Drug Portfolio Analysis

Barbara Gilmore-Halliwell & Diane Webb
June 18, 2008
Agenda

- Drug Development Industry Issues & Concerns in 2008
  - Fewer FDA Approvals
  - Blockbusters vs. Targeted Therapeutics
  - Drug Safety
  - Drug Development Costs
  - Political Landscape 2008

- Drug Development Approval Process Overview
  - Drug / Diagnostic: milestones & differences
  - FDA & EMEA
  - Companion Diagnostics & Targeted Therapeutics
  - Challenges (Regulatory / Reimbursement)

- Clinical Trials
- Deals & Alliances
- Portfolio Analysis – Resources by phase of development
- Drug Pipeline Databases
- Conclusion – Implications & Considerations
Drug Development Industry Issues & Concerns in 2008:

- Fewer FDA Approvals
- Blockbusters vs. Targeted Therapeutics
- Drug Safety
- Drug Development Costs
- Political Landscape 2008
Fewer FDA Approvals

Figure 1 | FDA drug approvals. New molecular entities and biologic license applications approved by the US FDA by year.

Drug Approvals / Failures: Implication for Alliances

Table 1 | Drug development scorecard: January 2006 to December 2007

<table>
<thead>
<tr>
<th>Source</th>
<th>FDA approvals</th>
<th>Phase III failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotech industry</td>
<td>47 (45%)</td>
<td>68 (74%)</td>
</tr>
<tr>
<td>Biotech–pharma alliances</td>
<td>16 (16%)</td>
<td>18 (21%)</td>
</tr>
<tr>
<td>Acquisitions/licenses by pharma</td>
<td>4 (4%)</td>
<td>0</td>
</tr>
<tr>
<td>Pharma industry</td>
<td>36 (35%)</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>Total</td>
<td>103</td>
<td>91</td>
</tr>
</tbody>
</table>

Source: Nature Reviews Drug Discovery 2008;7:197-8
Pipeline problems:
Increasing the urge to merge

Box 1 | The great biotech buyout

The past few months have seen a spate of M&A deals in the biotechnology and pharmaceutical industry, as the current climate is forcing firms to plug the gaps in their product pipelines.

<table>
<thead>
<tr>
<th>Company</th>
<th>Target</th>
<th>Price</th>
<th>Main purpose of purchase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer</td>
<td>PowderMed</td>
<td>≤US$400 million*</td>
<td>Influenza vaccines</td>
</tr>
<tr>
<td>Genzyme</td>
<td>AnorMED</td>
<td>US$580 million</td>
<td>Mozobil for haematopoietic stem-cell transplantation</td>
</tr>
<tr>
<td>Genentech</td>
<td>Tanox</td>
<td>US$919 million</td>
<td>Improve returns on Xolair (omalizumab)</td>
</tr>
<tr>
<td>Merck</td>
<td>Sirna</td>
<td>US$1.1 billion</td>
<td>Access to RNA interference technology</td>
</tr>
<tr>
<td>Lilly</td>
<td>ICOS</td>
<td>US$2.1 billion</td>
<td>Full ownership of Cialis (tadalafil)</td>
</tr>
<tr>
<td>Gilead</td>
<td>Myogen</td>
<td>US$2.5 billion</td>
<td>Bolster Gilead’s pulmonary programme</td>
</tr>
<tr>
<td>Abbott</td>
<td>Kos</td>
<td>US$3.7 billion</td>
<td>Acquire cholesterol treatments</td>
</tr>
</tbody>
</table>

*According to press reports.

Source: Nature Drug Discovery V.5 2006
## 2007-2008 Patent Expiry

Source: EvaluatePharma 2008

### All Financial Data in US $ (mln)

<table>
<thead>
<tr>
<th>Rank</th>
<th>Product</th>
<th>Generic Name</th>
<th>Company</th>
<th>Therapeutic Subcategory</th>
<th>Annual Sales WW - Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>93</td>
<td>Fluticasone/Flontraol</td>
<td>fluticasone propionate</td>
<td>GlaxoSmithKline</td>
<td>Corticoids</td>
<td>1,215</td>
</tr>
<tr>
<td>91</td>
<td>Neorecormon</td>
<td>epoetin beta</td>
<td>Roche</td>
<td>Anti-anemics</td>
<td>1,233</td>
</tr>
<tr>
<td>78</td>
<td>Seloken ZOK/Toprol XL</td>
<td>metoprolol succinate</td>
<td>AstraZeneca</td>
<td>Beta blockers</td>
<td>1,282</td>
</tr>
<tr>
<td>20</td>
<td>Norvasc</td>
<td>amlodipine besylate</td>
<td>Pfizer</td>
<td>Calcium antagonists</td>
<td>1,438</td>
</tr>
<tr>
<td>75</td>
<td>Pulmicort</td>
<td>budesonide</td>
<td>AstraZeneca</td>
<td>Corticoids</td>
<td>1,454</td>
</tr>
<tr>
<td>77</td>
<td>Zyrtec/Reactine</td>
<td>cetirizine</td>
<td>Pfizer</td>
<td>Anti-histamines</td>
<td>1,454</td>
</tr>
<tr>
<td>19</td>
<td>Fosamax</td>
<td>alendronate</td>
<td>Merck &amp; Co</td>
<td>Bone calcium regulators</td>
<td>1,454</td>
</tr>
<tr>
<td>58</td>
<td>Prograf</td>
<td>tacrolimus</td>
<td>Astellas Pharma</td>
<td>Immunosuppressants</td>
<td>1,454</td>
</tr>
<tr>
<td>9</td>
<td>Effexor</td>
<td>venlafaxine</td>
<td>Wyeth</td>
<td>Anti-depressants</td>
<td>1,454</td>
</tr>
<tr>
<td>13</td>
<td>Risperdal</td>
<td>risperidone</td>
<td>Johnson &amp; Johnson</td>
<td>Anti-psychotics</td>
<td>1,454</td>
</tr>
<tr>
<td>81</td>
<td>Keppra</td>
<td>levetiracetam</td>
<td>UCB</td>
<td>Anti-epileptics</td>
<td>1,454</td>
</tr>
<tr>
<td>68</td>
<td>Depakote</td>
<td>divalproex sodium</td>
<td>Abbott Laboratories</td>
<td>Anti-epileptics</td>
<td>1,454</td>
</tr>
<tr>
<td>33</td>
<td>Topamax</td>
<td>topiramate</td>
<td>Johnson &amp; Johnson</td>
<td>Anti-epileptics</td>
<td>2,453</td>
</tr>
<tr>
<td>86</td>
<td>Casodex</td>
<td>bicalutamide</td>
<td>AstraZeneca</td>
<td>Hormone therapies</td>
<td>4,826</td>
</tr>
<tr>
<td>60</td>
<td>Betaferon/Betaferon</td>
<td>interferon beta-1a</td>
<td>Bayer AO</td>
<td>MS Therapies</td>
<td>7,022</td>
</tr>
<tr>
<td>42</td>
<td>Lamictal</td>
<td>lamotrigine</td>
<td>GlaxoSmithKline</td>
<td>Anti-epileptics</td>
<td>2,196</td>
</tr>
<tr>
<td>82</td>
<td>Imigran/Imitrex</td>
<td>sumatriptan</td>
<td>GlaxoSmithKline</td>
<td>Anti-migraine preparations</td>
<td>2,196</td>
</tr>
<tr>
<td>60</td>
<td>CellCept</td>
<td>mycophenolate sodium</td>
<td>Roche</td>
<td>Immunosuppressants</td>
<td>2,196</td>
</tr>
<tr>
<td>40</td>
<td>Prevacid</td>
<td>lansoprazole</td>
<td>TAP Pharmaceutical Products</td>
<td>Antacids &amp; anti-ulcerants</td>
<td>2,196</td>
</tr>
<tr>
<td>49</td>
<td>Valtrex/Zelitrex</td>
<td>valacyclovir</td>
<td>GlaxoSmithKline</td>
<td>Anti-virals</td>
<td>2,196</td>
</tr>
</tbody>
</table>

**Source:** EvaluatePharma 2008
Clinical and Approval Times Vary Across Therapeutic Classes, 2002-04

Source: Tufts CSDD, 2006
Approval Success Rates for NCEs Also Vary by Therapeutic Class

Blockbuster vs. Targeted Therapeutic:

- Segmented markets not as profitable as mass markets
- Goals of big pharma moving toward targeted therapeutics & personalized medicine
Blockbuster: Definition

- Blockbuster drugs defined as those with peak sales of $1 billion annually.
- General population use
- Clinical trials large ($$$)
- 79% IND’s fail in clinical development
- Efficacious in 40-60% of the population
FDA Concerns: Safety & Efficacy Issues

Keys issues with medicines today are ..... Safety and efficacy
FDA Safety Concerns

Post Marketing Adverse Event Reports --

Source: CDER Report to the Nation August 2007 (www.fda.org/CDER)
Costs of Drug Development

Key Facts

Research and Development
- Time to develop a drug = 10–15 years\(^1\)

Development Costs
- Cost to develop a drug
  - 2001 = $802 million\(^2\)
  - 1987 = $318 million
  - 1975 = $138 million
- Cost to develop a biologic
  - 2006 = $1.2 billion\(^3\)

- Development Cost 2010 → $2.0 Billion

- Due to an increasing number of drugs being discontinued, forcing companies to write-off investment of failed products.
Prescription Drug Costs as a Percentage of Healthcare -
Healthcare Spend -

Current Spend –
- 8¢ of every $1.00 on Diagnostics
- 92¢ of every $1.00 on Therapy

Better use of diagnostics would decrease the costs of therapy.
Top Contributors to RX Spend by Therapeutic Category (2007)

Sources: Medco data; Drug Trend Report, 2007, p. 15.
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Top RX Driver Trends – H1 2006 vs. H1 2007

Source: Medco Health Sciences (2007)
Political Landscape 2008

- August 2006 – Senator Barack Obama introduced the Genomics & Personalized Medicine Act
- January 2007 – Senators Kennedy & Enzi introduced the Genetic Information Nondiscrimination Act
- May 21, 2008 – GINA (Genetic Information Non-discrimination Act) signed into law
Planning is critical....
Drug Approval Process Overview: Information Maze

