



WHITE PAPER



10 Business Trends to Observe in 2009

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10 Business Trends to Observe in

2009

2008 will be remembered as the year of a huge financial meltdown that led to a global economic crisis – the toughest one seen for the last decades. Nevertheless, 2008 also was a real successful year for many companies in the Life Science Industry including Pharmaceuticals, Medical Devices, Diagnostics and Biotechnology. This is especially true for those companies that correctly predicted the changing trends in their market and then used these trends to

build greater competitive advantage. In this special White Paper, TCG identifies 10 trends that can create significant opportunity for you in 2009.

Trend 1: Partnerships take on more importance

The global financial meltdown is having one benefit at least. It is forcing health care executives to do what they should have done years ago: NOT try to be all things to all people. This will force their companies to focus on therapeutic areas and product lines they know the best, and to partner out non-core assets to larger companies who have the skills to maximize the value in the shortest time possible. Out-licensed opportunities and in-licensing products in areas of core expertise are the keys to success.



Partnerships: Use the right strategy for out- and in-licensing

Trend 2: Pre-clinical licensing: Iceberg ahead

Biotechnology executives who hope that pre-clinical licensing deals will save their companies are doomed to fail. Pre-clinical licensing deals will be few and far between in the foreseeable future. Pharmaceutical companies, regardless of what Wall Street analysts say, have enough early stage products — they need later stage products to quickly fill their marketing needs. The few deals they will do will be for products where the data packages are exceptionally strong. Biotechnology companies should get wise fast.



The way of biotech companies looking to sell pre-clinical deals is treacherous

Trend 3: Credit tightening creates opportunities

Reduced access to credit is especially brutal for one segment of the life science industry: companies that are not cash-flow positive. Companies with products in the later stages of development, not quite ready for the market, are the most likely to be affected. For well capitalized companies, 2009 will be an excellent year to strike favorable partnerships with, or acquisitions of, cash-poor companies with products ready for the market in a short period of time.



Time to put on the brakes? Companies that are not yet cash flow-positive face hard times

Trend 4: Tougher FDA Enforcement

One of the new laws under discussion – the so-called FDA Globalization Act – will give the FDA greater flexibility in how it decides to inspect non-US manufacturing facilities to address the recent contamination problems observed all over the country. In addition the “Sentinel Initiative”, which passed in 2008, provides the FDA with greater authority over post-marketing surveillance for different types of drugs and devices. This trend is likely to continue under the new Obama administration.



New laws provide the FDA with greater authority

Trend 5: New markets for established products

The writing is on the wall, and European medical device and small pharmaceutical companies with products to sell have read the signs. In an era of increasing global market growth, they are spending money aggressively to capture US, Asian and South American markets. This spreads the risk among multiple markets and broadens their portfolios through product acquisitions. Especially with the expected downturn in the 2009 European economy, this strategy might be the key for further growth.



Decipher the writing on the wall: Spread the risk among multiple markets

Trend 6: Electronic medical records coming

The new US President wants to improve care through more use of Electronic Medical Records (EMR). Going to EMR systems and health information technology could lower costs and improve efficiency since paper-based medical records make it difficult to coordinate care, to measure quality and can actually increase medical errors. Manufacturers of medical devices need to incorporate EMR system connectivity for their products particularly for new ones planned for 2009 and 2010.



President Obama wants to improve care through more use of Electronic Medical Records

Trend 7: No money for “hospital-acquired costs”

The Centers of Medicare and Medicaid Services (CMS) stopped paying for certain “hospital-acquired” costs as of October and will add more conditions in 2009. Their action will have a major financial impact on hospitals since they include air embolisms, blood incompatibility, pressure ulcers, catheter infections, patient falls and, for next year, surgical site infections, deep vein thromboses and poor glycemic control. Product developers are designing new ways to cut these events to appeal to a key buying segment.



The CMS decision will have a major financial impact on hospitals

Trend 8: Government funding will increase

The new US Administration plans to expand the Children’s Health Insurance Program (CHIP) and medical care for military Veterans. Plus, the new DHHS Secretary, Tom Daschle, will work with Congress to develop a comprehensive Medical Insurance plan for the US. Spending for medical care in some areas is expected to increase sharply – despite the other budget priorities for the Obama administration. As 2008 saw more governmental involvement in the financial and auto sectors, 2009 could see them in healthcare.



