By Carolyn Gretton

## *R&D Productivity Measures*

# Consistently Undervalued

**TREND:** The omission of biologics from new drug approval counts needs to be addressed to provide a more accurate reading of R&D productivity.


Dr. Jonathan de Pass

According to research by EvaluatePharma, most counts of FDA new drug approvals in **2010** failed to include likely blockbusters Provenge, Dendreon's immunotherapy for prostate cancer, and Prevnar **3**, Pfizer's pneumococcal vaccine, because they were approved by the agency's Center for Biologics Evaluation and Research (CBER), rather than the Center for Drug Evaluation and Research (CDER).

By excluding CBER approvals from these counts, approval rates are being underscored by an estimated **20%,** and projected **2016** sales of **$11.6** billion are not being factored into R&D productivity measures, EvaluatePharma estimates.

"With such intense scrutiny of pharmaceutical productivity at the moment, FDA approval rates are an important number to get right," says Chief Executive Jonathan de Pass, M.D. "Approvals by CBER are only going to become more important in the future, with advances in areas like gene therapy and the significant investment going into improved hemophilia therapies, for example."

*For more information, visit evaluatepharma.com.*

### TOP 10 NEW PRODUCT APPROVALS IN 2010

| Rank | Product | FDA Division | Approved Indication | Company | Projected U.S. sales in 2016 ($ millions) |
|---|---|---|---|---|---|
| 1 | Prevnar 3 | CBER (BLA) | Pneumococcal infection prophylaxis | Pfizer | $2,304 |
| 2 | Provenge | CBER (BLA) | Prostate cancer | Dendreon | 2,059 |
| 3 | Victoza | CDER (NME) | Type 2 Diabetes | Novo Nordisk | 1,134 |
| 4 | Gilenya | CDER (NME) | Multiple sclerosis | Novartis | 1,101 |
| 5 | Pradaxa | CDER (NME) | Stroke prevention in atrial fibrillation | Boehringer Ingelheim | 898 |
| 6 | Latuda | CDER (NME) | Schizophrenia | Dainippon Sumitomo Pharma | 605 |
| 7 | Actemra | CDER (BLA) | Rheumatoid arthritis | Roche | 573 |
| 8 | Jevtana | CDER (NME) | Prostate cancer | Sanofi-Aventis | 572 |
| 9 | Ampyra | CDER (NME) | Multiple sclerosis (improve walking ability) | Acorda Therapeutics | 516 |
| 10 | Prolia | CDER (BLA) | Postmenopausal osteoporosis | Amgen | 441 |

Source: EvaluatePharma. For more information, visit evaluatepharma.com.

## *Generics Firms Turning to M&A* FOR MARKET FOOTHOLD


Kate Kuhrt

The generic pharma industry is positioned for an uptick in mergers and acquisitions amid intense competition in the small-molecule generics category and pricing pressures in established generics markets such as Europe.

According to the Thomson Reuters report, Gaining Market Share in the Generic Drug Industry Through Acquisitions and Partnerships, generic pharma firms are likely to respond to these challenges by seeking M&A deals that allow them to diversify product portfolios, secure pipelines of high-quality active pharmaceutical ingredients (APIs), expand into emerging markets, and achieve economies of scale.

Kate Kuhrt, director of generics and API intelligence at Thomson Reuters, notes that generics companies are also diversifying their product portfolios by moving into niche areas such as follow-on biologics. "Many generic companies have relied on M&A rather than organic growth to achieve these strategies," she adds.

*For more information, visit thomson.com.*

## *Specialty, Hospital Sales Forces* ANTICIPATE DOUBLE-DIGIT GROWTH

Years of contraction have cut thousands of sales representatives from industry rosters, but highly targeted sales groups have ridden out the storm and are poised to build momentum. Cutting Edge Information research found that biopharmaceutical sales forces focused on specialists and hospitals are looking to grow by roughly 10% to 20% in the next two years.

According to the report, Specialty and Hospital Sales Force Management, 53% of hospital sales forces and 30% of specialty forces intend to expand over the next two years, while only 5% plan any cutbacks.

Cutting Edge Information President Jason Richardson calls the news "a positive sign of recovery" for the pharma sales category. "One effect of contraction is sales force 'right-sizing' to reach an

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appropriate number of personnel," Mr. Richardson adds. "Fortunately, many specialty and hospital forces were close to the right size to begin with."