- Plethora of resources competing for those budget dollars
- What do you really needed?
- What decisions are to be made?
- Organic development v. in-license?
- Drug / diagnostic combo?
Differences Between Small Molecules & “Targeted” Monoclonal Antibodies –

- **Small Molecules** *(Traditional Pharmaceutical Drugs)*
  - Oral or Intravenous
  - Target multiple pathways
  - Cheaper to manufacture
  - Short half-life
  - Enter cytoplasm, therefore target any molecule or pathway regardless of location

- **Monoclonal Antibodies** *(Biotech drugs)*
  - Intravenous only
  - Target *specific* protein
  - Expensive to manufacture
  - Inconvenient to administer but longer half-life
  - Confined to proteins in extra cellular matrix
Balanced Equation

- **Biotech Strengths**
  - IP for novel products
  - Distinguished products
  - Niche technologies
  - Innovative business cultures

- **Pharma Strengths**
  - Financial strength
  - Development & commercial expertise
  - Global reputation
  - Recognized voice at regulatory agencies
  - Marketing success
## FDA & EMEA - Comparison

<table>
<thead>
<tr>
<th></th>
<th>FDA</th>
<th>EMEA</th>
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</thead>
<tbody>
<tr>
<td>Employees</td>
<td>12,000</td>
<td>440</td>
</tr>
<tr>
<td>Review Language</td>
<td>English</td>
<td>11 Languages</td>
</tr>
<tr>
<td>Countries Covered</td>
<td>1- United States</td>
<td>15 Member Nations</td>
</tr>
<tr>
<td>Communications with Companies</td>
<td>Extensive – Relate to phases, filings &amp; pre-market</td>
<td>Does not communicate with companies until late in process.</td>
</tr>
<tr>
<td>Regulatory influence on drug pricing.</td>
<td>FDA not involved with pricing issues</td>
<td>Once approved, each country must price drug for marketing authorization of country</td>
</tr>
</tbody>
</table>
Pharma & Diagnostic Workflow Perspective -

1) Coordinate joint launch (where feasible / sensible)
2) Manage interdependencies between Rx and Dx workflows

Source: TM Jaeger, Hoffmann-LaRoche, CHI Molecular Medicine TriConference, March 2008
## Drugs with Companion Diagnostics

### All Financial Data in US $ (mln)

<table>
<thead>
<tr>
<th>Company</th>
<th>Annual Sales WW - Sales</th>
<th>Growth per Year (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angiomax/ Angiox</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Medicines Company</td>
<td>85</td>
<td>136</td>
</tr>
<tr>
<td>Erbitux</td>
<td>-</td>
<td>357</td>
</tr>
<tr>
<td>Bristol-Myers Squibb</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gleevec/Glivec</td>
<td>1,128</td>
<td>1,634</td>
</tr>
<tr>
<td>Novartis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Herceptin</td>
<td>876</td>
<td>1,156</td>
</tr>
<tr>
<td>Genentech</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iressa</td>
<td>228</td>
<td>389</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nexavar</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bayer AG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purinethol</td>
<td>33</td>
<td>25</td>
</tr>
<tr>
<td>Teva Pharmaceutical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Selzentry/Celsentri</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Pfizer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tarceva</td>
<td>-</td>
<td>13</td>
</tr>
<tr>
<td>Genentech</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tykerb</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ziagen</td>
<td>273</td>
<td>284</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Total</td>
<td>2,622</td>
<td>3,994</td>
</tr>
</tbody>
</table>

Source: EvaluatePharma® 2008

Tools & Solutions: Knowledge Express

Biomedical News Releases

Thermaclear teams up with Sephora in the quest for clear skin
SAN FRANCISCO, Calif. (September 14, 2007) - Thermaclear announced today that Thermaclear, its innovative, hand-held zona treatment device, is now available at Sephora.com, the leading specialty beauty retailer in the U.S. Thermaclear will also be featured on the newly designed shows on CNSM in late 2007.

Agilent Technologies' Mass Spectrometry Software Platform to Support ALL
DENVER, ASMS, June 2, 2006 - Agilent Technologies, Inc. (NYSE: A) chose the American Society of Mass Spectrometry meeting to announce that it is expanding its MassHunter Workstation software with many new functionalities, new modules and its support for all Agilent mass spectrometers (MS)...

Study: Dietary Ginger may work against cancer growth
Minneapolis, MN - October 25, 2000 - The substance that gives ginger its flavor appears to inhibit the growth of human colon cancer cells, according to research at the University of Minnesota's noise Institute in St. Paul, Minn. Working with mice that lack an immune system, researchers...

Biomedical Deals & Alliances

Chembio awarded NIH grant for rapid 18 test on DPP(TM) Platform
MEDFORD, NY, June 05, 2008 - ChemBio Diagnostics, Inc. (OTCBB: CHEM) (Chembio or the "Company") announced today that it has been awarded a $250,000 one-year Phase One Small Business Innovative Research (SBIR) grant from the United States National Institute of Health (NIH) to develop a...

ZymoGenetics and Merck Serono Initiate Second Phase 2/3 Clinical Study of...
SEATTLE, Jun 06, 2000 - ZymoGenetics, Inc (NASDAQ:ZGNS) announced today that its partner Merck Serono, a division of Merck KGaA, Darmstadt, Germany, initiated a Phase 2/3 trial of standard of care in patients with systemic lupus erythematosus (SLE). The study will evaluate the efficacy and safety of...

OFFICIAL SIGNING CEREMONY FOR WPI STRATEGIC ALLIANCE
MONTREAL, QUEBEC, CANADA - June 6, 2008 - Provolution Life Sciences Inc. (TSX:PLA) (Provolution) announced today that the official signing ceremony for the strategic alliance concluded earlier this year with the Harvard Institute of Biological Products (WPI) is underway.

New Technologies Posted

Immunodominance with Deletions in Domain II that Remove Immunogenic Epitopes
Anti CD22 immunodominance is a desirable linked Fv (MLFv) antibody fragment recombinantly linked to a toxic molecule, capable of killing cells. In particular, a 98 kDa active fragment of Fas associated protein (FAP) containing three specific domains (domain II, domain III and domain IV) has...
HCUPnet is a free, on-line query system based on data from the Healthcare Cost and Utilization Project (HCUP).

- It provides health statistics on hospital stays –
  - National, State & regional.

### Tools & Solutions – HCUP Database

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Total number of discharges</th>
<th>LOS (length of stay, days (mean))</th>
<th>Charges, $ (mean)</th>
<th>Charges, $ (median)</th>
<th>Costs, $ (mean)</th>
<th>Costs, $ (median)</th>
<th>Aggregate costs</th>
<th>Aggregate charges, $ (the &quot;national bill&quot;)</th>
<th>Admitted from emergency department</th>
<th>Admitted from other hospital</th>
<th>Admitted from long term care</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>38,171,798 (100.00%)</td>
<td>4.0</td>
<td>29,455</td>
<td>10,754</td>
<td>7,632</td>
<td>4,274</td>
<td>294,975</td>
<td>700,119,497,819</td>
<td>15,672,096 (43.12%)</td>
<td>1,350,324 (3.49%)</td>
<td>671,349 (1.40%)</td>
</tr>
<tr>
<td>1-17</td>
<td>1,764,401 (4.62%)</td>
<td>3.6</td>
<td>1,549</td>
<td>7,445</td>
<td>5,787</td>
<td>2,985</td>
<td>10,649,681</td>
<td>25,957,747,399</td>
<td>859,453 (48.72%)</td>
<td>83,120 (4.65%)</td>
<td>6,631 (0.69%)</td>
</tr>
<tr>
<td>18-44</td>
<td>16,329,379 (52.70%)</td>
<td>3.7</td>
<td>23,084</td>
<td>9,698</td>
<td>5,674</td>
<td>3,442</td>
<td>38,643,729</td>
<td>186,305,686,664</td>
<td>5,625,134 (31.12%)</td>
<td>235,671 (2.16%)</td>
<td>161,322 (0.66%)</td>
</tr>
<tr>
<td>45-64</td>
<td>8,556,050 (22.11%)</td>
<td>5.0</td>
<td>25,687</td>
<td>14,963</td>
<td>5,603</td>
<td>4,500</td>
<td>20,212,711</td>
<td>215,945,395,325</td>
<td>4,445,226 (52.00%)</td>
<td>351,014 (4.41%)</td>
<td>134,657 (1.56%)</td>
</tr>
<tr>
<td>65+</td>
<td>10,347,469 (26.75%)</td>
<td>5.7</td>
<td>27,410</td>
<td>10,285</td>
<td>5,102</td>
<td>3,620</td>
<td>22,317,647</td>
<td>60,403,278,793</td>
<td>5,621,332 (34.33%)</td>
<td>485,502 (4.69%)</td>
<td>220,770 (2.13%)</td>
</tr>
<tr>
<td>Missing</td>
<td>2,711,697 (7.01%)</td>
<td>5.0</td>
<td>22,258</td>
<td>15,885</td>
<td>5,218</td>
<td>5,470</td>
<td>21,937,347</td>
<td>182,230,756 (67.22%)</td>
<td>102,200 (3.77%)</td>
<td>39,849 (4.31%)</td>
<td>807 (0.05%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>15,773,422 (40.80%)</td>
<td>5.0</td>
<td>23,420</td>
<td>11,928</td>
<td>5,753</td>
<td>4,781</td>
<td>137,495,361</td>
<td>369,391,144,138</td>
<td>7,629,850 (48.37%)</td>
<td>606,615 (4.23%)</td>
<td>251,451 (1.59%)</td>
</tr>
<tr>
<td>Female</td>
<td>22,428,366 (59.20%)</td>
<td>4.4</td>
<td>19,403</td>
<td>10,101</td>
<td>6,065</td>
<td>4,629</td>
<td>156,047,101</td>
<td>410,360,677,777</td>
<td>5,954,193 (29.62%)</td>
<td>679,612 (2.65%)</td>
<td>317,612 (1.04%)</td>
</tr>
<tr>
<td>Owner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>5,194,846 (14.34%)</td>
<td>4.8</td>
<td>17,112</td>
<td>6,887</td>
<td>7,921</td>
<td>4,221</td>
<td>41,169,928</td>
<td>88,846,437,705</td>
<td>2,306,094 (44.39%)</td>
<td>165,808 (3.12%)</td>
<td>40,947 (0.96%)</td>
</tr>
<tr>
<td>Private, not-for-profit</td>
<td>26,023,111 (72.48%)</td>
<td>4.6</td>
<td>20,513</td>
<td>10,035</td>
<td>7,719</td>
<td>3,605</td>
<td>215,947,982</td>
<td>574,634,316,324</td>
<td>12,193,721 (43.51%)</td>
<td>1,023,436 (3.65%)</td>
<td>420,842 (1.52%)</td>
</tr>
<tr>
<td>Private, for-profit</td>
<td>5,904,881 (13.25%)</td>
<td>4.5</td>
<td>23,970</td>
<td>13,010</td>
<td>6,873</td>
<td>3,547</td>
<td>34,455,340,196</td>
<td>120,686,916,730</td>
<td>2,059,309 (41.15%)</td>
<td>115,699 (2.30%)</td>
<td>71,469 (1.43%)</td>
</tr>
</tbody>
</table>
Tools & Solutions – EvaluatePharma

