From:	Hagerty, Karen [JANUS]
To:	Bailey, Randi [OMP]; Bariahtaris, Steve [OMP]; Bartone, Nicholas [OMPUS]; Bondi, Joseph [OMPUS]; Brantley, Susan [OMP]; Browka, Monica [OMP]; Caruso, Dominic [JJCUS]; Chanlam, Andrew [OMP]; Chong, Siong Hin [OMPUS]; Couture, Susan [HCSUS]; DAleandro, Nicholas [OMP]; Desikan, Nithya [OMP]; Donnelly, Valerie A [PRDUS]; Durning, Chuck [OMP]; Faessler, Robert [OMP]; Fagundus, Anne [OMPUS Non J&J]; Fischer, Seth [OMP]; Fitzgerald, Dennis [PGSMUS]; Fitzgerald, James [OMP]; Fitzsimons, Barry [JJCUS]; Fowler, Neal F. [OMP]; Gardner, Trenton [OMP]; Gibson, Thomas [OMP]; Givens, Jennifer [OMP]; Gowe, Diana [OMP]; Grissinger, Michael [OMPUS]; Guido, Daniel [OMP]; Hartley, Ron [OMP]; Hewitt, David [OMP]; Heyman, Tom [JJCUS]; Jones, Susan T [OMP]; Jorn, Deborah [PGSMUS]; Kuntz, Ron [OMP]; Linkewich, Matt [OMP]; Lippman, Renee [OMP]; Litzenberger, Laura [OMP]; Longino, Eric [OMPUS]; Lorie, Justin [OMP]; Martel, Alain L. [OMP]; Mastroserio, Juliana [OMP]; Mathis, Jeff [JANUS]; Mauriz, Yolanda [OMP]; McDavid, Kevin [OMP]; Olsen, Donald [OMP]; Pascarella, Lou [OMP]; Peluso Nguyen, Roseann [OMP]; Pierson, Renee [OMP]; Reed-Holmes, Stephanie [GPCUS]; Renzo, Michael [OMP]; Rielly-Gauvin, Katherine [PGSM]; Rivero, Fausto [JANMX]; Rosenthal MD, Norman R [OMP]; Rothenberg, Craig [GPCUS]; Salgado, Angel [JANMX]; Schur, Anne Marie [OMP]; Short, Paul [OMP]; Smith, Jeff [OMP]; Stevens, Heidi [OMP]; Suehnholz, Raymond [OMP]; Tigeleiro, Susan [JJCUS]; Wajdowicz, Jean Marie [PGSMUS]; Washburn, Ken [OMP]; Webb, Sue [OMP]; Wilson, Carla R. [OMP]; Dax, Scott [PRDUS]; Flores, Christopher [PRDUS]
Sent:	3/15/2004 7:02:21 PM
Subject:	Analgesic Surveillance Report
Attachments:	Analgesic Surveillance March.pdf

All,
Attached is the Business Intelligence March 2004 *Analgesic Surveillance Report.* This report now covers Analgesics Markets across OMP and Janssen, including Ultracet, Duragesic, and Ionsys (formerly AP-22/E-trans). Also included is a consolidated pipeline chart. I look forward to working with you regarding your analgesic business intelligence needs across Janssen/OMP and welcome your feedback regarding this newly formed report.

Highlight's of this month's report include:

Franchise Issues

- FDA, DEA Working on Stricter Guidelines for Patients and Doctors regarding Scheduled Drugs to Curb Abuse
- DEA Pushing to Reschedule Vicodin (hydrocodones) from III to II

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- Endo and Noven Sign Agreement for Generic Duragesic
- Avinza Sales Goals Met for 2003; 2004 Market Share Goal at 6-7%, below previous estimates of 10-11%

Ultracet

- Johnson & Johnson Sues Teva to Prevent Generic Form of Ultracet until Patent Expiration

Ionsys

- I-Flow Reports Strong ON-Q Sales Growth; Driven by Outcomes Studies and Hospital Billing Pull-through Programs

Pipeline Developments

- Biovail NDA Tramadol QD (Ralivia ER®) Accepted by FDA
- Biovail Submits NDA for Ralivia FlashDose

Please visit our **Signal** website at to view this month's report as well as past issues. For your convenience, a copy of the report is also attached.