*For more information, visit cuttingedgeinfo.com.*

## *Pharma Supply Chains Due for* RADICAL OVERHAUL

As demand grows for more customized products and services and the nature of those products and services becomes more complex, next-generation pharmaceutical supply chains are expected to become an increasingly important source of differentiation, and to be a more prominent part in the strategic thinking of industry leaders.

The most recent report in the PwC Pharma 2020 series, Supplying the Future: Which path will you take?, predicts the pharma supply chain will undergo three key changes over the next decade: it will become fragmented, with different models for different product types and patient segments; it will become a means of market differentiation and source of economic value; and it will become a two-way street, with information flowing upstream to drive the downstream flow of products and services.

Wynn Bailey, head of supply chain strategies for PwC, notes that while the existing supply chain worked well under the traditional blockbuster paradigm, the shift from products to patients will require the adoption of quicker, more agile processes.

"The most successful pharma companies will be those that recognize the underlying value locked in their supply chain and can leverage it as a value and brand differentiator rather than just a cost," adds Steve Arlington, global advisory pharmaceutical and life-sciences leader.

*For more information, visit pwc.com.*

### OPTIONS FOR RESTRUCTURING THE PHARMACEUTICAL SUPPLY CHAIN

**Operations strategies for specialist therapies**

- Virtual manufacturer: Create a virtual network of integrated supply partners
- Service innovator: Build a service-oriented supply chain to enhance brands and differentiate company from its competitors

**Operations strategies for mass-market medicines**

- Low-cost provider: Build a reliable, no-frills supply chain to deliver products as economically as possible
- Profit center: Combine agile, economic manufacturing and distribution with the provision of satellite services to generate profits

Source: PwC.
For more information, visit pwc.com.

## *Gray Areas Make Postmarketing* SURVEILLANCE DIFFICULT

With both the pharma industry and its regulators making strides toward improving their drug safety efforts, a consistent approach to postmarketing surveillance of adverse events is critical, particularly in gray areas such as the Internet, where reporting practices vary widely.

According to the Best Practices study, Best Practices for Post-Marketing Surveillance of Adverse Events within the United States, roughly half of the participating companies said they do not collect adverse event (AE) reports from Internet sources such as blogs or interactive Web-based events. A majority of participants cited four primary sources for their AE reports: company call centers and disease management programs, company healthcare professionals in the field, marketing booths and other face-to-face events, and consumers who may represent the company.

According to the study, 48% of participants' drug safety teams are made up of doctors, nurses, and pharmacists, with the remainder comprised of scientists, information and project management professionals, and risk management administrators, among other staff.

*For more information, visit best-in-class.com.*


John Mangano

## *Physicians Prefer Direct Navigation* TO HEALTH-RELATED CONTENT

Physicians are much more likely to reach health-related content online by direct, non-referred access and natural searches, underscoring the importance of building brand awareness and effective search engine optimization strategies to reach physicians online, according to comScore.

The second in a series of public reports from the comScore/ImpactRx Physician Behavioral Measurement Solution found paid search-referred visits represented a relatively small percentage of physicians' overall traffic to health-related sites. Of all health-related subcategories, pharmaceutical sites saw the largest percentage of visits originating from paid search, at 7%.

"By observing physicians' actual online behaviors, we are able to understand the differences in how physicians research health content compared with patients," says John Mangano, comScore's VP of health marketing solutions. "Physicians have very different browsing behaviors from patients when it comes to accessing health information online, as they generally begin a session with a clearer picture of what they're trying to achieve."

*For more information, visit comscore.com.*

### WHERE ADVERSE EVENT REPORTS COME FROM


Source: Best Practices.
For more information, visit best-in-class.com.

## *Rewards-Based Adherence Can* SWAY PRESCRIBING PREFERENCES

According to a survey conducted by HealthcarePanel.org, physicians are much more likely to prescribe a particular brand of medication if the prescription includes a rewards-based medication adherence program for the patient. Survey respondents were asked to consider opposite scenarios involving two highly competitive branded oral diabetes agents, in which one drug was paired with HealthPrize Technologies' Internet and mobile-based adherence program and one was offered without the HealthPrize solution.