The new DHHS Secretary, Tom Daschle, plans to develop a Medical Insurance Plan for the US

Trend 9: FDA approval: More time and costs

User fees for the FDA approval will continue to increase, along with the time from application to final approval because of staff shortages. Delays in approval could get even longer if the nomination and confirmation of a new FDA commissioner is not concluded quickly after the inauguration on January 20. There is also a trend toward requiring economic data to be submitted along with safety and efficacy studies. This will make clinical trials more costly as they must be linked to cost vs. outcomes.



More hurdles: Acquiring economic data for FDA submission

Trend 10: Find time for customer relationships

During the economic downturn, many of your competitors are reducing their expenditures, sometimes for activities directly related to customer service and support. These are the last costs that should be cut, particularly as sales force contacts are reduced. Companies that find cost-effective ways to build and expand their relationships with customers – even if there are no immediate benefits – will be the ones that capture greater market share when the economy recovers.



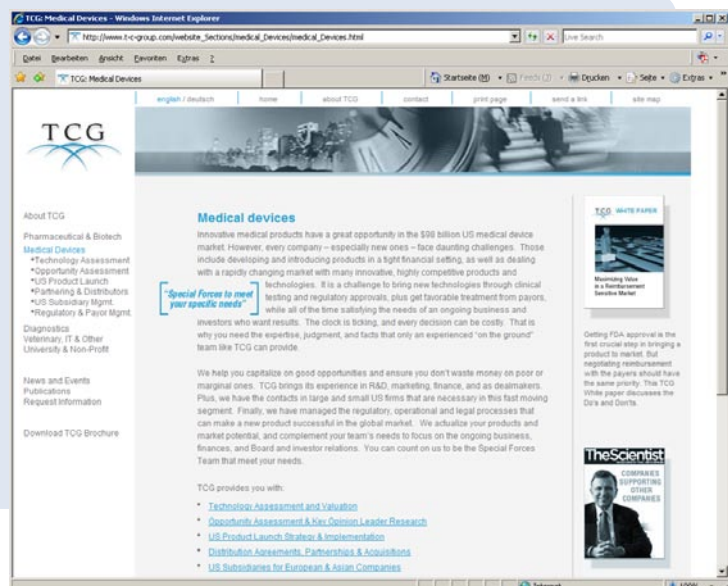
The key to success: Find cost-effective ways to expand customer relationships

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Mr. Burns has 25 years of management, market development, R&D and licensing experience in large and small firms including three divisions of Johnson & Johnson.



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Mr. Sheldon has more than thirty years experience in business, law, and education and his career has focused on the assessment of emerging technologies.



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Mr. Woodward has spent over 25 years in medical device, diagnostic, and healthcare service companies with strong experience in financial direction and management.

Your Expert Team

To get the most out of 2009, you should take advantage of professional business support. At TCG our experience is our most important credential. We've been on your side of the desk as executives at multinationals, as well as start-ups, where we successfully steered pharmaceuticals and other medical products from inception to market. With us, you get that experience in helping to establish winning products and companies in the high-stakes biotech and biomedical industry.

Everyone on our team is a seasoned and senior professional with operational experience. We bring you 150+ years of industry experience and "lessons learned" many consultants simply do not have. We apply that experience to license technologies and products (or even entire businesses) cost effectively, develop superior sales & marketing strategies, and serve you in a wide variety of services. Whatever your needs, you

won't waste time and money educating us. We grasp the situation quickly while partnering with you to plan and execute clear, sound, business strategies and tactics. And the same people who work with you on the strategy, work with you to implement the tactics. Unlike other consulting firms, we don't hand the work down to a young MBA on a lower level.

Our solutions are unique to each client because each client's situation is unique. And our services are cost effective because we save you time and money in the long run. We know how to plan for all contingencies so that you are prepared and the plan will work – the first time and every time. Whether you are entering a new market, launching a new product or making changes in your business direction, TCG will help you achieve your goals. If you seek a no-compromise SWAT team who can deliver results, call us today to see how we can help.