Analgesic Surveillance March.pdf
Best regards,
Karen N. Hagerty

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Business Intelligence
(609) 730 2673
khagerty@janus.jnj.com

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Analgesic Issues

- Bush Anti-Drug Plan To Focus On Prescription Drug Abuse
- FDA, DEA Working on Stricter Guidelines for Patients and Doctors regarding Scheduled Drugs to Curb Abuse
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- AETNA & Humana Sue Oxycontin Maker Over Blocking Generic Drugs
- Researchers Say Pain Is in the Mind of the Believer
- Combined Morphine/Oxycodone proven More Effective than Morphine Alone
- Pfizer sues Teva over Generic Celebrex

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Karen Hagerty

Analgesic Issues

Bush Anti-Drug Plan To Focus On Prescription Drug Abuse
President Bush's national anti-drug strategy will for the first time target the use of pain relievers, sedatives and stimulants for non-medical purposes, a problem that has exploded in the last decade. A key part of the strategy being released involves government efforts to help states develop monitoring systems to track a patient's use of prescription medicine. The monitoring programs flag cases that indicate a pattern of abuse, such as "doctor shopping," where a patient gets prescriptions for drugs from multiple physicians.

Twenty states have prescription monitoring programs, the report said. The program will be expanded to 11 more states by next year. The Drug Enforcement Administration plans to aggressively pursue pharmacies selling controlled substances illegally over the Internet, an effort that will include deploying modern Web crawler technology to search out those peddling prescription drugs online. Physician training and education programs will also be a part of the new campaign. *Dow Jones International News, March 01, 2004*

FDA, DEA Working on Stricter Guidelines for Patients and Doctors regarding Scheduled Drugs to Curb Abuse
The FDA and the Drug Enforcement Administration (DEA) are developing new, more explicit labeling guidelines for manufacturers of controlled substances like Purdue Pharma's OxyContin and Abbott Laboratories' Vicodin in an effort to curb widespread abuse of the prescription painkillers. FDA Commissioner Mark McClellan said labeling is the centerpiece of the agency's risk management toolbox, in part because it provides the basis for the content of advertising and promotional materials. McClellan said the FDA, DEA and the White House Office of National Drug Control Policy (ONDCP) will pen guidelines that identify what patients are appropriate for controlled substances, as well as expert treatment guidelines for the management of pain and education for physicians.

The increased attention to both the labeling and promotional material for controlled substances is part of the updated National Drug Control Strategy (NDCS) released by the White House. The FDA has been under increasing pressure to improve its oversight of controlled substances. The General Accounting Office (GAO) in January demanded the agency review and improve risk management plans for drugs that could potentially be categorized by the DEA as Schedule II products. In the GAO report, the DEA accused Purdue Pharma of aggressive marketing tactics that led OxyContin (oxycodone HCl) to be prescribed by physicians not well-versed in pain management. *Drug Industry Daily, March 2, 2004*

DEA Pushing to Reschedule Vicodin (hydrocodones) from III to II
The Drug Enforcement Administration is working to make one of the nation's most widely prescribed medications more difficult for patients to obtain as part of its stepped-up offensive against the diversion and abuse of prescription painkillers. Top DEA officials confirm that the agency is eager to change the official listing of the narcotic hydrocodone from Schedule III to the highly restricted Schedule II category of the Controlled

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Substances Act. The DEA says the change is necessary because hydrocodone is being widely misused -- with a 48 percent increase in emergency room reports of hydrocodone abuse from 1998 to 2001. DEA officials would not say when they might begin the process of changing the schedule, but other federal officials said they understand that the DEA wants to act soon.