EvaluatePharma®

Helping you find value in the pharma & biotech sector

Monday 2 June, 2008

Peer Group Analyzer My Portfolio Reports Tools My Account Help & Support

Smart Search

New/Manager Search Only

Browse Categories

Global Analysis (all companies) NOW Company Product Genentech Name Therapeutic Category Epi/ERA-TCO Code Pharmaceutical Class Technology Indication Orphan Drug Market Status (Current) Deal Type Deal Partner Product Source

Alpha Tools

NPV Analyzer NOW Caloridar of Events NOW EP Vantage NOW

Core Tools

Merge Companies Company Rank Peer Group Analyzer NOW

What's New

EvaluatePharma's Coverage Continues to Grow 14 New Companies Available...

Q1 2008 Results: Company Analysis 10-Jun-2008
Increased Coverage 22 New Companies Available 01-Jun-2008

EventAnalyzer


EvaluatePharma's Coverage Continues to Grow 14 New Companies Available...

EP Vantage

Current

> Global seeking sharper research focus 31-Jul-2008
> BIG predicting a windfall of profits from Januske 05-Jun-2008
> ASCO interview – Modified data should help deal talkas 05-Jun-2008
> J&J's new R&D head to make a splash 04-Jun-2008

Analysis

> AGA - DPP-IVs and GLP-1s steal the show 03-Jun-2008
> ASCO EventAnalyzer 2008's winners and losers 03-Jun-2008

Insider's attempt to enter US market met with scepticism 03-Jun-2008

Marketing a "broken company" 04-Jun-2008

EventAnalyzer


EvaluatePharma's Coverage Continues to Grow 14 New Companies Available...

EvaluatePharma’s Coverage Continues to Grow...
Tools & Solutions – 10K Wizard
Planning is critical.
Clinical Trials Databases

- ADIS Clinical Trials Insight ($$$) – link with ADIS RDI
- Cancer Clinical Trials, NIH (free)
  - [www.cancer.gov/clinicaltrials](http://www.cancer.gov/clinicaltrials)
- CenterWatch Clinical Trials Listing Service ($)
  - [www.centerwatch.com](http://www.centerwatch.com)
- CiteLine TrialTrove (Informa) ($$$) – Link with PharmaProjects
  - [www.citeline.com/trialtrove.html](http://www.citeline.com/trialtrove.html)
- ClinicalTrials.gov (NIH) (free)
  - [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- Inteleos ($)
  - [www.inteleos.com](http://www.inteleos.com)
ADIS – Clinical Trial Insight

Clinical Trials Insight

Ongoing Trials Browse

Select category 1

Therapeutic Area

Active

Therapeutic Area

Indication

Companies

Target Disease

Load Study Centre

Load Investigator

El Khoury A (11)

El Khoury B (11)

El Rahal A (5)

El Hadi A (11)

El Hadi R (11)

El Hadi P (3)

El Hadi R (3)

Therapeutic Area

Pancreatic cancer

Phase I trial in patients with metastatic disease

Recruiting

Complete clinical response, Objective clinical response, Partial clinical response, Progression-free survival, Recommended phase I dose, Survival

Results

Page 1 of 1 Results Pages

Output: Article Title Studies Status Study Endpoints

1


Recruiting

Complete clinical response, Objective clinical response, Partial clinical response, Progression-free survival, Recommended phase I dose, Survival

2

Cetuximab + irinotecan + 5-FU/leucovorin. Alkaline reactions. Various toxicities Phase I trial in patients with metastastic colorectal cancer (Last Modified: 2/2/2009)

Initiated

Biokiller levels, Disease progression, Pharmacokinetic parameters, Progression-free survival, Progression-free survival duration, Recommended dose

3

Regimen comparison in patients with solid tumours (Last Modified: 2/2/2009)

Recruiting

Clinical response, Maximum tolerated dose

4

Panitumumab + cetuximab + irinotecan. Therapeutic Use Colon cancer Phase I trial of second-line therapy in patients with locally advanced or metastatic disease (Last Modified: 2/2/2009)

Initiated

Objective clinical response rate, Progression-free survival, Recommended phase II dose, Survival

5

Brivanib + cetuximab adverse reactions. Various toxicities Phase I trial in metastatic disease (Last Modified: 2/2/2009)

In progress

Duration of objective clinical response, Maximum tolerated dose. Pharmacokinetics
ADIS – Clinical Trial Insight

Clinical Trials Insight

Revise Search → Back to Results → Document

Reference  Study Details  Study History  Descriptors & Links

Bevacizumab +/- irinotecan: therapeutic use
Glioblastoma
Phase II trial in patients with glioblastoma multiforme in first or second relapse

Location: USA
Endpoints: Duration of objective clinical response, Objective clinical response rate, Progression-free survival rate, Survival

<table>
<thead>
<tr>
<th>SUBJECTS</th>
<th>Type</th>
<th>No. of Patients</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>patients</td>
<td>167 (actual)</td>
<td>adult</td>
<td></td>
</tr>
</tbody>
</table>

Patient Inclusion Criteria: Signed informed consent; age greater than or equal to 18 years; histologically confirmed glioblastoma multiforme in first or second relapse; radiographic demonstration of disease progression following prior therapy; bidimensionally measurable disease with a minimum measurement of 1 cm in one diameter on magnetic resonance imaging (MRI) performed within 14 days prior to first treatment; an interval of at least 4 weeks since prior surgical resection; prior standard radiation for glioblastoma multiforme; recovered from effects of prior therapy (including the following: 4 weeks from cytotoxic agents; 6 weeks from intravenous; 3 weeks from procarbazine; 2 weeks from vincristine; 4 weeks from any investigational agents); 1 week from non-cytotoxic agents; 3 weeks from radiotherapy (or 4 weeks if a new lesion develops that is outside the primary radiation field relative to the pre-radiation MRI); Karnofsky performance status of at least 70 percent; life expectancy greater than 12 weeks; use of effective means of contraception in males and females of child-bearing potential; ability to comply with study and follow-up procedures.

Patient Exclusion Criteria: Prior irinotecan, bevacizumab or agent(s) that target the vascular endothelial growth factor pathway or vascular endothelial growth factor receptor; prior pemetrexed; 20 with carboplatin; prior intracerebral agent; need for urgent palliative intervention for primary disease; evidence of recent hemorrhage on baseline MRI of the brain (except presence of hemorrhage, resolving hemorrhagic changes related to surgery or presence of punctate hemorrhage in the tumor), received more than two treatment regimens for grade III and/or IV glioma; blood pressure reading greater than 150/100 mm Hg; history of hypertensive encephalopathy; New York Heart Association (NYHA) grade II or greater congestive heart failure; history of myocardial infarction or unstable
<table>
<thead>
<tr>
<th>Category</th>
<th>Clinical Trials By Therapeutic Category</th>
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<tbody>
<tr>
<td>Autoimmune Inflammation</td>
<td>Alopecia Areata (dermatology) (Jun 09)</td>
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<td>Asthma</td>
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<td>Malignant Dermatitis</td>
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<tr>
<td></td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<tr>
<td></td>
<td>Celiac Disease</td>
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<tr>
<td>Cardiovascular</td>
<td>Acute Coronary Syndromes</td>
</tr>
<tr>
<td></td>
<td>Arrhythmia</td>
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<tr>
<td></td>
<td>Congestive Heart Failure</td>
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<td>CNS</td>
<td>Alcohol Dependence</td>
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<td></td>
<td>Alzheimer’s Disease</td>
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<td></td>
<td>Amyotrophic Lateral Sclerosis</td>
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<tr>
<td></td>
<td>Anxiety</td>
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<tr>
<td></td>
<td>Attention Deficit Hyperactivity Disorder</td>
</tr>
<tr>
<td></td>
<td>Autism</td>
</tr>
<tr>
<td></td>
<td>Bipolar Disorder</td>
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<tr>
<td>Gastrointestinal</td>
<td>Benign Prostatic Hyperplasia</td>
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<td></td>
<td>Constipation</td>
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<td>Endometriosis</td>
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<td>Infectious Disease</td>
<td>Bacterial Skin Infection</td>
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<td>HIV</td>
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<td></td>
<td>HCV</td>
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<tr>
<td></td>
<td>HIV</td>
</tr>
<tr>
<td>Metabolic Endocrinology</td>
<td>Anemia</td>
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<td></td>
<td>Constipation</td>
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<td></td>
<td>Diabetic Complications</td>
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<td></td>
<td>Functional Diabetes</td>
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<tr>
<td>Oncology</td>
<td>Bladder</td>
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<tr>
<td></td>
<td>Brain</td>
</tr>
<tr>
<td></td>
<td>Leukemia, Chronic Lymphocytic Leukemia</td>
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<tr>
<td></td>
<td>Leukemia, Chronic Myelogenous Leukemia</td>
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</table>

