pharmaceuticals Inc., New Haven, Conn.
Business: Cancer, Antibodies
Date completed: 1/20/10
Type: Venture financing
Raised: $8.5 million
Investors: Celtic Therapeutics Holdings L.P.; Tichenor Ventures LLC
Note: The company said an additional $1.5 million can be applied to a product development program with an affiliate of Celtic Therapeutics or converted into series B convertible preferred stock if a product is not chosen by an undisclosed date.

Liquidia Technologies Inc., Research Triangle Park, N.C.
Business: Infectious, Drug delivery
Date completed: 1/19/10
Type: Venture financing
Raised: $20 million
Investors: Canaan Partners; Pappas Ventures; Morningside Venture Investments; New Enterprise Associates; Firelake Capital Management

Novita Therapeutics LLC, Lenexa, Kan.
Business: Diagnostic
Date completed: 1/15/10
Type: Venture financing
Raised: Undisclosed
Investors: Angel investors

Ohr Pharmaceutical Inc. (OTCBB:OHRP), Salt Lake City, Utah
Business: Autoimmune, Cancer, Endocrine
Date completed: 1/19/10
Type: Warrant exercise
Raised: $1 million
Shares: 5.6 million
Price: $0.18
Shares after offering: 38.2 million
Note: Warrantholders received a share and a five-year warrant to purchase a share at $0.55.

ProChon Biotech Ltd., Woburn, Mass.
Business: Musculoskeletal
Date completed: 1/20/10
Type: Venture financing
Raised: $4 million
Investors: ProChon Holdings B.V.; Musculoskeletal Transplant Foundation
Note: The offering is a convertible bridge loan.

Rosetta Genomics Ltd. (NASDAQ:ROSG), Rehovot, Israel
Business: Diagnostic
Date completed: 1/19/10
Type: Direct public offering
Raised: $5.1 million
Units: 2.5 million
Price: $2 (unit)
Shares after offering: 16.8 million
Placement agent: Rodman
Investors: Institutional investors
Note: Each unit comprises a share and a five-year warrant to purchase 0.5 shares, with each whole warrant exercisable at $2.50.

Proposed Offerings

Nutri Pharma ASA (OSE:NUT), Oslo, Norway
Business: Nutraceuticals
Date announced: 1/21/10
Type: Private placement
To be raised: NOK50-NOK100 million ($8.8 million-$17.7 million)
Placement agents: Pareto Securities; Orion Securities
Shares outstanding prior: 86.5 million
Price prior: NOK3.42
Note: NutriPharma's acquisition of Bionor Immuno AS (Skien, Norway) is contingent on NutriPharma raising at least NOK50 million ($8.8 million).

Sinovac Biotech Ltd. (NASDAQ:SVA), Beijing, China
Business: Infectious
Date announced: 1/20/10
Type: Follow-on
To be raised: TBD
Shares: TBD
Price: TBD
Shares: 8.7 million
Underwriters: UBS; Piper Jaffray
Overallotment: 1.3 million
Price prior: $7.51

Amended Offerings

Ironwood Pharmaceuticals Inc., Cambridge, Mass.
Business: Gastrointestinal
Date announced: 1/20/10
Type: IPO
To be raised: Up to $266.7 million
Shares: 16.7 million
Price: $14-$16
Shares after offering: 94.9 million

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Amended Offerings,
from previous page

Underwriters: JPMorgan; Morgan Stanley; Credit Suisse; Merrill Lynch; Wedbush
Overallotment: 2.5 million
Note: Ironwood amended its IPO and hopes to sell 16.7 million shares at $14-$16. The company filed to raise up to $172.5 million last November.

Other Financial News

Athersys Inc. (NASDAQ: ATHX), Cleveland, Ohio
Business: Endocrine, Neurology, Gene/Cell therapy
Date announced: 1/14/10

Athersys filed a shelf registration covering the sale of up to 20 million of its common stock and warrants. Athersys, which closed at $2.66 on Friday, has 18.9 million shares outstanding.

Diamyd Medical AB (SSE:DIAM B), Stockholm, Sweden
Business: Endocrine
Date announced: 1/20/10

Diamyd will implement a 2-for-1 stock split, effective Jan. 26. After the split, the company will have 28.7 million shares outstanding.

EntreMed Inc. (NASDAQ: ENMD), Rockville, Md.
Business: Cancer, Autoimmune
Date announced: 1/20/10

EntreMed received a letter from NASDAQ indicating that the company has not regained compliance with the $1 minimum bid price requirement for continued listing. The company requested a hearing and expects to appeal the staff's determination.

EpiCept Corp. (NASDAQ: EPCTD; SSE:EPCT), Tarrytown, N.Y.
Business: Cancer, Neurology
Date announced: 1/14/10

EpiCept implemented a 1-for-3 reverse stock split effective Jan. 15, and began trading under the symbol "EPCTD." Prior to the split, the company had 132.5 million shares outstanding.

Luna Innovations Inc. (NASDAQ:LUNA), Roanoke, Va.
Business: Supply/Service, Diagnostic, Inflammation
Date announced: 1/14/10

Luna Innovations received notice from NASDAQ that it regained compliance with the requirements for continued listing.

Repros Therapeutics Inc. (NASDAQ:RPRX), The Woodlands, Texas
Business: Genitourinary, Endocrine
Date announced: 1/15/10

Repros said NASDAQ accepted the company's plan to regain compliance with listing standards. The company has until May 5 to regain compliance.

Synta Pharmaceuticals Corp. (NASDAQ:SNTA), Lexington, Mass.
Business: Cancer, Autoimmune
Date announced: 1/19/10

Synta raised $3.7 million through the sale of 833,333 shares at $4.50 to cover overallotments from its Jan. 8 follow-on, bringing the total raised to $28.8 million. Synta, which closed Friday at $4.42, has 40.4 million shares outstanding.

Targeted Genetics Corp. (Pink:TGEN), Seattle, Wash.
Business: Gene/Cell therapy, Autoimmune, Infectious
Date announced: 1/21/10

Targeted Genetics was delisted from the NASDAQ for failure to comply with the exchange's listing requirements. The company is now listed on the Pink Sheets under "TGEN."