Pain specialists and pharmacy representatives are opposed to the rescheduling and say the new restrictions would be a burden on the millions of Americans who need the drug to treat serious pain from arthritis, AIDS, cancer and chronic injuries, and that many sufferers are likely to be prescribed other, less effective drugs as a result. Patients, for instance, would have to visit their doctors more often for hydrocodone prescriptions, because they could not be refilled; doctors could no longer phone in prescriptions; and pharmacists would have to fill out significantly more paperwork and keep the drugs in a safe. *The Washington Post February 15, 2004*

Competitive Product Updates

DURAGESIC

Endo and Noven Sign Agreement for Generic Duragesic
Noven Pharmaceuticals, Inc and Endo Pharmaceuticals Inc. signed an agreement under which Noven will license the U.S. and Canadian rights to its developmental transdermal fentanyl patch to Endo. The agreement also establishes an ongoing collaboration between the two companies for the development of additional prescription transdermal products.

Based on the current patent and exclusivity status of Duragesic(R), the companies believe that the generic fentanyl patch could be launched in January 2005, assuming FDA approval is received by that time. Noven has retained all rights to the fentanyl patch outside of the U.S. and Canada, and is exploring strategies to commercialize the product in other territories.

Noven received $8.0 million from Endo upon signing the agreement. Upon Endo's first commercial sale of the fentanyl patch, Noven is entitled to receive an additional payment ranging from $5.0 million to $10.0 million, depending on the timing of launch and the number of generic competitors on the market. Noven will manufacture and supply the product at its cost, and the two companies will share profits on undisclosed terms.

In addition, Noven and Endo have established a collaboration to identify and develop additional new transdermal therapies. As part of this effort, Noven will undertake feasibility studies to determine whether certain compounds identified by the parties can be delivered through Noven's transdermal patch technology. Endo is
expected to fund and manage clinical development of those compounds proceeding into clinical trials. *First Call, February 26, 2004*

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OXYCONTIN®

FDA's ANDA Approvals

Applicant: Amide
Product: Oxycodone HCl USP 15 mg & 30 mg, tab.
Number: 76-636
Date Approved: 2/6/04

Applicant: Impax
Product: Oxycodone HCl extended-release tab., 10 mg, 20mg, and 40 mg
Application No: (76-446)
Date Approved: 12/23/2003
Type of Approval: Tentative Abbreviated

AVINZA®

Avinza Sales Goals Met for 2003; 2004 Market Share Goal at 6-7%, below previous estimates of 10-11%

Ligand reported that 2003 weekly prescription market share reached 3.8% within the company goal of 3-4%. Growth of prescriptions was stated to be in line with other new pain drugs entries at this launch stage. The company strongly believes that results will continue to improve as formulary access, retail pharmacy, distribution, and Organon's primary care sales force productivity increases.

Ligand and Organon continued to make substantial progress in increasing access to AVINZA in managed care. AVINZA has preferred national formulary status with pharmacy benefits managers that cover more than 175 million lives, and Ligand expects this to improve further as several pending contracts are executed. In addition, as of February 2004, Ligand estimates that 42 state Medicaid programs cover AVINZA without restrictions. Cumulatively, 14 states have placed AVINZA in a preferred formulary position relative to at least one of the market leaders. Key formulary additions over the past 90 days include California, Tennessee and Texas, three of the top five Medicaid states.

Ligand expects net product sales between $210 and $230 million, with AVINZA product sales approximately two-thirds. AVINZA weekly retail Rx market share exiting December 2004 between 6-7%. Gross margin on overall product sales estimated at 79-81%
Business Wire Date: March 03, 2004

Ligand and Cardinal Health Execute New Five-Year Agreement to Manufacture and Package Avinza

Ligand Pharmaceuticals Incorporated announced today it has entered into an agreement with Cardinal Health for the manufacturing and packaging of AVINZA. Under a long-term contract, AVINZA will be manufactured at the Cardinal Health facility located in Winchester, Kentucky. Ligand and Cardinal Health have an existing relationship for the fill/finish of Targretin(R) capsules.