**Other Citeline Services**
- TrialShare - Competitive Intelligence Maps
- SiteTrove - Investigator and Site Database
- Pipeline - Drug Intelligence

**Support**
- Client Services
  - Get technical support, schedule training, suggest a feature, etc.
- Research Support
  - Request research on a trial, help with search strategies, specialized data exports, etc.
- Account Services
  - Have a question about your subscription? Don’t see a disease listed?
### Citeline TrialTrove

### Search Criteria: Epidermal growth factor receptor (EGFR) antagonist

Viewing 312 ongoing trials out of a total of 513 in your subscription

<table>
<thead>
<tr>
<th>Phase</th>
<th>Disease Type</th>
<th>Patient Segment</th>
<th>Sponsorship</th>
<th>Primary Drugs</th>
<th>Other Drugs</th>
<th>Protocol ID / Trial Identifier</th>
<th>Status</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>I</td>
<td>Colorectal</td>
<td>III, IV</td>
<td>Merck KGaA</td>
<td>Ertux</td>
<td>Bevacizumab, oxaliplatin, leucovorin</td>
<td>NCT00001234, NCT00001235</td>
<td>Closed</td>
<td>View</td>
</tr>
<tr>
<td>I</td>
<td>Colorectal, Head/Neck, Lung, Non-Small Cell, Pancreas, Renal</td>
<td>III, IV, Refractory/Relapsed</td>
<td>Institute for Drug Development, NC</td>
<td>Ertux</td>
<td></td>
<td></td>
<td>Open</td>
<td>View</td>
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<tr>
<td>I</td>
<td>Pancreas</td>
<td>III</td>
<td>NC, Vanderbilt Ingram Cancer Center</td>
<td>Ertux</td>
<td>Necitumab, radiation therapy</td>
<td>NCT00001235</td>
<td>Closed</td>
<td>View</td>
</tr>
<tr>
<td>I</td>
<td>CNS, Oligodendroma</td>
<td>N/A</td>
<td>Ludwig Institute for Cancer Research</td>
<td>ch606</td>
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<td></td>
<td>Open</td>
<td>View</td>
</tr>
<tr>
<td>I</td>
<td>Colorectal, Gastrointestinal</td>
<td>III, IV, Refractory/Relapsed</td>
<td>BMS</td>
<td>Ertux</td>
<td>Trastuzumab, bortezomib, vorinostat</td>
<td>NCT00001236</td>
<td>Closed</td>
<td>View</td>
</tr>
</tbody>
</table>
Inteleos – Clinical Trials Section

Clinical Trials Search or Analysis

Select Field

Search

Condition

Analysis

Drill-Down Analysis
Comparison Analysis
Pipeline Matrix

Starting with

Containing

Brain Neoplasms
Brain Neoplasms, Primary Malignant
Brain Pathology
Brain Stem Gloma,
Brain Stem Neoplasms, Primary
Brain Tumor
Brain Tumor, Primary
Brain Tumor, Recurrent
Brain Tumors
Branch Retinal Vein Occlusion
BRCA1 Protein
BRCA2 Protein
Breaththrough Bleeding
Breaththrough Pain
Breast
Breast Cancer
Breast Cancer Metastatic
Breast Cancer With Bone Metastasis

My Query

SEARCH: Select the field(s) you wish to search from the drop-down menu; choose the term(s) from the associated list and add them to ‘My Query’. Combine fields and terms to create simple or complex queries.
Deals & Alliance Resources Comparisons

- EvaluatePharma
- IDeals (Thomson Scientific)
- MedTrack
- Recombinant Capital’s ReCap
- Windhover
EvaluatePharma: Search by Deal Type – In-licensed, Joint Venture, Company Acquisition, Product Acquisition, Out-licensed Technology
## EvaluatePharma – Top In-Licensed Drugs by Deal Value

### Sample Deal Report from EvaluatePharma®

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Deal Type</th>
<th>Product</th>
<th>Deal Partner/ Product Source</th>
<th>Status on Deal Date</th>
<th>Deal Date</th>
<th>Upfront Payment in $ (m)</th>
<th>Deal Value in $ (m)</th>
<th>Deal Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Genzyme</td>
<td>In-licensed</td>
<td>mipomersen</td>
<td>Isis Pharmaceuticals</td>
<td>Phase III</td>
<td>1/7/2008</td>
<td>175</td>
<td>1.900</td>
<td>JANVIE® in-licensed VV rights from Isis Pharmaceuticals; (part of larger strategic alliance); Genzyme paid $130m to buy 10% shares of Isis stock; will pay strum upfront fee, potential zoonotic development &amp; regulatory milestone payments plus up to $750m in commercial milestone payments. Genzyme &amp; Isis will share profits; initially 70/30 Genzyme/Isis split &amp; reaching on a sliding scale. $665 when annual VV revenues reach $260m. Deal also gives Genzyme preferred access to future Isa drugs for CNS &amp; certain rare diseases.</td>
</tr>
<tr>
<td>2</td>
<td>GlaxoSmithKline</td>
<td>In-licensed</td>
<td>Tarcept</td>
<td>Novartis Pharmaceuticals</td>
<td>Phase II</td>
<td>7/27/2007</td>
<td>20</td>
<td>1.490</td>
<td>JULIO7 Entered collaboration with Tarcept covering pain, smoking cessation, addiction, obesity and Parkinson’s disease. Glaxo to pay $50m upfront including $15m in start-up investment. Milestones up to $1.5bn &amp; tiered double-digit royalties on sales. In return for VVW rights to develop &amp; market candidates from TRCT’s novel receptor receptor program. Glaxo has option to assume development after Pt. TRCT retains co-promotion option for pain to specialists &amp; hospital based physicians in U.S.</td>
</tr>
<tr>
<td>3</td>
<td>GlaxoSmithKline</td>
<td>In-licensed</td>
<td>Oral/288118</td>
<td>Oncotec Pharmaceuticals</td>
<td>Preclinical</td>
<td>12/10/2007</td>
<td>-</td>
<td>1.345</td>
<td>DECST Research Alliance with Oncotec for cancer stem cell antibody programme; Glaxo to pay upfront fees (comprised of cash as well as an equity investment), milestones up to $1.4bn &amp; double-digit royalties on sales. In return for Oncotec’s financial support of the Oncotec Trasirin programme.</td>
</tr>
<tr>
<td>4</td>
<td>GlaxoSmithKline</td>
<td>In-licensed</td>
<td>Eliquis</td>
<td>Synta Pharmaceuticals</td>
<td>Phase II</td>
<td>10/8/2007</td>
<td>75</td>
<td>967</td>
<td>DECST Glaxo pays $80m up front to Synta. OCTO7 in-licensed VVW ex US rights from Synta; Glaxo to pay upfront payments $80m, milestone up to $475m; regulatory milestone payments up to $90m &amp; non-refundable, tiered royalties. TIM &amp; Synta to share all development costs. Glaxo to purchase up to $450m of Synta’s common stock.</td>
</tr>
<tr>
<td>5</td>
<td>Merck &amp; Co</td>
<td>In-licensed</td>
<td>Deforolimus (UK: 00659)</td>
<td>ARIAD Pharmaceuticals</td>
<td>Phase II</td>
<td>7/12/2007</td>
<td>75</td>
<td>927</td>
<td>JULI License VVW rights from ARIAD in exchange for $75m upfront, up to $450m in regulatory milestone payments, up to $260m in sales-based milestones, at least $200m in preclinical development expenses. Merck is responsible for the global development costs, up to $155m in global development milestone payments. In the case of VVW ex US based double-digit royalties &amp; US co-promotion (ARIAD keeps US sales &amp; pays Merck 50% of profits). Companies to each fund 50% of cost of US development. TIM to pay 10% of the cost of ex-US development. ARIAD intends to manufacture the API. Merck will be responsible for US manufacture and sales.</td>
</tr>
<tr>
<td>6</td>
<td>Astellas Pharma</td>
<td>In-licensed</td>
<td>CTS2-21106</td>
<td>Colontec</td>
<td>Phase I</td>
<td>4/25/2007</td>
<td>75</td>
<td>749</td>
<td>APF657 VVW rights in-licensed from Colontec. Colontec will receive an upfront payment of $50m; an equity investment of $230m &amp; up to $290m in milestones. In addition, Colontec has the rights to receive development milestones for next generation beta-secretase inhibitors discovered under the terms of the research collaboration. Astellas will fund 100% of the pre-Phase II development costs. Astellas will share the Phase II development costs. Astellas has exclusive worldwide commercialization rights while Colontec retains the right to co-promote in the U.S., where profit will be shared. Colontec will receive royalties on sales outside the U.S.</td>
</tr>
<tr>
<td>7</td>
<td>Sanofi-Aventis</td>
<td>In-licensed</td>
<td>L-2 Trap</td>
<td>Regeneron Pharmaceuticals</td>
<td>Phase I</td>
<td>11/29/2007</td>
<td>95</td>
<td>707</td>
<td>NOVOT in-licensed VVW rights from Regeneron, REGN to receive $50m up front payment, $475m in R&amp;D funding over next 5 yrs, equity investment of $332m &amp; up to $560mn milestone payment for monoclonal antibody (MAb) target; (another 4 (Kd) mAb target; (another 4 (Kd) mAb target; (another 4 (Kd) mAb target; (another 4 (Kd) mAb target; (another 4 (Kd) mAb target; (another 4 (Kd) mAb target; (another 4 (Kd) mAb target) &amp; any other MAbs developed through collaboration. Sanofi-Aventis will have the option to extend its research agreement for up to an additional three years. Regeneron will have the right to co-promote any and all collaboration products worldwide. In U.S., profits will be split equally. Ex-U.S., profits will be split on a pre-determined sliding scale with Sanofi-Aventis’ share ranging from 55% to 30%. Payments include product fees: to $26m Research &amp; Development Project &amp; $3m Inhibitor.</td>
</tr>
<tr>
<td>8</td>
<td>Boehringer Ingelheim</td>
<td>In-licensed</td>
<td>Immunology Research Project</td>
<td>Ablynx</td>
<td>Research project</td>
<td>9/7/2007</td>
<td>-</td>
<td>656</td>
<td>BEPO7 Ablynx &amp; Boehringer ingelheim collaborate jointly in the discovery of up to 10 Nanobody therapeutic agents against agreed targets across multiple therapeutic areas including immunology, oncology &amp; respiratory. Boehringer expects to pay up to $75m during R&amp;D term (including €15m in equity), plus up to €120mn in development milestone payments per Nanobody &amp; royalties. Ablynx has certain co-promotion rights in Europe.</td>
</tr>
</tbody>
</table>

