Abstract
A decrease in R&D productivity has been a major business challenge in the pharmaceutical industry for years. Today, some companies are seeing improvement as a result of organizational transformation of R&D functions and external collaborations. Since 2010, Deloitte, in association with Thomson Reuters, has been quantifying the return on investment of selected life sciences companies. This paper will examine this improvement based on quantitative analysis of productivity and the return from compounds in late-stage development.
Introduction

Over the course of the four years of this analysis, the cohort of 12 companies has launched 105 products and transferred $770 billion of projected value into their commercial portfolios to the benefit of patients. Over the same period, the research and development (R&D) engines of these companies have pulled 167 assets into late stage development, with a total risk adjusted value of $819 billion.

Despite these positive indicators, the projected return on investment in innovation that the cohort’s late stage pipeline is expected to deliver has continued to decline across the four years, from 10.5 per cent in 2010 to 4.8 per cent in 2013. The cohort result hides wide variations in company performance. Some companies are achieving higher rates of return and others are struggling to safeguard growth.

This report presents the results of analysis of IRR among the cohort of 12 companies and discusses factors that resulted in decline of IRR and potential measures to improve it.

Dynamic returns

Assessment of dynamic returns allows the impact of key drivers of change in life science research and development (R&D) performance to be measured for a given time period. There are a number of change drivers included in this report:

- new compounds entering the late stage pipeline: a
- changes in revenue forecasts of existing late stage pipeline drugs – those drugs in the late stage pipeline in the previous year: b
- approvals due to commercialization of late stage pipeline drugs: c
- terminations either through company-originated termination or unsuccessful application for marketing authorization: d
- stalled compounds not officially terminated but unlikely to launch, for instance due to the publication of unfavorable clinical trial data: e
- margin and cost factors such as changes in R&D costs and tax rates: f - j

Figure 1 presents the impact of each of these drivers for the same cohort of companies over a cumulative four-year time period, 2010-13.

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**Figure 1. Drivers of change in IRR, 2010–13**

<table>
<thead>
<tr>
<th>Year</th>
<th>New</th>
<th>Existing</th>
<th>Approved</th>
<th>Terminated</th>
<th>Stalled</th>
<th>Margin</th>
<th>R&amp;D cost (pure)</th>
<th>Phasing</th>
<th>Licensing</th>
<th>Tax rates</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>$1,369</td>
<td>$819</td>
<td>$(203)</td>
<td>$(770)</td>
<td>167</td>
<td>60</td>
<td>$105</td>
<td>-1.8</td>
<td>-1.6</td>
<td>-0.8</td>
<td>+0.6</td>
</tr>
<tr>
<td></td>
<td>10.5</td>
<td>157</td>
<td>-406</td>
<td>-105</td>
<td>60</td>
<td>-1.8</td>
<td>14</td>
<td>-0.5</td>
<td>-1.6</td>
<td>-0.8</td>
<td>+0.6</td>
</tr>
<tr>
<td></td>
<td>$913</td>
<td>167</td>
<td>-406</td>
<td>-105</td>
<td>60</td>
<td>-1.8</td>
<td>14</td>
<td>-0.5</td>
<td>-1.6</td>
<td>-0.8</td>
<td>+0.6</td>
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<td>-0.8</td>
<td>+0.6</td>
</tr>
</tbody>
</table>

Source: Deloitte UK Centre for Health Solutions, Deloitte LLP and Thomson Reuters research
While the number of assets in company late stage pipelines has remained stable since 2010, indicating that pipeline flow has remained intact, the total projected value of late stage pipelines has declined from $1,369 billion to $913 billion. Since 2010, specific aspects of the economics of value generation (cash outflows versus cash inflows) that are holding back R&D returns at a cohort level are:

- A 43 per cent reduction in projected peak sales per asset from $816 million to $466 million, likely due to the impact of austerity measures and the industry's need to calibrate their innovation investments with the needs of payers earlier and more consistently.

- The adverse impact of terminations, late stage failures continue to take too much value out of the cohort's pipeline, amounting to $243 billion over the four year period.

- An increase in the level of overall R&D investment as the anticipated impact of R&D cost saving programs have yet to be realized in full. The cost to develop and launch a new medicine has increased 18 per cent to $1.3 billion over the four year period.

- Phasing of R&D investment, assets are spending longer in complex and expensive late stage development, particularly between 2012 and 2013, and total development time has increased from 13.2 years to 14 years. Companies are taking longer to collect more evidence and to decide whether to progress assets through to the next phase of development.