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Under the terms of the new agreement, upon the successful completion of technology transfer and regulatory approval, manufacturing will commence for a five-year term. Ligand has an option to extend for an additional two-year period. During the interim, Ligand and Cardinal Health will work closely together in the qualification and validation of the facility. Ligand and Cardinal Health intend to file for regulatory approval in 2005. Financial terms of the contract were not disclosed.

ULTRACET®

Johnson & Johnson Sues Teva to Prevent Generic Form of Ultracet until Patent Expiration

Ortho-McNeil Pharmaceutical is suing Teva Pharmaceutical to block the introduction of a generic version of Ultracet. Ortho-McNeil is seeking a court order that would prevent FDA approval of a generic version of the painkiller Ultracet until the patent expires in 2011.

IONSYS®

I-Flow Reports Strong ON-Q Sales Growth; Driven by Outcomes Studies and Hospital Billing Pull-through Programs.

Sales for I-Flow's Regional Anesthesia market segment, which includes ON-Q Classic, ON-Q C-bloc(TM), ON-Q Elite, Soaker(TM) Catheter and the award-winning PainBuster(R) Pain Management System, increased 125% to $5,226,000 for this year's fourth quarter versus $2,327,000 for the same period in 2002. U.S. sales of ON-Q excluding PainBuster increased 112% for the quarter and 81% for the year, as compared to the same period amounts in the prior year.

Hospital Pull-Through Programs

In January 2004, I-Flow initiated its new ON-Q Third Party Billing Program enabling Ambulatory Surgery Centers (ASCs) to provide patients with this emerging standard in post-surgical pain relief and I-Flow with reimbursement for the cost of the device. Piloted in 2003, the program facilitates the adoption of ON-Q by physicians and minimizes paperwork for participating ASCs. I-Flow's InfuSystem subsidiary, which has built relationships and secured contracts with insurance companies for more than 18 years, will process claims submitted by the centers and directly bill a patient's insurance company. In addition to the ON-Q Third Party Billing, I-Flow introduced a program to educate surgeons on how to submit for payment for the procedure to insert the ON-Q catheter following surgery.

Clinical/Outcomes Results Spark interest from Doctors and Patients alike

Typically, I-Flows studies have reported reductions in hospital stays by one to three days, reductions in narcotics use by 40% to 70% and reductions in
treatment costs by 8% to 30%. It also found that hospital stays for ON-Q patients were reduced by an average of three days from the average of eight days typically needed for recovery, and patient charges were reduced by an average of 18% for cardiovascular surgery.

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A study on the efficacy of ON-Q pain relief treatment following foot and ankle surgery published in Anesthesia & Analgesia found that ON-Q patients had a 70% average decrease in narcotics use, 67% average reduction in pain after surgery and 65% average reduction in length of hospital stay. The results of these clinical and outcomes studies have sparked media interest about the benefits of ON-Q and have resulted in stories like the one that appeared in the December 2003 Reader's Digest, which has a circulation of more than 11 million. These ON-Q mentions in mainstream magazines and newspapers have subsequently led to an increasing awareness by surgeons and patients alike. *Business Wire Date: February 24, 2004*

Pipeline Developments

DURAGESIC®

PALLADONE®

There is no news to report regarding this drug.

OXYMORPHONE ER®

Oxymorphone Extended Release Effective Alternative for Treatment of Osteoarthritis Pain

Oxymorphone extended release (ER) appears to be well tolerated and effective for treatment of moderate to severe chronic pain in patients with osteoarthritis, researchers stated at the American Academy of Pain Medicine 20th Annual Meeting. "Our study shows great pain control in patients over a dosing frequency of 12 hours," said E. Gould, PhD, presenter, Endo Pharmaceuticals, Inc, Chadds, VA. "This study followed osteoarthritis patients for over a year and the pain relief was maintained for over a year with very little dose 'creep' over that period of time." *Janssen Business News March 5*

ULTRACET®

TRAMADOL QD

Biovail NDA Tramadol QD (Ralivia ER®) Accepted by FDA

FDA has accepted NDA for once-daily Tramadol, which will be named **Ralivia ER**. Upon approval, Ralivia ER will be available in 100 mg, 200 mg, and 300 mg tablet. Biovail said it will either market the products with its own sales force or sign a licensing deal, whichever it determines offers the best economics.

