

Catenion's ASAP for Bio-pharma
A **Science-driven** "Accelerated Search & Acquisition
Process" to Support BD&L

Catenion

Catenion is a management consulting firm devoted to helping bio-pharmaceutical and medical products companies significantly increase the returns on their R&D and Marketing investments by creating more innovative and effective strategies and organisations.

Executive Briefing

Accelerated Search & Acquisition Process

Executive Summary

Science and technology are moving so fast and in often unanticipated directions that open innovation strategies have become the standard in the biopharma industry.

While it is notoriously difficult to measure the economic success of licensing deals, determining the value created by acquisitions is more straightforward.

A recent analysis performed by Catenion indicates that over the past 25 years, just 41% of acquisitions in the biopharma space created value and this percentage trended negatively during this period. However, a number of companies have been very successful at pursuing inorganic growth from acquisitions. Examples include Gilead, J&J and Shire, which according to our analysis have created ~\$224 bn in value from M&A between them.

Whether BD&L takes the form of acquisitions or licensing deals, whether it is pursued as a core strategy (e.g. Tesaro's in-licensing of Niraparib) or in response to pipeline failures (e.g. Vera stem's in-licensing of Duvelisib), the key question for companies of any size is how to pick the right target asset or company and how to value their scientific/clinical robustness and economic potential?

So how do they do it? One of the major reasons is that they have put in place a comprehensive and robust process to effectively identify, value & execute on their ideal target candidate. Catenion has worked with many firms over the years, which has led us to develop the ASAP, our Accelerated Search & Acquisition Process.

The ASAP complements our clients' BD&L efforts with a systematic, comprehensive and strongly data- & science-driven approach to elucidate the key element of risk in the pharma industry: An asset's probability of success. The ASAP enables Catenion's high-calibre team of PhDs with many years' experience in the industry to systematically weed through more than 7,000 companies and approximately 23,000 clinical drug candidates to identify assets or companies that best fit the strategic needs of our client and have the strongest scientific profile and differentiation potential and hence, the highest value potential.

The ASAP bridges all the early stages of the BD&L process up to deal closure and post-deal integration strategy. Target screening is firmly rooted in the client's BD&L strategy and goes through a multi-step process starting with a semi-automated screen which filters and prioritises targets according to the client's strategic priorities using Catenion's proprietary 'crowd-sourcing' methodology. This is followed first by high-level and then deep-dive analyses of the long- & short-listed assets and/or companies respectively, using all available public data, from the published literature to patents and SEC filings.

The process can be run either independently or (more frequently) in collaboration with the client team to bring their insights on board.

Performance of the ASAP speaks for itself: Taking this approach has led to robust identification of high-value firms as judged by their collective stock performance – in two recent examples, the companies recommended to clients have outperformed the NASDAQ Biotech Index by more than 100% (cf. Figure 6).

Extracting value from BD&L is challenging

Inorganic growth is an essential facet of the pharmaceutical industry for most firms. Whether it is a biotech reinforcing its pipeline through in-licensing or a large-pharma undertaking a mega-acquisition, a mixture of asset sources allows for effective pipeline de-risking, increases sustainability and can replace revenue lost to patent cliffs.

However, consistently extracting value from M&A is challenging. A recent analysis done by Catenion indicates that over the past ~25 years just 41% of acquisitions created value and this trended negatively during this period; from 58% pre-2002 to 36% post-2013. There are several possible explanations for this including the dramatic rise of market capitalisations by ~4-fold, the move to targeting earlier-stage and higher-risk assets/companies, particularly in oncology, as well as the

possibility that analyst forecasts are not capturing the full value of assets still in development. However, some of the industry's most successful companies utilise BD&L extremely effectively. For example, Gilead has made seven acquisitions since 1999 with all but one generating value for the firm, to the tune of ~\$32 bn. This started with NeXstar for \$792 mn in today's dollars, which now has a present value of ~\$4.7 bn. Gilead's most successful acquisition to-date is that of Triangle Pharma in 2003 for \$489 mn which brought on-board the HIV drug Truvada valued at ~\$21 bn. Even the acquisition of Pharmasset for an 89% premium at \$11 bn which was widely considered to be too expensive (Gilead's share price dropped 12% on the news) has increased in value by 46% vs. the acquisition cost to date (cf. Figure 1).

