

Diagnostics 2011:
M&A surges, companion
diagnostics accelerate,
and early detection offers
new prospects—
Executive summary

Diagnostics 2011
Second edition
December 2011



Diagnostics 2011, the latest edition of PwC's biennial review of the rapidly growing *in vitro* diagnostics (IVD) sector, examines a surge in deal activity in the sector, expanded companion diagnostics partnerships with the pharmaceutical industry and trends in the emerging field of early-detection testing.

M&A activity growing, generating exceptional values

Recent trends in M&A

Deal-making activity in the IVD sector is growing strongly in terms of valuations. Helping drive up values are new entrants to the IVD sector, such as financial investors, life sciences research groups, clinical laboratories, and medical technology players. The surge in values and the diversity of the bidders underscore a widespread belief in the growth prospects of selected IVD market segments as well as the potential for cross-industry synergies.

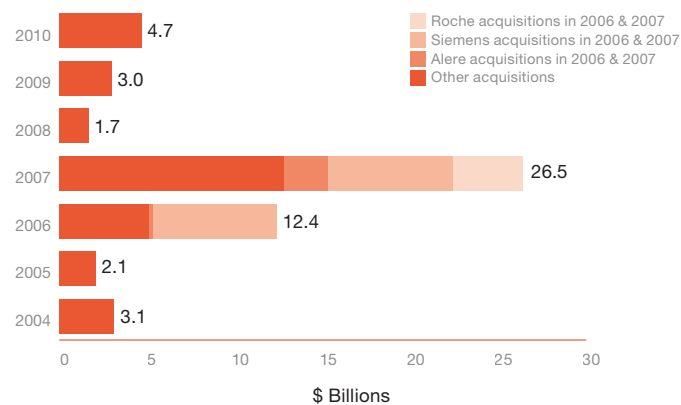
The value of disclosed deals rose 57 percent in 2010, to \$4.7 billion, up from \$3.0 billion in 2009. The higher

amounts reflected the impact of a small number of high-value deals, led by buyout firm Cinven's \$1.1 billion acquisition of clinical electrophoresis company Sebia. The Cinven deal highlighted the renewed role of private equity firms.

Other factors also contributed to the increase, including a restructuring of business portfolios that led to more divestitures and acquisitions: Two of the top-10 deals of 2010 resulted from Genzyme's decision to sell off noncore businesses.

The growing strategic convergence of medical technology with *in vitro* diagnostics was a third factor. The third-largest deal of 2010, GE Healthcare's \$587 million acquisition of Clariant, complemented GE's primarily imaging-based diagnostics business.

Value of disclosed M&A deals in the IVD sector 2004–2010



Source: PwC analysis using data from Thomson Financial, Windhover, Mergermarket, Zephyr and other publicly available sources

Following an investment earlier in 2010 in molecular diagnostics company CardioDx, the Clariant deal emphasized the company's strategic interest in the IVD sector.

Some of the biggest deals involved increased consolidation of the point-of-care testing sector: The purchases of Epocal and Standard Diagnostics by Alere (formerly Inverness Medical Innovations) both ranked among the top 10 deals of 2010.

Efforts to add complementary products to existing portfolios were a final factor driving the biggest deals of 2010. Quidel's acquisition of Diagnostic Hybrids and Illumina's purchase of Helixis were the result of companies broadening their portfolios.

Despite the increase in values, the absolute number of M&A deals in the IVD sector has been flat, with 46 announced deals in 2009 and 45 in 2010, both well down from the 84 deals announced in 2007.

Highlights from the first half of 2011

The trend toward rising M&A deal values in the IVD sector has continued in 2011. A series of multi-billion-dollar deals announced during the first seven months is expected to more than triple total M&A deal value from 2010, to more than \$15 billion.

Danaher's \$6.8 billion offer for Beckman Coulter, one of the top-nine IVD players of 2009, was significant not only because of its size, but also its impact on IVD market share. Deals such as this one could reshuffle the rankings of the top IVD players, forcing smaller players to respond by entering into deals to acquire a specific technology or strengthen their presence in a specific market.

Although most of the announced deals have been generated by the clinical laboratory and life sciences research sectors, there has been renewed interest from the pharma sector. Novartis, for instance, made a \$330 million offer to buy Genoptix early in 2011, which could signal the start of greater interest by pharma companies.