"Physicians realize that their clinical decisions regarding dosage and medication changes are often compromised by a lack of objective adherence data on their patients," explains Katrina Firlik, M.D., HealthPrize's chief medical officer.

*For more information, visit healthprize.com.* PV

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## THERAPEUTIC MARKET FAST TRAX...

### DIABETES

The existing insulin market is characterized by the emergence of new drug delivery devices with improved technology, and this trend is likely to continue in the next few years on the back of government initiatives to combat the rapid global growth of diabetes. As a result, the global insulin market is forecast to post an estimated compound annual growth rate (CAGR) of 20% during the 2010-to-2015 period.

Source: RNCOS, Insulin Delivery Systems Market Analysis (2008-2012).

*For more information, visit rncos.com.*

### IMMUNE DISEASE

In 2010, the global drug market for the treatment of immune disease was estimated at about $72.2 billion, and is forecast to grow at a CAGR of 2.6% to reach $82.2 billion by 2015. Immunomodulators account for the vast majority of the market, as the demand for symptom-treating drugs has declined due to advances in targeting the underlying causes of immune disorders.

Source: BCC Research, Therapeutics for Immune System Disorders.

*For more information, visit bccresearch.com.*

### INFECTIOUS DISEASE

For the treatment of Clostridium difficile infection (CDI), the highest percentage of surveyed U.S. clinicians and payers selected ViroPharma's Vancocin (oral vancomycin) as having the best overall clinical profile compared with other available therapies. Vancocin was also considered the most efficacious CDI therapy by most surveyed infectious disease specialists and hospital pharmacy directors.

Source: Decision Resources, DecisionBase 2011 report, Clostridium Difficile Infection: Emerging Therapies with Lower Recurrence Rates are Poised to Challenge the Dominance of Current Therapies.

*For more information, visit decisionresources.com.*

### MULTIPLE SCLEROSIS

Surveyed neurologists unanimously agree that the oral dosing format of Novartis' Gilenya is its greatest advantage; but they also indicate that initial trial and adoption has been hampered by patient resistance, monitoring frustrations, managed care issues, and continued concerns related to potential safety issues. Although the percent of neurologists who have begun to prescribe Gilenya has jumped significantly since November 2010, Gilenya's current share and average patient volume remain relatively low, reflecting narrow adoption within individual practices.

Source: BioTrends Research Group, LLC, LaunchTrends: Gilenya.

*For more information, visit bio-trends.com.*

### OBESITY

The U.S. obesity drugs market was valued at more than $130 million in 2009 and is expected to record a five-year CAGR of 4%, with sales reaching almost $160 million in 2014. But due to the rising obesity epidemic, the market for a weight loss drug that proves safe and effective over the long term has the potential to reach blockbuster status and generate billions of dollars in sales.

Source: Medtech Insight, U.S. Market for Obesity Drugs.

*For more information, visit medtechinsight.com.*

### ONCOLOGY

The oncology category continues to be a competitive, high-growth area, and companies are scrutinizing their strategies and tactics to support market education that informs thought leaders, physicians, patients, and payers about their new oncology products. Commercial executives in the oncology area often make clinical and compound data disclosures earlier than in other therapeutic areas, with 40% of commercial oncology leaders surveyed saying they communicate mechanism of action data at the preclinical stage, compared with 29% of all participants.

Source: Best Practices, Shaping the Marketplace to Support Successful Oncology Product Launches: Tactics for Educating KOLs, Physicians, Patients and Payers.

*For more information, visit best-in-class.com.*

## Other market insights...

### *M&A Robust*

### IN 2010

The pharma/healthcare information and technology mergers and acquisitions market was robust in 2010, according to Berkery Noyes' report 2010 Pharma & Healthcare Information and Technology Industry M&A Trends Report. Merger and acquisition activity in the pharma and healthcare information and technology sector surged 81% for a total value of $11.62 billion in 2010, compared with $6.43 billion in 2009. Total transaction volume increased 13% to 224 transactions in 2010.

*For more information, visit berkerynoyes.com.*

### *The Price of*

### E-MARKETING

As companies invest more heavily in e-marketing campaigns, life-sciences suppliers are challenged to cut through the noise, according to BioInformatics' report eMarketing to Life Scientists: Raise Your Voice Above the Noise. E-marketing can be an exciting and cost-effective way to positively impact revenue, but a heavy price can be paid for missing the mark. Failed campaigns can result in being blacklisted by companies, added to do-not-send lists, reported as spam, blocked from forums, and losing sales because of a website that's hard to navigate.