**Milestones (Development):**

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Milestones (Development)</th>
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<tbody>
<tr>
<td>1</td>
<td>Genzyme</td>
<td>$25</td>
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<tr>
<td>2</td>
<td>GlaxoSmithKline</td>
<td>$1.464</td>
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<td>3</td>
<td>GlaxoSmithKline</td>
<td>$1.345</td>
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<td>4</td>
<td>GlaxoSmithKline</td>
<td>$577</td>
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<td>5</td>
<td>Merck &amp; Co</td>
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<td>6</td>
<td>Astellas Pharma</td>
<td>$640</td>
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<td>7</td>
<td>Sanofi-Aventis</td>
<td>$272</td>
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<tr>
<td>8</td>
<td>Boehringer Ingelheim</td>
<td>$649</td>
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</table>
Sample View of Peer Group Analyzer – Comparing Mid Cap Companies
Thomson’s - IDeals

Drugs: Priority Alert

Adolor and GSK launch Enterog for post-operative ileus in the US

Adolor Corp, June 10, 2008

News Release

Adolor and GlaxoSmithKline (GSK) have launched their mu opioid receptor antagonist, Enterog (alvimopan), in the US for post-operative ileus (POI).

The drug was approved by the FDA in May 2008 [908026].

Michael R Dougherty, President and CEO of Adolor, said: “Enterog is the only approved product with a demonstrated ability to accelerate gastrointestinal recovery following bowel resection surgery. POI is a serious condition that can have negative consequences for patients, and impose considerable expense on the healthcare system. We are working closely with GSK to enroll hospitals across the US to make Enterog available to bowel resection surgical teams and patients.”

In April 2002, Adolor and GSK agreed to codevelop the drug [447874].

In February 2007, a Friedman Billings Ramsey analyst believed that the overall market opportunity was sufficiently large to accommodate both Enterog and its primary competitor, Wyeth and Progenics Pharmaceutical’s subcutaneous formulation of methylcyclotetramine bromide. The analyst expected Enterog to gain FDA approval for POI by early 2008 and commented that there was a possibility that Enterog’s efficacy and safety profile would resonate more with doctors [779552], [914770].
Thomson Scientific - IDeals

Antimicrobial

Blood system agent
CNS modulator
Cardiovascular agent
Cell control agent
Dermatological agent
Diagnostic agent
Gastrointestinal system agent
Gene target
Genetic modulator
Hormone modulator
Immunomodulator
Ion modulator
Local hormone modulator
Metabolic modulator
Musculoskeletal system modulator
Neurotransmitter modulator
Ophthalmological agent
Other actions
Protein target
Renal system agent
Reproductive system modulator
Respiratory system agent

Select a general therapeutic area

OR
Start by selecting a drug class by mode of action

Neoplasm
Cardiovascular disease
Degeneration
Dermatological disease
Endocrine disease
Fatigue
Gastrointestinal disease
Genetic disorder
Genitourinary disease
Growth disorder
Gynecology and obstetrics
Hematological disease
Immune disorder
Infection
Inflammation
Injury
Metabolic disorder
Mouth disease
Musculoskeletal disease
Neurological disease
Nutritional disorder
Ocular disease
Otorhinolaryngological disease
Prophylaxis
Psychiatric disorder
Respiratory disease
Temperature disorder
Toxicity & intoxication
Ulcer
Unidentified
Thomson-Pharma’s Deal Search
# Deal & Alliance - MedTrack

### Basic Search

**Search by**
- Company Name

**Search Period**
- Time Period: No Restriction
- Date Range:
  - From:
  - To:

**Geography**
- Select Region(s) or Countries:
  - NORTH AMERICA
    - USA
  - Canada
  - EUROPE
    - Austria
    - Belgium
    - Czech Republic
  - Denmark
  - Finland
  - France

### Categories

**Select Deal Categories based on**
- Product
- Technology
- Miscellaneous

**Therapeutic Category**
- All Areas
  - Autoimmune and Inflammation
  - Blood and Lymphatic System
  - Cancer
  - Cardiovascular and Circulatory System

**Deal Parties**
- All Parties
  - Pharma/Pharma
  - Pharma/Biotech
  - Biotech/Pharma
  - Drug Delivery

**Deal Types**
- All Deals
  - Acquisition
  - Co-development
  - Co-Marketing
  - Co-promotion

**Clinical Trial Phase**
- All Phases
  - Research
  - Preclinical
  - Phase I
  - Phase II

**Area of Deal Focus**
- All Areas
  - Nutrition
  - Devices
  - Services
  - Technology

### Financial Terms

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<th>Payment Type</th>
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<th>Max (in $millions)</th>
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<td>Royalty</td>
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<td>Termination Fees</td>
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<td>Upfront cash</td>
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<td>Upfront Equity</td>
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</table>

**Note:**
The Payment Types listed above are terms or conditions specified by the company or classifications determined from the public information evaluated. A specific Payment Type may not retrieve all possible deals from a search. For more accurate search results, please try multiple criteria.
## MedTRACK – Company Comparison

### Selected Companies for Comparison

**Biotechnology:**
- Amgen Inc. (AMGN)

**Pharmaceuticals:**
- Bristol-Myers Squibb Co. (BMY)
- Genentech Inc. (DNA)
- Roche Holding AG (RHHBY)

### Comparison by Multi Period Financials

#### Annual Income Statement

<table>
<thead>
<tr>
<th></th>
<th>AMGN</th>
<th>BMY</th>
<th>DNA</th>
<th>RHHBY</th>
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<tbody>
<tr>
<td><strong>2007</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>REVENUES:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sales</td>
<td>14,311.0</td>
<td>19,348.0</td>
<td>11,724.0</td>
<td>42,977.2</td>
</tr>
<tr>
<td>Other Revenues</td>
<td>460.0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total Revenues</td>
<td>14,771.0</td>
<td>19,348.0</td>
<td>11,724.0</td>
<td>42,977.2</td>
</tr>
<tr>
<td><strong>EXPENSES:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost Of Goods Sold</td>
<td>2,308.0</td>
<td>6,026.0</td>
<td>1,500.0</td>
<td>12,668.6</td>
</tr>
<tr>
<td>Cost Of Goods Sold, Total</td>
<td>2,308.0</td>
<td>6,026.0</td>
<td>1,500.0</td>
<td>12,668.6</td>
</tr>
<tr>
<td>GROSS PROFIT</td>
<td>12,463.0</td>
<td>13,322.0</td>
<td>10,224.0</td>
<td>30,308.7</td>
</tr>
<tr>
<td>Selling General &amp; Admin Exp.</td>
<td>3,485.0</td>
<td>6,227.0</td>
<td>2,077.0</td>
<td>10,050.5</td>
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<tr>
<td>R &amp; D Expense</td>
<td>3,247.0</td>
<td>3,080.0</td>
<td>2,293.0</td>
<td>7,214.7</td>
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<tr>
<td>Stock-Based Compensation</td>
<td>-</td>
<td>133.0</td>
<td>403.0</td>
<td>540.1</td>
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<tr>
<td>Selling Gen. &amp; Admin Exp., Total</td>
<td>6,732.0</td>
<td>9,440.0</td>
<td>4,773.0</td>
<td>17,813.3</td>
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<tr>
<td>Amort. Of Intangible Assets</td>
<td>295.0</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Depr. &amp; Amortization, Total</td>
<td>295.0</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td><strong>OPERATING PROFIT</strong></td>
<td>5,436.0</td>
<td>3,882.0</td>
<td>5,451.0</td>
<td>12,495.3</td>
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<tr>
<td>Interest Expense - Non Finance Div.</td>
<td>-328.0</td>
<td>-422.0</td>
<td>-76.0</td>
<td>-256.7</td>
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<tr>
<td>Interest Expense, Total</td>
<td>-328.0</td>
<td>-422.0</td>
<td>-76.0</td>
<td>-256.7</td>
</tr>
<tr>
<td>Interest And Invest. Income</td>
<td>309.0</td>
<td>241.0</td>
<td>270.0</td>
<td>959.5</td>
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</table>
MedTRACK – Un-partnered Deals?

### MedTRACK Disease View

**Pipeline**
- **Financial**
- **Both**
- **Product**
- **Sales**
- **Contact**
- **Patents**
- **Deals**
- **Milestones**
- **News**
- **Epidemiology**

**Your selected criteria:**
- **Cancer** ➔ **Multiple Myeloma**

63 companies passed criteria in **All Companies**

**Search within results by:**
- **Keyword**

**Entire List | Result Pages:** 1 2 3 4 5 6 7

**Product Partnering Filter:**
- **All Multiple Myeloma Products | Partnered | UnPartnered**

**Go to Full Pipeline**

**Page 1 of 7**

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Symbol</th>
<th>Total Products</th>
<th>Total Trials</th>
<th>PC 1</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>PA</th>
<th>A</th>
<th>M</th>
<th>DN</th>
<th>DPA</th>
<th>More Info</th>
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<td>0</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Q C S G N</td>
<td></td>
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<tr>
<td>Affirmed Therapeutics AG</td>
<td></td>
<td>10</td>
<td>0</td>
<td>1</td>
<td></td>
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<td>Q C S G N</td>
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<td>Amgen Inc</td>
<td>AMGN</td>
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<td>1</td>
<td>1</td>
<td></td>
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<td></td>
<td>Q C S G N</td>
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<tr>
<td>AmpliMed Corporation</td>
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<td>6</td>
<td>1</td>
<td>1</td>
<td></td>
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<td>Q C S G N</td>
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<td>Antyla, Inc.</td>
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<td>0</td>
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<td></td>
<td></td>
<td>Q C S G N</td>
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<tr>
<td>Ascenta Therapeutics, Inc.</td>
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<td></td>
<td></td>
<td>Q C S G N</td>
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<tr>
<td>AstraZeneca Plc</td>
<td>AZN</td>
<td>291</td>
<td>1</td>
<td>1</td>
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<td></td>
<td></td>
<td></td>
<td>Q C S G N</td>
<td></td>
</tr>
</tbody>
</table>
Recombinant Capital’s ReCap

If you're new to our website, the links on the top of this page and to the right are free, including Signalsmag.com. You'll need to be a subscriber to use the databases on the left. Here's how to subscribe: Subscription information.