Whatever happens during the remainder of 2011, the IVD sector's market dynamics seem to have attracted a renewed level of investor interest. Through July, the year already ranks as one of the best since 2004 in terms of M&A deal value, second only to the \$27 billion of deals announced during 2007.

The future of IVD M&A

Looking out to 2015, M&A activity in the IVD sector will be shaped by the confluence of several factors. With new market entrants continuing to add IVD businesses to attain critical

mass, current players have a choice of responding in kind or risking a decline.

One major source of M&A activity is likely to be pharma companies that are building drug-diagnostics co-development programs to support targeted therapeutics. While instances of pharma companies acquiring these capabilities by purchasing diagnostics businesses have been rare recently—the last notable example was the Innogenetics-Solvay Pharma deal in 2008—Novartis's offer for Genoptix could represent a turnaround.

Pharma companies are increasingly likely to consider bringing companion diagnostics capabilities in house or acquiring stakes in niche IVD players to complement their evolving product portfolio, especially if the model of IVD-based early detection can be validated. Molecular or tissue diagnostics firms—the most relevant areas for today's companion diagnostics programs—are the most likely targets.

New entrants and cash-rich private equity houses also could continue their activity. One other possible scenario: The entry of major diagnostics or pharma companies that have not previously been involved with the IVD sector. This would become more likely if noninvasive *in vitro* diagnostics become common for early detection of major cancers.

IVD-Pharma companion diagnostics partnerships increase

Recent trends in IVD companion diagnostics

In July 2011, the FDA released draft guidance on companion diagnostics. Together with signals from payers and markets and the growing trend toward personalised medicine, the guidance is an indicator of expanded investment in companion diagnostics.

The market signals are clear. Some payers prefer drugs that come with a companion test, and some mandate genetic testing before reimbursing treatment regimens that are expensive and ineffective in certain subpopulations.

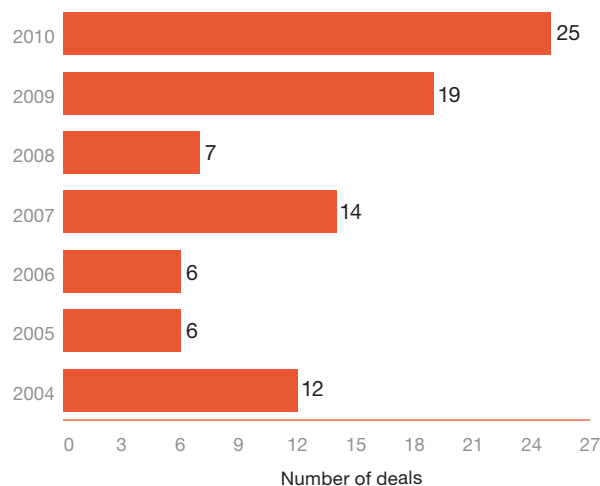
IVD-pharma partnerships grew from seven in 2008 to 19 in 2009 and 25 in 2010. (Typically, more deals are closed

than reported because some pharma companies do not disclose all partnerships.) The largest pharma companies have been the most active, with GSK alone accounting for seven of the 44 partnerships in 2009–10, almost twice as many as the next most active players, Pfizer and Roche.

Neurological conditions, such as Alzheimer's, and infectious diseases

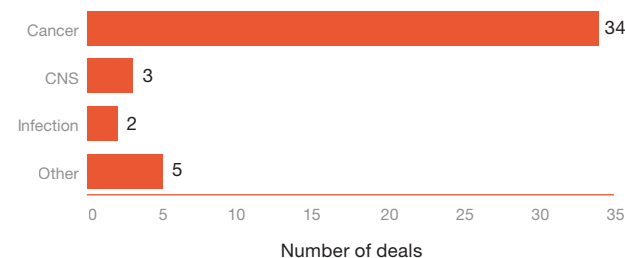
made an appearance alongside cancer in IVD-pharma diagnostics partnerships in 2009–10, with five of the 44 focused on these areas (and 34 focused on cancer, including 12 that addressed major cancers). While cancer remains the main focus, driven by large patient populations, the diversification into other disease areas is noteworthy. In 2008, all but one deal focused on cancer.

