This is Kymanox’s first newsletter. The timing of this issue is significant. Each year companies and individuals alike take time to review the previous year and make plans and resolutions for the next year. Some “Year-in-Review” articles are written before the end of year and fail to capture all the data which provide proper perspective that comes only with the passage of time.

Please use the information herein to organize and archive your 2005 thoughts as well as inspire you to reinvigorate the 2006 plans you’ve already set in motion. It’s no secret that at this time of year most New Years initiatives lose steam — evidence of this trend abounds at your local health club!

The focus of this initial issue is on news and data that each of us should be familiar with, but may not have had the time to follow and review due to heavy workloads and hectic schedules. Hopefully you’ll find some of the tables useful enough to keep near your desk for the entire year.

Best wishes for a successful 2006!

Regards,

Stephen M. Perry, PMP
Notable Gainers in 2005

According to Burrill and Company, “The Burrill Biotech Select Index widely outperformed the NASDAQ and Dow Jones Industrial on a year-to-date basis — an incredible testimony to the industry’s successful year (up 22% versus +1.3% for NASDAQ and -0.61% for the Dow).”

Abgenix (ABGX) shareholders got a nice ~50% valuation boost this past December when Amgen announced its buy offer of $2.2B. Some other companies had notable gains in 2005 as shown on the right.

Companies that are following Genzyme’s core business model, which is focused on rare diseases and genetic screening, also made some splashes in 2005 and may continue to do well in 2006.

Sources: Yahoo! Finance (29JAN06) and G. Steven Burrill on www.burrillandco.com (29JAN06)

Urge to Merge

Another key story of 2005 was the size, number and quality of merger and acquisition transactions. Bigger Pharma companies with cash on hand (e.g., Pfizer, GSK and Norvartis) bought entire biotech companies or parts of those companies to ensure their long-term pipeline and overall growth. Collaborations were also hot in 2005 and will continue to be popular because of gained efficiencies and risk minimization. Below is a table of selected transactions that were announced in 2005:

<table>
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<tr>
<th>Acquirer</th>
<th>Acquired</th>
<th>~Value ($B)</th>
<th>Acquirer</th>
<th>Acquired</th>
<th>~Value ($B)</th>
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<tr>
<td>Novartis</td>
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<td>Allergan</td>
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<td>GlaxoSmithKline</td>
<td>Corixa</td>
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<td>Amgen</td>
<td>Abgenix</td>
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<td>Johnson &amp; Johnson</td>
<td>Peninsula Pharmaceuticals</td>
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<tr>
<td>Pfizer</td>
<td>Vicuron Pharmaceuticals</td>
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<td>Sosei</td>
<td>Arakis</td>
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</tr>
<tr>
<td>Shire</td>
<td>Transkaryotic Therapies</td>
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<td>Roche</td>
<td>Glycart Biotechnology AG</td>
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<td>Beckman Coulter</td>
<td>Agencourt Bioscience</td>
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<td>OSI Pharmaceuticals</td>
<td>Eyetech Pharm.</td>
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<td>EpiCept</td>
<td>Maxim Pharmaceuticals</td>
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<td>Quest Diagnostics</td>
<td>LabOne</td>
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<td>Invitrogen</td>
<td>BioSource International</td>
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<td>Jazz Pharmaceuticals</td>
<td>Orphan Medical</td>
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</table>

TABLE TOTAL 21.3

Sources: Yahoo! Finance (29JAN06) and G. Steven Burrill on www.burrillandco.com (29JAN06)

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FDA: Personnel Δ’s + Drug Approvals in 2005

Although Biopharma had a good year in terms of its financials, the regulatory environment and its governing body, the FDA, had a difficult year. Big Pharma’s high-profile recalls (e.g., Vioxx and Celebrex) pushed the always-moving pendulum back to “ultra-cautious.” Biopharma was not spared. The recall of Tysabri, which is now seeking restatement, also played a part in FDA’s woes. A selection of the numerous and significant personnel changes within FDA in 2005 are highlighted in the adjacent table.

A total of 13 drug products were approved in 2005. Three of these compounds, denoted with an *, utilize rDNA biosynthesis (e.g., CHO cell, E.Coli) for production. It is possible approvals will be harder to obtain this year. Hopefully, FDA’s own initiatives will help offset some of the expected regulatory slowdown. The “fast-tracked, personalized medicine” initiative was announced this past March. “Process Analytical Technology (PAT)” for manufacturing has been gaining momentum recently; PAT is an outflow of the FDA’s “21st Century cGMPs: A Risk-Based Approach” initiative.

### Trends to Watch in 2006

According to data presented by Doug Braunstein at JP Morgan’s 24th Annual Healthcare Conference, healthcare expenditures for 2006 are expected to be $2 trillion; this represents a 5-fold increase from 1983 spending levels. As the US population ages, along with other countries like Japan, the growth in healthcare spending will continue at a more accelerated pace. Take the Baby Boomer effect into account and the numbers start to really explode!

Although the US is still the clear leader and epicenter of Biopharma, India and China will start making significant moves in 2006. With their labor advantages, India and China will take on in earnest a large number of less-complex projects, like generics. Down-the-road, pricing pressures will intensify and US companies will have to make plans to compete on a head-to-head basis. There will then exist a large economic driving force for efficiency and waste reduction, replacing the “first-to-market-at-any-cost” strategies of the past. To achieve this, companies will need to maximize employee output. Tools and techniques from the field of project management will be especially important.

Networking will be critical for collaborative efforts within companies, partnerships and the entire industry.

Lastly, outsourcing to 3rd-party manufacturers (CMOs) will become increasingly common. Companies with excess capacity will suddenly find themselves acting as a CMO while, perhaps, simultaneously using CMOs on other select projects. The management and organization of these outsourced arrangements will be critical to control timelines, quality and costs.
Kymanox was founded in 2004. The company is focused on providing product and service solutions to companies and individuals in the Biopharma Industry. The company name was derived from Greek and means Ideal Knowledge Transfer. Kymanox specializes in technology transfer and related services as well as professional project management. To provide the most value to its clients, a team approach is used so that both large and small projects can be managed effectively. A key focus area for Kymanox is helping virtual to mid-sized companies manage and/or control their 3rd-party manufacturing activities. Lastly, Kymanox puts a strong emphasis on networking; if Kymanox can’t help or provide the necessary solution, it is likely one of its partners or contacts can.

Mark Your Calendars!

Kymanox has made note of these selected events for informational purposes only. People new to the industry may find this sprinkling of conferences and meetings helpful. Old timers may appreciate the reminder; these meetings come up on you fast!

Bio 2006 is coming to Chicago this April for the first time. This is an important event for the Midwest region. It demonstrates that Biopharma has a strong presence in Chicagoland and that area manufacturing and related service companies have been recognized by their (coastal) peers.

Hopefully you will be able to attend of one of these — or similar — events this year.

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