Over the past four years R&D returns have steadily declined

For the period 2010 to 2013, the positive impact of revenues from new compounds entering the late stage pipeline was sufficient to fill the gap left by the successful commercialization of assets as they launched. However, the level of pipeline replenishment has been insufficient to offset commercialization along with the cost of failure (terminated and stalled compounds) and reductions in forecasts for existing compounds. Additional downward pressure from operational drivers such as pure R&D cost (R&D expense incurred to progress the basket of assets into the late stage pipeline), phasing (amount of time and investment incurred in late stage pipeline development) and tax rates was not balanced by improvements in operating margin and licensing costs.
Number and value of late stage compounds
A detailed analysis of movement in year-on-year returns is more revealing in terms of drivers of performance. Three year-on-year time periods (2010-11, 2011-12, 2012-13) were also analyzed to identify trends in dynamic returns (Figure 2).

More specifically, 2010-11 was a period of successful launches, 2011-12 was a period of bringing new assets into the late stage pipeline and 2012-13 was a year of balance – value from new assets balanced value transferred to the commercial portfolio.

Over the past four years, the number of late stage compounds within the cohort has remained stable at around 200. The total forecast inflow of these assets declined from $1,369 billion in 2010 to $913 billion in 2013.

The increase in movement of compounds seen in 2011 12 was not maintained in 2012-13. While the number of approvals and terminations declined from 39 to 34 and 22 to 19, respectively, the number of new compounds entering the pipeline fell from 78 to 55, leading to an overall reduction in compound movements.

Trends consistent for the time periods 2010-11, 2011-12 and 2012-13
Comparing year-on-year changes in returns highlights some key trends consistent across the three time periods. New compounds entering the pipeline continued to provide significant uplift to year-on-year returns. However, each year this uplift was insufficient to balance the transfer of late stage pipeline value to the commercial portfolio when combined with losses due to terminations, stalled compounds and reductions in revenue forecasts for existing compounds.

Minor improvements in operating margins and reductions in licensing costs had a positive impact for each of the three time periods considered. Increases in overall R&D cost and tax rates resulted in a small, negative impact on year-on-year returns.

Figure 2. Drivers of change in IRR by year, 2010–13

Source: Deloitte UK Centre for Health Solutions, Deloitte LLP and Thomson Reuters research
Dynamic returns in 2012-13 mirrored those of 2010-11

The time periods 2010-11 and 2012-13 exhibited similar dynamic trends:

- more value was transferred to the commercial portfolio than was brought into the late stage pipeline
- an increase in the amount of time and investment incurred in late stage pipeline development exerted a negative impact on dynamic returns, and this was particularly pronounced in 2012-13
- the 2011 and 2013 yearly IRRs exhibited a significant decline from the previous year, at -2.8 and -2.4 percentage points respectively.

In contrast, for the period 2011 to 2012:

- the significant uplift from new compounds more than compensated for the value transferred to the commercial portfolio
- changes in R&D phasing (the amount of time assets spend in each phase of development) had a small, positive impact on performance returns

Overall, R&D organizations are commercializing effectively, this is particularly apparent over the last year, but they are failing to match this level of performance in other drivers of R&D returns, for example cost containment and rate of innovation. Companies need to maintain their current trajectory in terms of moving compounds into the late stage pipeline and on to commercialization. However, the pace of change in factors underlying the economics of R&D needs to accelerate for the sector to achieve a sustainable level of returns.

Conclusion

Although the adverse global economic climate appears to be easing, market conditions are likely to continue to prove challenging for life sciences companies. Payers will continue to apply downward pressure on price, with premium pricing reserved for the few, truly innovative drugs that can demonstrate improvements over existing therapies. Market access hurdles and demands for better outcomes data will continue to present the industry with a challenging environment in which to drive improved R&D returns.

As seen in the result of analysis of the cohort of 12 companies, the situation is not very optimistic. Readers will understand that there is no single silver bullet that will improve R&D.

However, it is worth noting that 105 products have been launched by the cohort of 12 companies over past 4 years, transferring $770 billion of projected value into their commercial portfolios. Moreover, the value of individual products has been drastically increased and costs other than R&D have been reduced. The keys to future success will include (1) how to ensure that enough assets advance to late stage development and (2) how to avoid loss caused by terminations. We hope productivity will be improved though all endeavors of pharmaceutical companies.

For further information, please contact us for a copy of the most recent Deloitte report, discussing results of competitive analysis for the 12 cohort companies, strategies for improvement in R&D productivity, and recommended methods for measuring asset value and IRR*.

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