String-of-pearls: Gilead

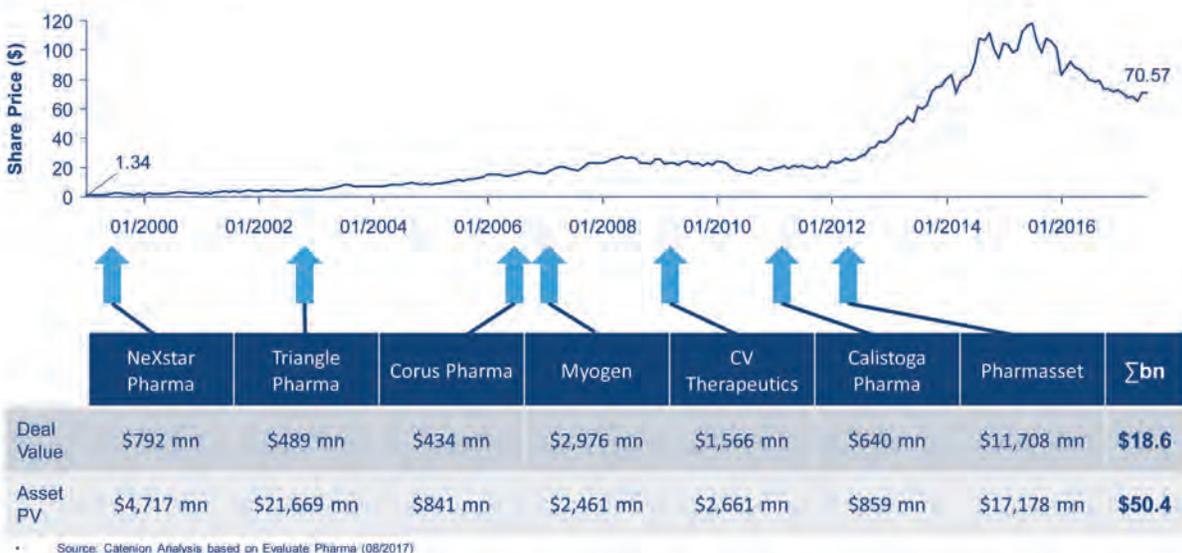


Figure 1 – One of the major reasons Gilead has been so successful is that it has extracted positive value from almost all the acquisitions it has made – to the tune of +270% or \$31.8 bn.

Another poster child for this 'string-of-pearls' strategy is Shire which has made 17 acquisitions since the turn of the century generating some ~\$58 bn of value overall. The most successful big-pharma with this strategy is J&J, having created ~\$134 bn in value from eleven acquisitions.

The biotech world also does its fair share of BD&L; this can be part of the company's strategy or in response to lack of progress of their pipeline. A good example of the former is Tesaro which has always followed a search and develop model: Their lead molecule Niraparib was in-licensed from Merck & Co for ~\$181 mn and is now worth ~\$6.5 bn. A recent example of the latter is Verastem's in-licensing of Infinity Pharmaceutical's

Duvelisib for just \$28 mn, which has recently generated positive Ph III data.

How do these companies consistently extract value through BD&L? One of the major reasons is that they follow a comprehensive and robust process to effectively identify, value & execute on their ideal candidate. Such a process should be:

- Tailored to the strategic goals of the company
- Systematic & comprehensive to ensure all possible targets are considered and "no stone is left unturned"
- Highly data-driven to accurately assess a target's value & risks
- Pragmatic & lean to ensure speed on execution

Overview of the ASAP

Catenion has worked with many firms over the years, from mid-sized pharma to biotech, to establish or improve on a 'gold standard' BD&L process. In addition, we also regularly run asset and/or company searches for clients using our proprietary search & evaluation tools. Thus, the ASAP (Accelerated Search & Acquisition Process) is the result of many years of interaction with leading industry players. The foundational element

of the ASAP is a science- and data-driven approach to evaluate assets' technical and commercial risk. Alongside the scientific foundation of the ASAP, another key element is a structured, transparent and effective process to identify high-value target assets and firms in a cost- and time-efficient manner – typically in approximately three months. The ASAP process contains four stages (cf. Figure 2):