Take a peek inside the Analyst's Notebook. In this addition to our web services, we showcase a collection of material from Recap’s consultants, including slide presentations, trend analyses, alliance discussions and much more. In the Notebook, you will find a couple of old favorites: the (newly updated) Average Deal Terms slide feature, and the Daily Deal. Also, don't miss the Key Deals discussion of a recent development in biotech partnering, or the page of slide Presentations, including our most recent presentation for the BIO 2006 conference.

We continue to offer our Power Brokers visualization tool, utilizing our directors database to show the connections between 9,418 individuals who serve on biotech company boards of directors. Power
# Recombinant Capital’s ReCap

## Ten Deals That Changed Biotech

This companion to the [Signale Magazine article](#) contains information available in Recap’s subscription data service, rDNA.com. For this special report, however, we’ve made the data available to all readers. To learn more about rDNA.com, check out the [information site](#) or call Recombinant Capital (925) 952-3870.

<table>
<thead>
<tr>
<th>Agreement</th>
<th>Date</th>
<th>Type</th>
<th>Size</th>
<th>Equity</th>
<th>Roy.</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lilly / Genentech</td>
<td>8/78 - 7/80</td>
<td>D,L</td>
<td></td>
<td>8%</td>
<td>Humulin recombinant insulin</td>
<td></td>
</tr>
<tr>
<td>2. Kirin Brewery / Amgen</td>
<td>5/84 - 10/89</td>
<td>CoD,JV,L</td>
<td>$44.5</td>
<td>5%</td>
<td>EPO, G-CSF &amp; GM-CSF in Japan</td>
<td></td>
</tr>
<tr>
<td>3. GlaxoSmithKline / BioChem Pharma</td>
<td>1/86 - 6/88</td>
<td>E,JV,L,R</td>
<td>$46.9</td>
<td>$34.0</td>
<td>15% Epivir 3TC nucleoside analogue for AIDS &amp; HBV</td>
<td></td>
</tr>
<tr>
<td>4. Roche / Genentech</td>
<td>9/90</td>
<td>Acq</td>
<td>$2014.0</td>
<td>60% acq. &amp; governance agreement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Allergan / Ligand Pharmaceuticals</td>
<td>6/92 - 1/95</td>
<td>E,JV,Ter,W</td>
<td>$39.0</td>
<td>$24.0</td>
<td>50% Screening via retinoid receptors</td>
<td></td>
</tr>
<tr>
<td>6. Lilly / Centocor</td>
<td>7/92 - 6/96</td>
<td>CoD,Di,E,L,O</td>
<td>$124.5</td>
<td>$50.0</td>
<td>50% Centoxin &amp; ReoPro (CentoRx - abciximab) ex-Japan</td>
<td></td>
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</tbody>
</table>

---

# Deals & Alliances - Comparison

<table>
<thead>
<tr>
<th></th>
<th>Coverage</th>
<th>Sources</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Evaluate Pharma</strong></td>
<td>Historic sales 1986 - present</td>
<td>SEC Filings, Annual &amp; quarterly reports, presentations to analysts &amp; investors, FDA, USPTO, equity analysts</td>
<td>Benchmark ‘peer group’ companies &amp; portfolios&lt;br&gt;NPV tools - Unique to EP – forecasts to 2028&lt;br&gt;Gain insight into all sales at risk from patent expiry</td>
</tr>
<tr>
<td><strong>IDEals</strong></td>
<td>1998 - present</td>
<td>Investigational Drug Database (IDDB) records</td>
<td>Subset of data from Investigational Drugs Database (IDDB)&lt;br&gt;Searchable by therapeutic area and mode of action</td>
</tr>
<tr>
<td><strong>MedTrack</strong></td>
<td>1998 – present&lt;br&gt;(note: ownership change from LSA to DataMonitor in 2006)</td>
<td>▪ SEC filings&lt;br▪ Press releases&lt;br▪ Company websites&lt;br▪ Meetings abstracts&lt;br▪ Literature&lt;br▪ News&lt;br▪ Proprietary spiders to Company websites</td>
<td>Partnered &amp; un-partnered search capabilities&lt;br&gt;Excellent export &amp; share capabilities&lt;br&gt;Databases within include – D&amp; A, Epidemiology, Pipeline profile, deal screener, trend analysis, price to news, venture finance, company explorer, company merger tool, patent expiry&lt;br&gt;Excellent customer service</td>
</tr>
</tbody>
</table>
## Deals & Alliances - Comparison

<table>
<thead>
<tr>
<th></th>
<th>Coverage</th>
<th>Sources</th>
<th>Special Notes</th>
</tr>
</thead>
</table>
| ReCap          | 1988-present | SEC filings & exhibits Press Releases                                 | - On-demand service for analysis of materials contracts (extra $$$)  
- Comprehensive consulting services  
- Trend data available without subscription  
- Databases available from their website (valuation, alliances, clinical trials, IP)  
- Data difficult to export & share |
| Windhover (SIS)| 1991-present | SEC filings & exhibits Press Releases Company communications Analyst reports Secondary news sources Editor’s Meetings with Companies Publication – Medtech Insight |
|                |              | - Comprehensive deals, alliance and diagnostics database  
- Host analyst partnering conferences  
- New search & advanced search options  
- Links to companion Windhover products (Journals - In Vivo, Start-Up, RPM Report) – linked to deals db  
- Values deals by TA, company size, phase  
- Excellent customer service |
## Deals & Alliance Source Comparison

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<tr>
<th></th>
<th>Partnered/ Un-partnered Searchable?</th>
<th>Diagnostics</th>
<th>Inventor (person)</th>
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<td>Evaluate Pharma</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>Ideals</td>
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</tr>
<tr>
<td>MedTrack</td>
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<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>ReCap</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Windhover</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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</table>
## Analysis: Requestor’s role dictates info needed.

<table>
<thead>
<tr>
<th></th>
<th><strong>Early Stage Company</strong></th>
<th><strong>Established Pharma / Large Biotech</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Development</strong></td>
<td>• Pipeline work</td>
<td>• Availability of patients for clinical trials (based upon competitive landscape &amp; other ongoing clinical trials). Both capture potential patients.</td>
</tr>
<tr>
<td></td>
<td>• Complexity &amp; cost of clinical trials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Development strategies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Manufacturing outsourcing</td>
<td></td>
</tr>
<tr>
<td><strong>Regulatory &amp; Legal</strong></td>
<td>• Quality</td>
<td>• Fit with existing pipeline</td>
</tr>
<tr>
<td></td>
<td>• Broad application of product (IP) for future</td>
<td>• IP value</td>
</tr>
<tr>
<td><strong>Product Development &amp; New Product Planning</strong></td>
<td>• Market potential</td>
<td>• Market potential</td>
</tr>
<tr>
<td></td>
<td>• Competitive landscape</td>
<td>• Fit with existing pipeline</td>
</tr>
<tr>
<td></td>
<td>• Market entry possibilities</td>
<td>• Fit with existing sales force</td>
</tr>
<tr>
<td></td>
<td>• Marketing rights licensing</td>
<td>• Competitive landscape</td>
</tr>
<tr>
<td><strong>Management</strong></td>
<td>• Track record of internal folks</td>
<td>• Lead molecules / consolidation of pipeline</td>
</tr>
<tr>
<td></td>
<td>• Development &amp; commercial competitors</td>
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## Analysis: Public vs. private company?

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<thead>
<tr>
<th>Data Needed</th>
<th>Public Company</th>
<th>Private Company</th>
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<td><strong>Product &amp; Pipeline</strong></td>
<td>- Pipeline Databases</td>
<td>- Pipeline Databases</td>
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<tr>
<td></td>
<td>□ ADIS R&amp;D Insight</td>
<td>□ ADIS R&amp;D Insight</td>
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<tr>
<td></td>
<td>□ IMS R&amp;D Focus</td>
<td>□ IMS R&amp;D Focus</td>
</tr>
<tr>
<td></td>
<td>□ Thomson Pharma – IDDB</td>
<td>□ Thomson Pharma – IDDB</td>
</tr>
<tr>
<td></td>
<td>□ Pharma Projects</td>
<td>□ Pharma Projects</td>
</tr>
<tr>
<td></td>
<td>□ Prous Integrity</td>
<td>□ Prous Integrity</td>
</tr>
<tr>
<td></td>
<td>□ Inteleos</td>
<td>□ Inteleos</td>
</tr>
<tr>
<td></td>
<td>□ <a href="http://newsdirectory.com">www.drug name.com</a></td>
<td>□ <a href="http://newsdirectory.com">www.drug name.com</a></td>
</tr>
<tr>
<td></td>
<td>□ Drugs @ FDA</td>
<td>□ Drugs @ FDA</td>
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<tr>
<td><strong>Company Information &amp; Manufacturing Capacity</strong></td>
<td>- Company – BioScan, Coombs, Hoovers, IMS, VeriSpan</td>
<td>- Company – BioScan, Coombs, Hoovers, newspapers local to company location</td>
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<tr>
<td></td>
<td>□ Manufacturing Capacity – analyst reports, 10K &amp; news</td>
<td>□ Deals databases</td>
</tr>
<tr>
<td><strong>Financials &amp; Forecasts</strong></td>
<td>- SEC Filings (Hoover, 10K Wizard)</td>
<td>- Local Press (<a href="http://newsdirectory.com">http://newsdirectory.com</a>)</td>
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<td>□ D&amp;B</td>
<td>□ D&amp;B</td>
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<tr>
<td></td>
<td>□ Wall Street analysts</td>
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<tr>
<td></td>
<td>□ IMS, EvaluatePharma, BioPharm Insight</td>
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### Analysis continued…..