*For more information, visit gene2drug.com.*

### *European*

### KOLS

The scrutiny placed on relationships between drug companies and key opinion leaders (KOLs) in the United States is making its way across Europe, according to Cutting Edge Information's report Determining European KOL Compensation: Fair-Market Value Benchmarks. The average hourly rate for European key opinion leaders is 37% lower than for U.S. counterparts with similar qualifications, due in large part to Europe's more stringent compensation limits. On average, the annual spending cap for European companies' KOLs is €33,533; the average cap for compensation to U.S. KOLs is about €45,000.

*For more information, visit cuttingedgeinfo.com.*

### *Clinical Chemistry*

### ON UPSWING

The global clinical chemistry market is forecast to grow at 5.1% over the 2009-to-2016 period, reaching $14.26 billion by 2016, driven by increasing availability of tests covering a wide range of disease areas and expanding the pool of potential customers, according to GlobalData's report Clinical Chemistry Global Market Briefing to 2016. The clinical chemistry markets in emerging countries such India, China, and Brazil are expected to continue to grow at above-average compound annual growth rates (CAGRs) of 15%, 15%, and 10% respectively over the period from 2009 to 2016 amid an expanding population base and increasing access to quality, affordable medical care.

*For more information, visit globaldata.com.*

## On-Site Clinical

### MONITORING

Biopharma companies looking to cut development costs are examining alternatives to the traditional regularly scheduled, on-site clinical monitoring model. About 47% of sponsor respondents said they would prefer to use clinical research associates (CRAs) who perform regional visits to sites and handle six to nine protocols, and have 30% lower travel costs, according to Industry Standard Research's report The Future of Clinical Monitoring.

*For more information, visit isrreports.com.*

## COPD Driving

### RESPIRATORY DEVICE MARKET

The global market for anesthesia and respiratory devices is experiencing steady growth amid rising incidence worldwide of chronic obstructive pulmonary diseases, obtrusive sleep apnea, and asthma. The total global anesthesia and respiratory devices market is projected to be worth $12.7 billion by 2015, out of which GE Healthcare will account for almost 12% of total revenue. The market's CAGR is forecast at 9.2% from 2010 to 2011, according to MarketsandMarkets' report Global Anesthesia and Respiratory Devices Market (2010-2015).

*For more information, visit marketsandmarkets.com.*

## Anticounterfeiting

### MARKET

The global anti-counterfeit packaging market for food and pharmaceuticals is expected to be worth $79.3 billion by 2014, for an estimated CAGR of 8.6% from 2009 to 2014. The North American market is expected to account for almost 62% of total anti-counterfeit technology revenue, but the Asia market likely will have the highest growth rate due to an untapped market and significant levels of counterfeiting, according to MarketsandMarkets report Global Anti Counterfeit market for Food and Pharmaceuticals (2009-2014).

*For more information, visit marketsandmarkets.com.*

## Drug Delivery Gives Boost

### TO DRUG LIFE CYCLE

Drug delivery technologies are revenue-boosters for the pharmaceutical industry, enhancing drug life-cycles by extending patent rights and adding a competitive edge by improving safety and efficacy.

The global market for the top 10 drug delivery technologies is expected to grow at an estimated CAGR of 17% from 2010 to 2015, for a total value of $156 billion in 2015. Patent expirations and rising demand for effective delivery of novel biopharmaceuticals via unconventional modes such as pulmonary, nasal, and transdermal are driving growth in this market, according to MarketsandMarkets' report Top 10 Drug Delivery Technologies Market (2010 - 2015).

*For more information, visit marketsandmarkets.com.*

## Nanotechnology

### GOES CONSUMER

Nanotechnology-based products are expected to have a huge impact across a broad swath of industrial sectors in the coming years, and to enter the consumer market in large quantities. The global nanotechnology market is projected to grow at a CAGR of around 19% during the 2011-to-2013 period, for an estimated market value of $1.6 trillion.

Growth will largely be driven by massive investment in nanotechnology R&D and commercialization by governments and companies worldwide, according to RNCOS' report Nanotechnology Market Forecast to 2013.

*For more information, visit rncos.com.* PV