- 1. Development of a BD&L Strategy** – this is tailored to the client's goals and is essential for the process to deliver optimum targets.
- 2. Target Screening** – a sequential process to establish a prioritised 'option space' from the ~7,000 available companies with ~23,000 drugs in active clinical development between them – this part of the ASAP will be discussed in more detail below (cf. Figure 3).
- 3. Reach out & Transactability Assessment** (optional, but can be supported by Catenion) – before committing resources to a deep due-diligence, it is key to establish if a transaction is feasible both financially and culturally through an initial high-level discussion and valuation.
- 4. Confidential Due Diligence** – deep assessment of all the available data to establish the technical probability of success of the target asset/s as well as a commercial valuation.

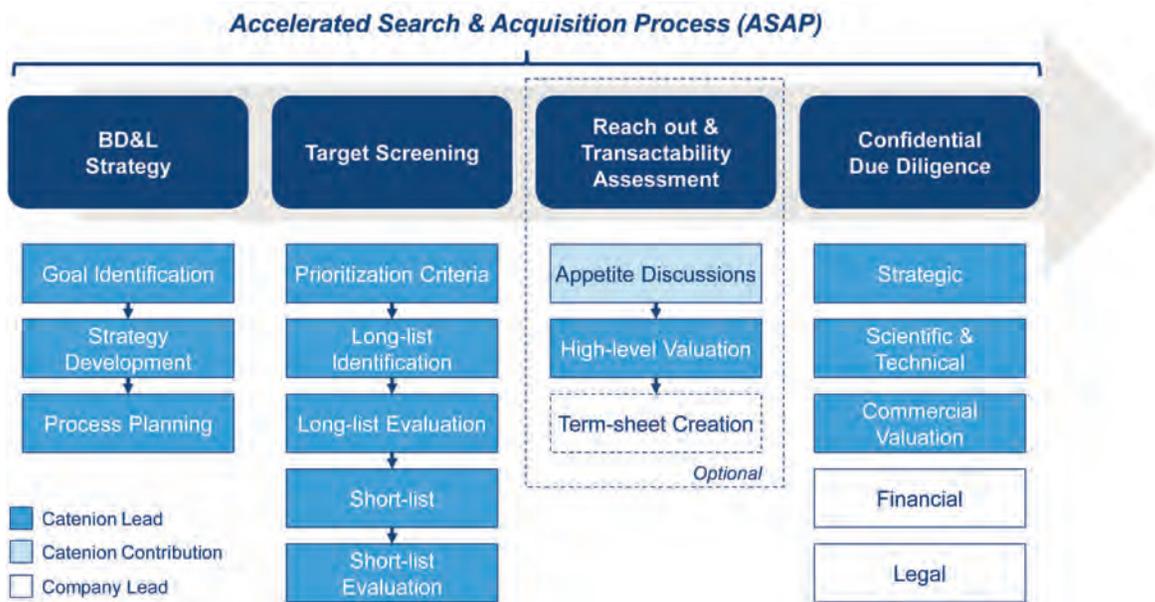


Figure 2 – The ASAP process can be fully supported by Catenion with the exception of term sheet creation, as well as legal and financial DD.

The ASAP starts with a review of the client’s BD&L strategy

Any process to identify BD&L targets must be linked to the overall corporate strategy and have clearly defined targets. For example, a company might want to increase revenue as the primary goal, profit or pipeline diversity; perhaps it wants to expand into a new therapeutic area or to gain access to novel technologies. Each of these

goals requires a distinct BD&L strategy in terms of both transaction structure (e.g. joint venture, acquisition, etc.) as well as target company profile. Catenion have developed a methodology to identify key gaps of the organization and its BD&L strategy which could potentially undermine its potential to reach corporate goals.

Systematic science-driven target screening lies at the core of the ASAP

With roughly 7,000 available companies working in the biopharma space, a pragmatic and robust process is required to identify the most interesting companies or assets without ‘boiling the ocean’ or

risking to overlook potentially attractive targets. Over many years and projects, we have created just such a highly efficient work stream that is composed of four discrete steps (cf. Figure 3).