Number of companion diagnostics partnerships with pharma 2004–2010



Source: PwC analysis, using data from Windhover, IVD Technology, and company press releases

Number of companion diagnostics partnerships by disease area 2009–2010



Source: PwC analysis, using data from Windhover, IVD Technology, and company press releases

The future of companion diagnostics

The appetite for IVD-pharma companion diagnostics deals will remain strong because the same drivers have continued in 2011 and are likely to intensify. This year, deal activity started promisingly, with 15 partnerships identified in the first half of the year. One notable trend is that the larger pharma companies still account for the majority of partnerships, but smaller specialty firms are closing the gap, accounting for seven of the 15 arrangements thus far.

Despite the increased demand, challenges remain. Many industry players believe that the economics of diagnostics are undermined by the low pricing and reimbursement of diagnostics and the low share of value that partnerships typically generate for IVD firms.

Overcoming these roadblocks could create significant opportunities. This would be especially true if efforts to detect Alzheimer's and other neurological conditions progressed. The presence of several neurology deals during the first half of 2011, consistent with 2009–10, suggests that neurology is an increasingly important area.

By 2020, if drug-diagnostic co-development becomes routine for drugs for which the use of biomarkers is relevant, most leading pharma companies are expected to develop significant in-house diagnostics capabilities. As a result, the volume of external alliances would remain high, but the trend would lose momentum.

Early detection provides new prospects for improved outcomes

For diseases such as most cancers, early detection and treatment can significantly improve survival prospects. The five-year survival rate for each of the four most common cancers improves by at least four times when the cancer is detected early and still localised, compared with detection after the cancer has spread: Early detection of prostate cancer via the prostate-specific antigen (PSA) test increases the five-year survival rate from 3 percent to 100 percent.

While the case for early-detection testing seems clear-cut, issues remain. Some *in vivo*-based screening tests are seen as having sensitivity that is too low, too many false positives because of low specificity, low compliance because of invasiveness and discomfort, risks from exposure to radiation, and high cost. IVD tests have not made significant inroads in replacing current standards for early detection of the major cancers: With the exception of the PSA test, *in vivo*, not *in vitro*, procedures dominate.

However, innovative research on screening technology has continued and is beginning to produce results. Consequently, a significant pipeline of new *in vitro* diagnostics-based tests is emerging and could offer new hope for improved early detection. At least 23 such tests are in development, and some of them have performance profiles that suggest they could be strong enough to vie with *in vivo* procedures for a central role.

To date, small, emerging diagnostics companies have dominated the origination of IVD-based technology for early detection of cancer. However, larger companies have an important role to play for commercialisation, and pharma companies also may become more prominent players because of their cash-flow profiles and commercial synergies.

The next several years could mark an important validation period for the concept of IVD-based early detection. At least five new IVD tests for early detection were cleared for marketing in the United States or Europe during 2009–10, and at least another 10 are expected to be cleared during 2011–12. Results for most of the new tests in development, including data from prospective clinical studies, new biomarkers and larger-scale clinical studies, should become available.

Profile of an ideal test for early detection



Source: PwC analysis following discussion with industry contacts

Strong performance, validated by robust data, will be critical to obtaining reimbursement and gaining a pivotal role alongside the current standard of care. Ultimately, strong market adoption will be driven by the benefits of noninvasiveness, high sensitivity and specificity, together with favorable health economics.

If a number of IVD-based early detection tests pass these hurdles and achieve strong market adoption, it could change the industry mindset, especially because of market and regulatory pressures towards effective early treatment as a way to control costs and the potential for blockbuster-like revenues.

New developments supporting the growth of personalised medicine

The FDA's release of draft guidance on companion diagnostics was only the latest in a series of developments in government, industry, and science and technology that will promote the development of personalised healthcare.

Other events having an effect included the U.S. government's plans to develop a genetic testing registry; the FDA's issuance of a black-box warning for a blockbuster drug, which could drive the development of companion diagnostics to guide the use of such a drug; advances in genetic research related to obesity, which illustrate the convergence between wellness and personalised medicine; the founding of an association in Europe to promote personalised medicine; and the entry of new players such as Nestlé.

Conclusion

Steps for sustained advances in the IVD sector

During the past two years, positive growth prospects have resulted in new deals, new investments and new advances in IVD science and technology. However, these advances cannot be sustained without the continued commitment of stakeholders: Governments, regulators, payers and industry must create a favorable environment for progress.

Among the areas that need to be addressed are pricing to reflect the value of tests rather than only their cost; accelerated and harmonised reimbursement processes; regulatory pathways that are clarified for each type of diagnostic—stand-alone and companion; and clarity for the design of clinical trials for drug-diagnostic co-development.