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<tr>
<th>Data Needed</th>
<th>Is the company public?</th>
<th>Is the company private?</th>
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</thead>
</table>
| **Business News** | - Subscription based news - (BioCentury, BioWorld, SCRIP, Pink Sheet, IDRAC news etc.)  
- News Alerts (Factiva, Lexis Publisher, NewsEdge)  
- Free (Bio & FDLI Smart Briefs, Fierce Biotech, First Word, DMS Alerts, BioPharm Insight, PharmaVoice, DMS Alerts) | - Local press where the company is located. Global news available at:  
[www.newsdirectory.com](http://www.newsdirectory.com)  
- Deals & alliance databases under the “public” company the deal was done |
| **Scientific News** | - Scientific alerts (Commercially available or NCBI)  
- Prous Drug News Daily | - Conference proceedings |
| **Other** | - Patents | - Patents |
Business News Sources:

**Daily Biotech & Pharma Industry News Updates –**
- AdvaMed SmartBrief (no cost)
- BioCentury - (subscription based)
- BioSpace Diagnostics (no cost)
- BioSpace GenePool (no cost)
- Biotechnology Industry Organization (BIO) SmartBrief (no cost)
- BioWorld Today (subscription based)
- Device Space Daily (Medical Device & Diagnostics daily news (no cost)
- DMS Alerts- (no cost) - Deals & Alliance News
- FDC Reports Pink Sheet – (Subscription)
- Food & Drug Law SmartBrief (FDLI) (no cost)
- FierceBiotech (no cost) – RSS available
- First Word (no cost & subscription based depending on level)
- Informa Healthcare –SCRIP (subscription based) – RSS available
- Prous Drug News Daily (subscription)

**Weekly Biotech & Pharma Industry News Update(s)**
- CHI Weekly Update (Cambridge Health Institute) (no cost)

**Monthly Biotech & Pharma Industry News Update(s) –**
- BioPharm International (no cost)
- IMS Health – World Market Summary (no cost)
- PharmaVoice (basic no cost, premium subscription available)
Pipeline – Focus by stage
Where to look & what to look for will depend on phase of development -

<table>
<thead>
<tr>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Submission</th>
<th>Launch</th>
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</table>
| - Scientific lit  
  - Conference lit  
  - Patents  
  - Health Stats  
  - Pipeline dbs  
  - Business news | - Pipeline dbs  
  - Scientific lit  
  - Clinical trials  
  - Analysts  
  - HCUP data | - Pipeline dbs  
  - Scientific lit  
  - Conferences  
  - Clinical trials  
  - Business news  
  - Analysts | - Pipeline dbs  
  - Scientific lit  
  - Conferences  
  - Clinical trials  
  - Analysts  
  - Business News  
  - Deals dbs | - Pipeline dbs  
  - Regulatory (IDRAC)  
  - FDA | - Analysts  
  - SEC filings  
  - Business News  
  - PDR/ GenRX  
  - Redbook  
  - IMS & Scott Levin Audits |
Drug Development – Early Research

<table>
<thead>
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<th>Nomenclature</th>
<th>Sources</th>
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<td>Chemical names</td>
<td>Conference proceedings</td>
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<tr>
<td>Laboratory Codes</td>
<td>Patents</td>
</tr>
<tr>
<td>CAS registry numbers</td>
<td>Drug pipeline databases</td>
</tr>
<tr>
<td></td>
<td>Scientific literature</td>
</tr>
</tbody>
</table>
### Clinical Trials Questions

- Safety & Efficacy
- Maximum tolerated dose
- Half-life
- Interactions with other drugs

### Studies that provide answers

- Formulation development
- Safety & efficacy
- Competitive products & their trials
- Don’t ignore terminated trials
- Label considerations
Drug Pipeline Development – Clinical

Nomenclature
- Non-proprietary names
- USAN (U.S. adopted names)
- INN (International non-proprietary names)
- In addition to the lab codes, CAS RN’s and chemical names (previous phases)

Sources
- Scientific literature
- Meetings & conference proceedings
- Pipeline databases
- Clinical trial databases
- Analysts & forecast resources
Changes in the Investigational Drug Research Process

- **Increase** in the number & size of clinical trials per New Drug Application
  - 1985 – 1988: Average # = 36 (3,200 patients tested/NDA)
  - 2000 - 2005: Average # = 70 (4,500-5,000 patients/NDA)

- Leading US Pharmaceutical companies increased # of new drug trials 52% since 2002
  - (Source: Outlook 2007 from Tufts Center for the Study of Drug Dev)

- Clinical testing phase gradually lengthening
  - Rise from mean time of 5.5 years in 1980’s to 6.5 years in the 1990’s/
  - In 2002 – 2004 duration extended 7 years
    - (Source: PhRMA 2007 Innovation.org)
Clinical Investigations are going global -

Distribution of 1572 Forms by Location of Investigative Site

<table>
<thead>
<tr>
<th>Year</th>
<th>U.S.</th>
<th>Western Europe</th>
<th>Rest of World</th>
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<tr>
<td>1997</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>1999</td>
<td>90%</td>
<td>10%</td>
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<td>2001</td>
<td>80%</td>
<td>20%</td>
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<td>2003</td>
<td>60%</td>
<td>40%</td>
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<tr>
<td>2005</td>
<td>50%</td>
<td>50%</td>
<td>0%</td>
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</tbody>
</table>

Note: A 1572 form must be submitted to the FDA by a clinical investigator prior to initiating a study in human subjects.

Source: Tufts Center for the Study of Drug Development
## NDA Preparation & Filing

<table>
<thead>
<tr>
<th>NDA Filing</th>
<th>Approval /Launch Prep</th>
</tr>
</thead>
</table>
| - Follows clinical trials  
- Clinical trial data analysis phase  
- NDA / BLA electronic submissions  
- Manufacturing / CRM inspection  
- Label reviews  
- Publication planning  
- MD / RN Educations | - FDA has 6 months for standard review; priority reviews are shorter  
- In most cases, FDA review time exceeds 6 months. Average is 2 years. PDUFA purpose is to shorten time to approval  
- Once NDA approved, drug marketable |
Pipeline Development – NDA/Launch/Post Marketing

<table>
<thead>
<tr>
<th>Nomenclature</th>
<th>Sources</th>
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<tbody>
<tr>
<td>▪ USAN/USP (established name)</td>
<td>▪ Patent literature</td>
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<tr>
<td>▪ Proprietary names / Chemical names</td>
<td>▪ Business literature</td>
</tr>
<tr>
<td>▪ Generic names</td>
<td>▪ Clinical literature</td>
</tr>
<tr>
<td>▪ Brand names</td>
<td>▪ Analysts &amp; Forecasts</td>
</tr>
<tr>
<td></td>
<td>▪ FDA &amp; internet regulatory sites (IDRAC)</td>
</tr>
</tbody>
</table>
Drug Pipeline Databases

- ADIS - R&D Insight
- IMS R&D Focus – IMS Health (IMS Global Services)
- Investigational Drugs Database (IDDB) – Thomson Scientific
- Inteleos (Elsevier)
- Pharmaprojects – (Informa Healthcare)
- Prous Integrity
- Others Portals Containing Pipeline Data: BioPharm Insight / MedTrack
### Epoetin alfa - Kirin-Amgen

Epoetin - Amgen: Epoetin-α, Epoetin-alpha; Epogen®; Epoimmun®; Eprex®; Erypo®; Espo®; KRN 5702; Procrit®; recombinant human EPO; recombinant human erythropoietin; rHuEPO

#### Lehman Market Analysis

<table>
<thead>
<tr>
<th>Company</th>
<th>Indication / Class</th>
<th>Region</th>
<th>Patent Expiry</th>
<th>Launch Date</th>
<th>Probability Of Success</th>
<th>Licensed Status</th>
<th>Peak Sales</th>
<th>Year Of Peak Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amgen</td>
<td>Anaemia, dialysis only / Red blood cell stimulation</td>
<td>US</td>
<td>Jun-2012</td>
<td>1989</td>
<td>100%</td>
<td>Royalty</td>
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<td>2011</td>
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<td>Amgen</td>
<td>Anaemia, non dialysis / Red blood cell stimulation</td>
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<td>$3030m</td>
<td>2002</td>
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<td>Chugai</td>
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<td>Japan</td>
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<td>100%</td>
<td>In licensed</td>
<td>$750m</td>
<td>2012</td>
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</table>
Investigational Drug Database “IDdb”

**Adolor and GSK launch Entereg for post-operative ileus in the US**

Adolor Corp, June 10, 2008

**News Release**

Adolor and GlaxoSmithKline (GSK) have launched their mu opioid receptor antagonist, Entereg (alvimopan), in the US for post-operative ileus (POI).

The drug was approved by the FDA in May 2008 [1008026].

Michael R. Douglass, President and CEO of Adolor, said, “Entereg is the only approved product with a demonstrated ability to accelerate postoperative recovery following bowel resection surgery. POI is a serious condition that can have negative consequences for patients, and impose considerable expense on the healthcare system. We are working closely with GSK to enroll hospitals across the US to make Entereg available to bowel resection surgical teams and patients.”

In April 2008, Adolor and GSK agreed to co-develop the drug [447874].

In February 2007, a Friedman Billings Ramsey analyst believed that the overall market opportunity was sufficiently large to accommodate both Entereg and its primary competitor, Wyeth and Progenics Pharmaceuticals’ subcutaneous formulations of methylnaltrexone bromide. The analyst expected Entereg to gain FDA approval for POI by early 2008 and commented that there was a possibility that Entereg’s efficacy and safety profile would resemble more with dexrazoxane [724552] [414291].