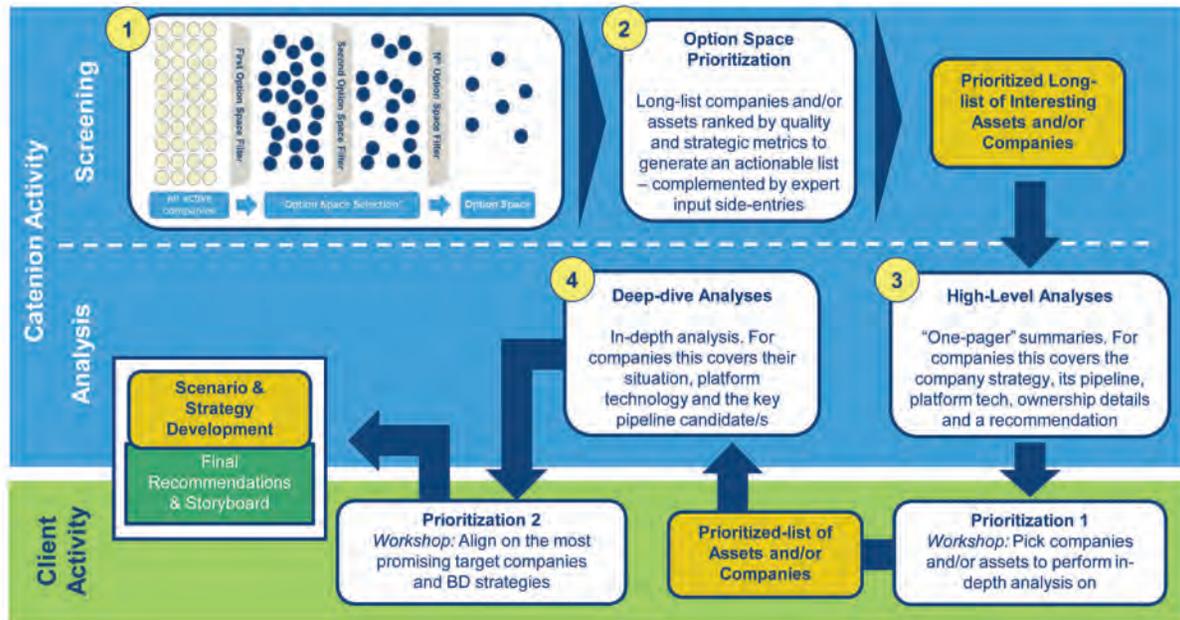


Figure 3 – The ASAP Target Screening Process has four discrete steps: 1-2) narrowing and ranking of the option space of companies or assets, 3) high-level analysis for potential & strategic fit and 4) an in-depth exhaustive analysis.

1. Filtering to the Option Space – the first step is to apply hard filters which exclude companies and/or assets out of strategic scope, for example assets not in target therapeutic space or companies with a market capitalisation beyond reach. As many filters as desired can be applied such that the option space of companies or assets best reflects the firms strategic intent; (for an example, cf. Figure 4).

Catenion ASAAP – Filtering Process



Figure 4 – Search-specific filters are applied in a semi-automatic process to establish a first long list of potential targets fulfilling the client's search objectives.

2. Option Space Prioritisation – Typically after applying these filters, one is left with far more assets and/or companies than can be reasonably analysed given time and/or budget constraints. To overcome this limitation Catenion have developed a proprietary methodology to rank the targets first by ‘quality’ and then by ‘strategic fit’. For the former the Catenion team crowd-source market, analyst, industry and regulatory sentiment to build an accurate picture of the targets’ quality – importantly, this also clearly identifies assets which are mostly overlooked and does not follow current ‘hype’. In addition, our consultants also lean on their extensive experience in the industry & BD&L to include side-entries (not identified by the screen but proposed by client team members); however, these are typically few in number as the overlap with the semi-automated methodology is high.