In addition, the share of value going to the diagnostic side in IVD-pharma partnerships might need to be revisited. Traditionally, diagnostics have represented less than 2 percent of healthcare spend while influencing more than 60 percent of critical healthcare decisions. Rebalancing the equation could encourage greater investment in diagnostics, accelerating the development of these tools.

Not taking action in these areas would damage the survival prospects of many emerging IVD players, especially those that are taking chances by being among the most innovative. If that occurs, then diagnostics innovation could be discouraged; continued investment into diagnostics ventures could be depressed; and patient access to important new health technologies could be delayed.



Contacts

Principal contacts

Laurent Probst
Partner, Pharmaceuticals & Life Sciences
Industry Leader, PwC Luxembourg
laurent.probst@lu.pwc.com
+352 49 48 48 25 64

Loïc Kubitza
Director, Pharmaceuticals & Life Sciences,
Advisory Services, PwC Luxembourg
loic.x.kubitza@lu.pwc.com
+352 49 48 48 57 16

Gerald McDougall
Principal, Healthcare
Advisory Services, PwC US
gerald.j.mcdougall@us.pwc.com
+1 267 330 2468

Matthew Rosamond
Director, Healthcare
Advisory Services, PwC US
matthew.rosamond@us.pwc.com
+1 646 471 0953

Pharmaceuticals & Life Sciences

Leadership

Simon Friend
Partner, Global Pharmaceuticals & Life Sciences
Industry Leader, PwC UK
simon.d.friend@uk.pwc.com
+44 20 7213 48 75

Steve Arlington
Partner, Global Pharmaceuticals &
Life Sciences Advisory Services Leader, PwC UK
steve.arlington@uk.pwc.com
+44 20 7804 3997

Michael Swanick
Partner, Global Pharmaceuticals and
Life Sciences Tax Leader, PwC US
michael.f.swanick@us.pwc.com
+1 267 330 6060

Marketing

Attila Karacsony
Director, Pharmaceuticals & Life Sciences, PwC US
attila.karacsony@us.pwc.com
+1 973 236 5640

Sara Solomon
Manager, Global Pharmaceuticals &
Life Sciences, PwC UK
sara.solomon@uk.pwc.com
+44 20 7804 1014

Healthcare

Leadership

David Levy, MD
Principal, Global Healthcare
Industry Leader, PwC US
david.l.levy@us.pwc.com
+1 646 471 1070

Fiona Nicholas
Partner, EMEA Healthcare
Industry Leader, PwC Arab Emirates
fiona.nicholas@ae.pwc.com
+971 4 304 3108

Guy Brandenbourger
Partner, Healthcare
Industry Leader, PwC Luxembourg
guy.brandenbourger@lu.pwc.com
+352 49 48 48 57 16

Marketing

Todd Hall
Director, Global Healthcare
Marketing, PwC US
todd.w.hall@us.pwc.com
+1 617 530 4185

Cristina Santoro
Global Healthcare
Coordinator, PwC Italy
cristina.santoro@it.pwc.com
+39 06 570 83 24 17

www.pwc.com
www.pwc.com/pharma
www.pwc.com/healthcare
www.pwc.com/medtech

This publication has been prepared for general guidance on matters of interest only, and does not constitute professional advice. You should not act upon the information contained in this publication without obtaining specific professional advice. No representation or warranty (express or implied) is given as to the accuracy or completeness of the information contained in this publication, and, to the extent permitted by law, PricewaterhouseCoopers does not accept or assume any liability, responsibility or duty of care for any consequences of you or anyone else acting, or refraining to act, in reliance on the information contained in this publication or for any decision based on it.

© 2011 PwC. All rights reserved. Not for further distribution without the permission of PwC. "PwC" refers to the network of member firms of PricewaterhouseCoopers International Limited (PwCIL), or, as the context requires, individual member firms of the PwC network. Each member firm is a separate legal entity and does not act as agent of PwCIL or any other member firm. PwCIL does not provide any services to clients. PwCIL is not responsible or liable for the acts or omissions of any of its member firms nor can it control the exercise of their professional judgment or bind them in any way. No member firm is responsible or liable for the acts or omissions of any other member firm nor can it control the exercise of another member firm's professional judgment or bind another member firm or PwCIL in any way. NY-12-0250