**Other Drug Alerts**

- **Clear all**
- **Avid Radiopharmaceuticals begins phase II Alzheimer’s trial of 18F-AV-45**
  Avid Radiopharmaceuticals Inc, March 17, 2008
- **Radius selects RAB-14b as lead from androgen antagonist sarcopenia program**
  Radius Health Inc, June 4, 2008

**SEARCH center**

To build an advanced search across Drugs and Patents, start by selecting one of these indexes:

- ACTIONS
- COMPANIES
- STRUCTURES
- INDICATIONS
- DEVELOPMENT STATUS
- WORD/PHRASE
- TECHNOLOGIES
- DRUG NAMES
- COUNTRIES/REGIONS

Alternatively, write a Boolean query to search across the entire database or edit/save searches.

**IDdb Alerts**

**Drug Alerts**

- Search Drug Alerts
- All
- This update
- SEARCH
- Alternatively go to: Text Search

**Browse Database**

- **Browse Database**
- **Browse Indexes**
- **Search Center**

**IDdb Portal**

- **IDdb Portal**

**Personal**

- **Personal**

Need help? see our advanced search tutorial [TUTORIAL]

Click HERE for help
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Thomson-Pharma Sources:

• Biosis
• Conference Fast Track
• Current Chemical Reactions
• Current Contents
• Current Opinion Journals:
  • Drug Discovery Development
  • Investigational Drugs
  • Molecular Therapeutics
• Current Patents Gazette
• Data Stream
• Delphion
• Derwent Biotechnology Resource
• Derwent Chemistry Resource
• Derwent Drug File
• Dolphin
• DrugDex
• GENESEQ
• GENESEQ FASTAlert
• GlobalTOPIC
• IBES
• IDb
• IDdeals
• IDrac
• Index Chemicus
• INPADOC
• Investext
• Medstat
• NewsEdge
• Orange Book
• Patent Citation Index
• Patent Fast Alert
• Patents Preview
• Proceedings
• PubMed
• SDdb
• Sharewatch
• SwissProt
• Thomson Patent Store
• Web of Science
• World Drug Alerts
• World Patent Index
• WorldScope
Thomson Pharma – Unique Features

- SWOT Analysis
- Sales market share
- SPC
- First Marketing Authorisations
- AHM Manufacturing
- Regulatory Filings
- Import Data
- Literature Evaluation
- Research data

Developed and launched by Amgen and marketed with various licences; epoetin alfa marketed as epoetin by Amgen and as epoetin beta by Amgen B. Johnson. IU is an abbreviation for international unit.
INTRODUCING INTELEOS, ELSEVIER’S DRUG TRACKING AND ANALYSIS TOOL.

Inteleos™ provides business intelligence support to professionals working in or providing services to the pharmaceutical and biotech industries. Inteleos tracks drug development and associated licensing activities from pre-clinical through to launch and post-marketing studies. In addition to critical drug development information, Inteleos provides easy-to-use analysis tools to support decision-making and drive strategy.

Updated daily, Inteleos content is:
- Accurate and timely so users know they’re making well-informed decisions
- Reliably sourced so users can be confident in the data
- Intuitively organized so users can find the information they’re looking for

Inteleos focuses on reporting information that can be used across business intelligence, market research, business development, product development, regulatory affairs, and sales and marketing activities. Inteleos customers include
- Pharmaceutical and biotech professionals
- Associated healthcare organizations, such as HMOs and medical insurers
- Consultancy firms
- Financial and legal organizations
- Academic and government institutions

Inteleos was developed in consultation with industry experts, involving extensive research and user testing. Inteleos continues to be updated based on feedback from both users and industry experts to ensure it surpasses the needs of its users.
# Inteleos – Search & Export Capabilities

## Inteleos Solutions for Drug Tracking & Analysis

**Welcome: Barbara Gilmore-Halliwell**

- my workspace
- my watch lists
- my folders
- my groups
- my profile
- user tips
- logout

### Search Results

<table>
<thead>
<tr>
<th>?</th>
<th>Drug Name</th>
<th>Originator/Developer/Marketer</th>
<th>Therapy Areas</th>
<th>Drug Classes</th>
<th>Indications</th>
<th>Highest Phase</th>
<th>Key Regions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>afibrocept</td>
<td>Regeneron Pharmaceuticals, Sanofi-Aventis, Bayer Healthcare</td>
<td>advanced cancer, prostate cancer</td>
<td>Antineoplastics, Ophthalmics</td>
<td>First-line treatment of hemoptysis</td>
<td>Phase III</td>
<td>US; Brazil; Canada</td>
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<tr>
<td></td>
<td></td>
<td>Regeneron Pharmaceuticals, Sanofi-Aventis, Bayer Healthcare</td>
<td>colorectal cancer</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>diabetic macular edema, lung adenocarcinoma</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>lung non small cell cancer</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>Hodgkin lymphoma, every cancer</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>pancreas cancer, prostate cancer</td>
<td></td>
<td></td>
<td></td>
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<td>retinal macular age-related degeneration, solid tumor</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>pegaptanib sodium</td>
<td>Gilead Sciences, OSI Pharmaceuticals, Pfizer</td>
<td>diabetic macular edema, cutaneous histoplasmosis</td>
<td>Ophthalmics, Vascular endothelial growth factor (VEGF) antagonists</td>
<td>Treatment of neovascular (wet) AMD</td>
<td>Phase III</td>
<td>US; EU</td>
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<tr>
<td></td>
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<td>OSI Pharmaceuticals, Pfizer</td>
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<tr>
<td></td>
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<td>Pfizer</td>
<td>retinal neovascularization</td>
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</table>

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Pharmaprojects
Thomson’s Prous Integrity

Knowledge Areas

- Drugs & Biologics
- Targets & Pathways
- Genomics
- BIOMARKERcenter
- Organic Synthesis
- Experimental Pharmacology
- Pharmacokinetics/Metabolism
- Clinical Studies
- Disease Briefings
- Companies & Research Institutions
- Literature
- Patents

Quick Access to Key Drugs & Biologics Information

Drug Name Search

Quick Access to Pipeline Information

Gateways to Development Status

Highlights

- June 9 - 15, 2008

Today’s News

Company News
- UCB and Otsuka to codvelop and copromote Keppra and Cimzia in Japan
- Amnista filed for chronic idiopathic constipation in Switzerland
- Enterix available for postoperative Ileus

Metabolic Drugs
- Radius selects preclinical DARM candidate for sarcopenia

Neurologic Drugs
- Epix initiates second trial in phase 1b Alzheimer’s disease program

Today’s Featured Patents

Click here to display today’s featured patent family entries in Integrity

Conferences

27th Congress of the European Academy of Allergology and Clinical Immunology (ERACI) (June 7-12, Barcelona) 2008
Prous Integrity – Target Search
### Prous Integrity – BioMarker Kit Development

#### Kit Development Status Search Results

<table>
<thead>
<tr>
<th>Kit</th>
<th>Use</th>
<th>Organization</th>
<th>Status</th>
<th>Country/Area</th>
<th>Reg. Auth.</th>
<th>Date</th>
<th>Source</th>
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</thead>
<tbody>
<tr>
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<td>Ventana Medical Systems, Inc.</td>
<td>Approved</td>
<td>US</td>
<td>FDA</td>
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<td>Dako Denmark A/S</td>
<td>Approved</td>
<td>US</td>
<td>FDA</td>
<td>25-09-1980</td>
<td>Ref. (4)</td>
</tr>
</tbody>
</table>

- **Biomarker:** HER2
- **Indication:** Cancer, breast
- **Population:** Primary - Lymph Node Negative
- **Role:** Prognosis - Risk Stratification
- **Technique:** (Substrate): FISH (DNA)
- **Authority:** ASCO

---

- **Indication**
- **Condition**
- **Role**
- **Population**
- **Type**
- **Biological Process**
- **Techniques**
- **Substrate**
- **Organization**
Smart Charts - Data Integration Tool

Create Combined Chart Wizard

Step 2 - Select charts to be combined:
- EGFR - Prous
- EGFR - ADIS
- EGFR - Pharmaproxects
- EGFR - Thomson-Pharma

Key chart:
- Mechanism = EGF receptor inhib

Charts to be combined:

Combined: EGFR Combined - (ADIS, IMS, IDDB, Pharmaproxects, Thomson - Pharma)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Common Drug Name</th>
<th>Synonyms</th>
<th>Database</th>
<th>Company</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>BMS-599626</td>
<td>BMS-599626</td>
<td>HER kinase inhibitor, Bristol-Myers Squibb pan HER kinase inhibitor, BMS</td>
<td>Thomson Scientific IDdb</td>
<td>Bristol-Myers Squibb Co</td>
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<td>BMS-599626</td>
<td>BMS 599626</td>
<td>IMS R&amp;D Focus</td>
<td>Bristol-Myers Squibb</td>
<td>Phase I</td>
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<td>BMS-599626</td>
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<td>HER1/2 inhibitors, BMS</td>
<td>Pharmaproxects</td>
<td>Bristol-Myers Squibb (USA)</td>
<td>No Development Reported</td>
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</tbody>
</table>

Identify unique compounds
Conclusion -

- There are several avenues to success when collecting information.
- Who are your customers?
- Where are budget dollars best spent?
- Where did the information in the database/portal come from? Was it a synthesis of existing data or purchase of an independent source?
Acknowledgements

- Wendy Bailey, PharmaProjects (Informa)
- Meredith Barnett, Inteleos (Elsevier)
- Ian Clarke, PharmaProjects (Informa)
- Tad Crawford, Thomson-Pharma
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- Christine DeMeo, Prous Integrity (Thomson)
- Jonathan Evans, PharmaProjects (Informa)
- Heather Fojt, EvaluatePharma
- Alan Kocotas, Knowledge Express (Infinata)
- Zorba Lieberman, CiteLine TrialTrove (Informa)
- Joe Malley, MedTrack (Life Science Analytics)
- Patrick Maloney, BioPharm Insight (Infinata)
- Clare Markillie, PharmaProjects (Informa)
- Carol Morita, Graphic Design
- Debbie Paul, EvaluatePharma
- Katherine Quinlan, Inteleos (Elsevier)
- Pete Sikora, CiteLine TrialTrove (Informa)
- Jeff Southwood, ADIS (Wolters Kluwer Health)
- Ann Wescott, Prous Integrity (Thomson)
- John Willmore, BizInt Solutions
Up Next: Case studies using pipeline dbs.