3. High-level Analysis – The next step is to look at the prioritised targets at a high-level and ask the question, ‘is the target fundamentally interesting to the client?’ This is achieved by condensing a wide variety of key information into a single slide for discussion with clients; for target companies this includes: The pipeline with key efficacy & commercial data, leadership, strategy, ownership structure, any platform technologies, key financials and major recent events. A similar slide with key asset details is used if the screen is asset-focused. The most interesting companies emerging from this analysis are then taken forward to the final step of the screening process during a prioritisation workshop with the client.

4. Deep-dive Analysis – The final step is to critically analyse all public data available for a target, this includes everything regarding the company as well as anything related to the target/pipe-line MoA in the public domain (e.g. published scientific papers, market intelligence reports, company reports, clinical & commercial databases, patents etc.). The analysis encompasses several dimensions in a structured format (cf. Figure 5) to ultimately capture the target’s attractiveness in terms of probability of success, clinical differentiation and commercial potential (essentially a discussion of the pros and cons of the analyst community’s estimates), as well as the feasibility of any transaction. These detailed analyses are discussed in-depth with the client in order to generate a final short list of assets and/or companies worthy of the effort of a full due diligence.

Step 4 – Deep-dive Analysis



Figure 5 – Dimensions covered during the deep-dive.

Confidential Due Diligence is the last major step in the ASAP

Once data-room access is established, the target's confidential data can be added to the 'deep-dive' analysis performed during the target screening – in this way we constantly build on the prior work for maximum efficiency. Catenion focuses its expertise on three aspects of the confidential due diligence: The scientific/ technical analysis of the asset or of the company's pipeline with the aim of quantifying the probability of success (as well as to identify non-PoS-related risks), the clinical development strategy with the differentiation potential crucial for commercial uptake and a commercial valuation culminating in a scenario-based eNPV for each late-stage asset. Catenion can also build a company valuation model if required.

Catenion's Due Diligence support uses the company's proprietary tool set including a 500-criteria strong R&D Risk Assessment Protocol and the Competitiveness Modelling approach for full development projects. We accompany client teams into the data room and provide in-depth, full-scale valuations of individual assets and companies. Results are documented in the form of a written report and explained to the client in a face-to-face meeting. In the R&D Risk Assessment

Protocol, individual risk criteria are aggregated into six risk classes which are relevant for decision-making: Conceptual Risk, Clinical Indication Risk, Compound Risk, Capability Risk, Product Supply Risk and Regulatory Risk.

All relevant quantitative and qualitative risks are bench marked against industry average; as a key outcome, the risk profile provides a sound basis for estimating the probability of success for the upcoming development stages.

For full development assets, we assess commercial potential with the help of indication-specific Competitiveness Models, in which we estimate sales potential for both the compound under investigation, as well as for the main competing compounds.

Given the understanding of a client's strategy gained during the ASAP process, once an offer has been decided on, Catenion can also support the definition of a deal structuring strategy; similarly, sometimes clients ask Catenion to provide them with strategic advice for post-merger integration.

What makes Catenion's ASAP superior to other approaches?

In summary, in Catenion's view, too many industry executives and advisors focus on the putative commercial potential of assets rather than dealing with their scientific robustness and clinical differentiation potential, which drive technical and commercial risk.

At its heart the pharmaceutical industry is driven by the probability of technical success, that is to say the chance the drug will gain regulatory approval. At the end of the day,

if the drug is clinically differentiated from the standard of care, significant sales are possible even in indications with a modest number of patients (e.g. Crizotinib in ALK+ NSCLC with ~\$600 mn peak sales). Therefore, analyses of the scientific, technical and clinical merit of a compound, or pipeline of compounds, is the foundation of the ASAP process – which enables Catenion's outstanding team of high-calibre PhDs with many years' experience in the industry

to work together with the client to maximise the experience and intellectual horsepower in the process.

Performance of the ASAP speaks for itself: Taking this approach has led to robust identification of high-value firms as judged by their collective stock performance – in

two recent examples, the companies short-listed for clients have outperformed the NASDAQ Biotech Index by more than 100%. In fact, out of the 22 companies comprised in these two samples, only one has reported negative data since the analysis was done (cf. Figure 6).