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Biovail Submits NDA for Ralivia FlashDose.
Biovail Corporation announced today that it has submitted a New Drug Application to the U.S. Food and Drug Administration (FDA) for Ralivia(TM) FlashDose(R), an orally disintegrating tablet version of the analgesic medication tramadol hydrochloride, intended for the treatment of moderate to moderately severe pain. The application for Ralivia FlashDose was submitted under the provisions of Section 505(b)(2) of the Food, Drug and Cosmetic Act. The goal of Biovail's biopharmaceutics program was to develop a formulation that would deliver an equivalent amount of drug to the systemic circulation as the listed drug Ultram(R), but in a dosage form that offers a choice of administration with or without water, thereby providing a benefit to patients of comparable efficacy and safety with a greatly simplified dosing regimen and potentially higher compliance.

Biovail is evaluating options for commercialization of the pain franchise and is currently in discussions with multiple potential partners regarding out-licensing Ralivia ER alone or in conjunction with Biovail's orally disintegrating pain products. Subject to FDA approval, Ralivia(TM) FlashDose(R) will be available in 50mg, tablets by prescription only. *CCNMatthews March 12, 2004*

Biovail To Complete Sales Force Reorganization In April, Adds Specialty Reps
Biovail will complete the reorganization of its sales force, including the addition of two specialty forces, in April, Senior VP-Commercial Operations Kris Peterson said. Biovail reported that they have realigned their primary care sales force to 475 territories, and are adding two specialty sales forces of roughly 60 representatives each. All the changes should be completed by April.

Biovail announced the sales force reorganization after the termination of its co-promotion agreement with Reliant for Cardizem LA (diltiazem extended-release) At the end of the reorganization, Biovail will have 475 primary care sales reps, down from 535, and 63 reps for both the cardiology/nephrology specialty force and the dermatology/obstetrics specialty force.

Labopharm Remains Confident Regarding Their Tramaodol QD Filing Timeline
Labopharm responded to the Biovail filing announement by saying they were not surprised. Although not stated explicitly, statements made by CEO could place the timing of their once-daily tramadol FDA filing within the next 3-6 months. Labopharm is expected to receive European approval for tramadol in 1H2004.

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Last month, Labopharm released data from two U.S. trials, one of which failed to achieve significance on the required endpoints but the company feels that its filing package is sufficient enough to receive U.S. approval once submitted. Labopharm also indicated that they are looking for a marketing partner.

HYDROCODONE

FDA's ANDA Approvals
Applicant: Andrx
Product: Vicoprofin generic in 7.5 mg/200 mg
Date Approved: Dec/03

IONSYS®

DELEX Begins Phase II for AeroLEF(TM) in Post-Surgical Pain
DELEX Therapeutics has announced that the first patients have been dosed in the Company's Phase II clinical trial of AeroLEF(TM) (aerosolized liposome encapsulated fentanyl) in post-surgical patients. The objective of this study is to confirm the analgesic effects of AeroLEF(TM) in adult patients experiencing moderate to severe pain following an elective knee procedure known as arthroscopic anterior cruciate ligament (ACL) surgery reconstruction. The Phase II study is being conducted at two centers: Toronto General Hospital of the University Health Network, and The Queen Elizabeth II Hospital in Halifax, Nova Scotia. DELEX intends to initiate a Phase II clinical trial targeting cancer pain during the second half of 2004. AeroLEF(TM) is DELEX's lead product candidate based on the ROSE-DS(TM) technology. DELEX believes AeroLEF(TM)'s rapid onset and prolonged duration of effect will offer important benefits and have broad application in patients experiencing acute pain, cancer pain, and breakthrough pain. *PR Newswire, March 2, 2004*

Intranasal Fentanyl for Breakthrough Pain Shows Rapid Delivery in Phase I Study
West Pharmaceutical Services, Inc., reported that Phase I clinical trial data on its nasal fentanyl product for breakthrough pain show rapid delivery of the drug to the bloodstream. The data was presented at the 8th Annual Drug Delivery Partnerships conference in Beverly Hills, California. The objective of the study was to compare the single-dose bioavailability and pharmacokinetics of three different novel nasal fentanyl formulations incorporating the company's proprietary delivery technology with the commercially available oral transmucosal dosage form.

The study involved 18 healthy male and female subjects. The study results showed that nasal treatments appeared to be absorbed more rapidly and gave higher plasma concentration values despite a lower dose level compared to the oral transmucosal dosage form. The product offers the potential for a quick onset of action for breakthrough pain relief. West is planning additional clinical trials, while simultaneously pursuing licensing opportunities. *NewsEdge, March 2004*

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Pipeline Chart

(updates or changes in red)

Drug	Company	Indications	Development Status	Anticipated Filing	Anticipated Launch
Chronic Pain					
Oxycontin Generic	Endo	Same as Oxycontin	FDA Approved; pending appeal	NA	1Q2005
Oxymorphone ER	Endo/Penwest	Mod to Severe	Approvable;	NA	1Q2005
Chronogesic	Endo/Durect	Chronic Pain	Phase III; on hold til late 2004		
Generic fentanyl	Endo/Noven	Same as Duragesic	Filed	Complete	1Q05
Generic fentanyl	Mylan	Same as Duragesic	Approved	Complete	1Q05 Pending litigation
Generic fentanyl	Lavipharm	Same as Duragesic	Active	1Q04	2-3Q2005
Generic fentanyl	Eon	Same as Duragesic	Active	NA	4Q05
Oxyprofen (oxycodone/ibuprofen)	Forest	Mod-Severe	Approvable with more data		1Q05
Oxytrex (oxycodone/naltrexone)	Pain Therapeutics	Chronic Pain	Phase III	2005	2007
Remoxy (oxycodone)		Chronic Pain	Phase I/II; Phase III start 1Q05	2007	
7 day fentanyl patch	3M	Mod to severe			2007
Palladone	Purdue	Mod	Under review		2Q05
Oxycodone/naltrexone	Purdue	Mod to Severe	Phase I		TBD
7 day buprenorphine patch	Purdue	Mild to Mod	Phase III;	2004	2005
Acute Pain					
Ralivia ER (tramadol QD)	Biovail	Acute pain	Under review	Filed Feb 2004	1H05
Tramadol/acetaminphen Flashtab					
Ralivia Flashtab			Under review	Filed Mar 2004	1H05
Tramadol QD	Labopharm	Acute pain		1H2004	1H05
Vicodin CR	Abbott	Acute pain	Phase II	2005	
Dilaulid CR		Acute pain	Phase III	Re-filing 2004	1Q2006
ProSorb-D	aaiPharma	TBD	Phase III	1H2004	
Darvocet	aaiPharma				1Q2005
Duloxetine	Lilly	Pain w/ depression	Phase III		
Cox-2					
Vioxx	Merck	Migraine Juvenile RA		Filed 2Q03 Filed 4Q03	TBD 1Q2005
Arcoxia		OA, RA, Acute pain, Menstrual Pain, Chronic back pain	Non-approvable	Filing accepted by FDA March 2004	2005

Drug	Company	Indications	Development Status	Anticipated Filing	Anticipated Launch
Bextra	Pfizer	Acute Pain Migraine		Re-filing Q104 Nov 2003	
Prexige	Novartis	OA, Acute Pain, Menstrual Pain RA	Phase III	Re-filed 1H04 Refiling	2Q2006 TBD
Mobic		RA	sNDA	TBD	
Post Op					
Bicifadine (non-narcotic analgesic)	DOV	Post Op	Phase III	2006	
Dynastat (injectable Cox-2)	Pharmacia	Post Op	Non-approvable	Re-filing 1H2004	