Historical ASAP Project Results

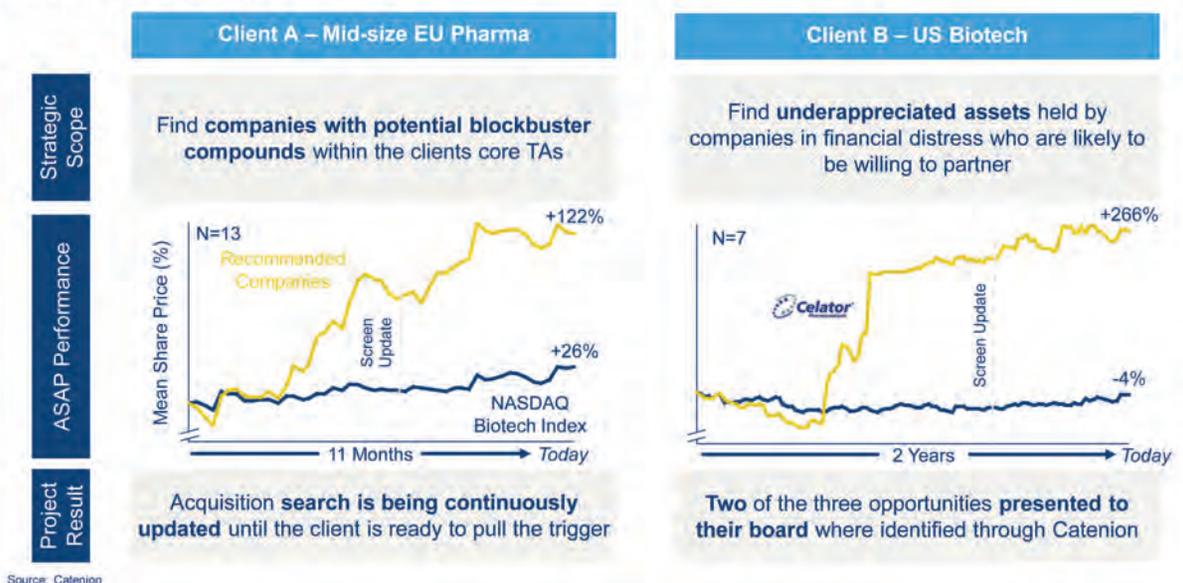


Figure 6 – Illustrative historical ASAP results. Company stock performance was tracked from the day the recommendation was given to the client until “Today”.

All content is provided "as is", without warranty of any kind, either express or implied, including, without limitation, implied warranties of merchantability and fitness for a particular purpose. Catenion and its third-party content providers make no warranties, express or implied, as to the ownership, accuracy, or adequacy of the content. Neither Catenion nor its third-party content providers shall be liable for any indirect, incidental, consequential, or punitive damages or for lost revenues or profits, whether or not advised of the possibility of such damages or losses and regardless of the theory of liability.

*Catenion GmbH, Hausvogteiplatz 12, 10117 Berlin – HRB95394 b
Geschäftsführer: Dipl.-Ing. Arno Heuermann*

*Content is licensed under a Creative Commons: Attribution (No Derivative Works 3.0),
www.creativecommons.org/licenses/by-nd/3.0*

Berlin (Headquarters)
Catenion
Hausvogteiplatz 12
10117 Berlin
Germany
phone: +49 30 2063 996 – 0
fax: +49 30 2063 996 – 22
e-mail: berlin@catenion.com

New York (Satellite Office)
Catenion
405 Lexington Avenue, 26th Floor
New York, NY 10174
United States
phone: +1 212 203 7276
fax: +1 917 368 8005
e-mail: newyork@catenion.com

London (Satellite Office)
Catenion
180 Piccadilly
London W1J 9HF
United Kingdom
phone: +44 20 7917 9511
fax: +44 20 7439 0262
e-mail: london@catenion.com

Tokyo (Satellite Office)
Catenion
Level 20 Marunouchi Trust Tower
1-8-3 Marunouchi, Chiyoda-ku
Tokyo 100-0005 Japan
phone: +81 35288 5270
fax: +81 35288 5271
e-mail: tokyo@catenion.com

www.catenion.com

Catenion