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General/ Company News

Endo Pharma, MakScientific To Develop Non-Opioid Pain Drugs
Endo Pharmaceuticals Inc. and MakScientific LLC have agreed to develop new drugs for pain. This marks another step in Endo's strategy in expand its line of non-opioid pain products due to the success of the Lidoderm. Endo Pharmaceuticals said selective CB2 receptor agonists have demonstrated analgesic activity preclinically and have potential to rival opioid class in pain control in a non-opioid way. Privately held MakScientific, based in Storrs, Conn. has technology that was originally developed by AlexiPharma Inc. and the University of Connecticut.

Under the agreement, MakScientific has granted Endo exclusive, worldwide rights to jointly develop and commercialize MakScientific's entire existing and future preclinical library of compounds with selective CB2, or cannabinoid receptor, agonist activity in the fields of pain and selected central nervous system disorders. In exchange, Endo Pharmaceuticals, Inc. will make an upfront license-fee payment in addition to payments based on regulatory milestones and royalties upon commercial sales. *Janssen Business News, March 2004*

AETNA & Humana Sue Oxycontin Maker Over Blocking Generic Drugs
Aetna Inc. and Humana Inc. are suing the maker of the painkiller Oxycontin, claiming Purdue illegally blocked the sale of less expensive generic versions.The antitrust lawsuit seeks restitution or the return of excess profits of an unspecified amount, The Hartford Courant reported Saturday. The lawsuit was filed recently in U.S. District Court in New York. The complaint alleges that Purdue obtained patents by misleading the U.S. Patent and Trademark Office about the effectiveness of Oxycontin at low doses. The drug manufacturer reaped "excess profits" of more than $1 billion, the lawsuit says. The patents allowed Purdue to sell the narcotic painkiller for more than if it faced competing generics, the lawsuit says. Aetna says in the complaint that it paid more than $100 million to U.S. pharmacies between 2000 and 2003 for members' Oxycontin prescriptions. Humana says it paid more than $20 million in 2002 and 2003. *Dow Jones International News Date: February 21, 2004*

Janssen-Ortho McNeil Pharmaceutical Services
Karen Hagerty

Researchers Say Pain Is in the Mind of the Believer
New findings from researchers at Michigan, UCLA, and Princeton offer additional evidence on how the brain thinks about pain. Mapping the neural anatomy of pain, the researchers documented the ways in which the brain creates a world of its own from the raw material of physical sensation. Using medical imaging scanners to monitor brain activity, revealed that simple faith in a placebo can alter the neural circuits in the brain that process pain, easing the agony. The greater the brain changes, the greater the reduction in pain, the researchers determined. The experiments were conducted with 14 patients with chronic abdominal pain. *Los Angeles Times, February 20, 2004*

Combined Morphine/Oxycodone proven More Effective than Morphine Alone
Combining morphine and oxycodone for patients with advanced cancer provided more pain relief and resulted in less vomiting than morphine alone. This result was demonstrated in an open label clinical study among 26 patients at the University of Sao Paulo in Brazil. In addition, patients receiving oxycodone complained of less nausea and vomiting, The rescue morphine analgesic consumption was 38% higher in patients receiving only morphine, compared to patients receiving both morphine and oxycodone.

Controlled release formulations of oxycodone as well as morphine were compared for cancer pain. The study started with an open-label, randomized titration phase to achieve stable pain control for 7 days, followed by a double-blind, randomized crossover phase in two periods, 14 days each. At any point, patients were allowed to use oral immediate-release morphine (IRM) as needed, in order to keep visual analogue scale less than or equal to 4. *NewsEdge Corporation, March 2004*

Pfizer sues Teva over Generic Celebrex
Pfizer, the world's biggest drug maker, has sued Teva Pharmaceutical to block a generic version of the painkiller Celebrex. Teva is seeking Food and Drug Administration approval. *The New York Times, March 6, 2004*

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