R&D spin-offs
Unlocking value for investors and focusing on the core business
June 2019
Creating value by spinning off

Background
While R&D efficiency has generally been improving in the pharma industry over the last few years, much of the innovation and many high-value products no longer come from Big Pharma, but from small, innovative biotech companies. The larger firms are responding by buying themselves into relatively late-stage drug candidates while externalizing inhouse R&D efforts. Typically they establish early research collaborations, e.g., with academia, and outsource development activities.

A spin-off, which involves divesting selected technology platforms, projects or the entire R&D function, is another option to make R&D efforts more flexible. The spin-offs typically produce operational headroom, which drives speed and innovation. In fact, a growing number of pharmaceutical companies have started to rethink their growth model and some even aim to completely separate their go-to-market function from innovation and research.

For the separation there are distinct success factors. The foundation is a coherent strategy of the parent company regarding where to focus inhouse R&D efforts and which activities to spin off. Next, proper valuation, buyer identification and a smooth transfer of the assets are key. Finally, the creation of a viable spin-off business with a new identity should also be a priority.

An R&D spin-off can be considered as a proactive strategic choice to deliver higher value for both companies, and successful implementation requires a robust separation program including efficient governance and risk management.

The challenges
R&D spin-offs are very complex and must satisfy many legal and regulatory requirements. Understanding a spin-off’s potential capital structure and associated cost is also critical in making a separation decision. Failure to meet any of those requirements can result in lost synergies, potentially high transaction and tax costs, conflicts of interest between the remaining company (RemainCo) and the spin-off (SpinCo), regulatory hurdles, brain drain and business disruption.

The answer
Considering the vast dispersion of returns that companies experience post-spin-off, we have outlined here the most critical elements that need to be addressed in a comprehensive manner in order to complete a successful set-up of a standalone entity.
Critical elements to address
Spin-off strategy
- Therapeutic area strategy and R&D strategy
- Strategy enabling action plan
- Identification of spin-off targets
- Valuation of the assets
- Identification of a suitable buyer
- Definition of the new ownership structure

Financial
- Structure Finance PMO
- Pro forma financial information
- Assessment of carve-out entity-specific accounting matters
- Carve-out (auditable) financial statements
- Reporting and key performance indicators (KPI) development
- Financial Vendor Due Diligence
- Day 1 Accounting support

Tax
- Adjusted earnings report
- Assessment of value impact of different divestment structures
- Exit readiness
- Seller information document
- Tax Vendor Due Diligence (VDD)
- Mitigation of price reductions for tax risks
- Planned tax structuring

Legal
- Establishment of the legal entity
- Obtaining all necessary regulatory approvals, licenses, registrations & credentials to operate, transfer employees, etc.
- Transfer formalities
- Legal framework arrangements: TSA

Operational
- Separation scope and concept
- Operating model definition of SpinCo and RemainCo
- TSA / SLA requirements
- Day 1 readiness
- Carve-out implementation
- Operational review and performance evaluation
- Stranded cost mitigation

Spin-off coordination
- Project management office (PMO)
- Portfolio reviews
- Data assimilation and alignment
- Data analytics, data rooms
- Modelling and business planning
- SPA negotiation support and completion accounts rehearsals
- SPA adjustment mechanism data/target setting (trade and other working capital)

Illustrative spin-off timeline

<table>
<thead>
<tr>
<th>Spin-off strategy</th>
<th>Workstreams</th>
<th>Rapid spin-off assessment</th>
<th>Separation concept, separation plan and execution</th>
<th>Post spin-off execution</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>4-5 weeks</td>
<td>12-15 weeks</td>
<td>6 months - 1 year</td>
</tr>
<tr>
<td>Financial</td>
<td>Perimeter/FDD</td>
<td>Prepare financials / Pro forma reporting / Closing accounts</td>
<td>Day 1 accounting</td>
<td></td>
</tr>
<tr>
<td>Tax</td>
<td>Pre-feasibility</td>
<td>Pre-spin restructuring</td>
<td>Detailed design</td>
<td>Post-spin implementation</td>
</tr>
<tr>
<td>Legal</td>
<td>Basic concept</td>
<td>Detailed concept</td>
<td>Document drafting</td>
<td>Post-spin implementation</td>
</tr>
<tr>
<td>Operational</td>
<td>Spin-off scope</td>
<td>Separation concept, plan</td>
<td>Day 1 readiness, TSA/SLAs</td>
<td>TSA exit, operating model implementation</td>
</tr>
<tr>
<td>Spin-off coordination</td>
<td>Governance set-up</td>
<td>Project coordination, management and monitoring (mair-tain deadlines and mitigate risks)</td>
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</tr>
</tbody>
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Board decision | Day 1
EY helps you to define the spin-off strategy to ensure that the overall strategic objectives are met.

### Key complexities to be addressed

- Defining the overarching R&D strategy based on the therapeutic area (TA) strategy
- Developing an action plan containing reorganization, spin-off (=divestment), outsourcing, and/or acquisition elements
- For spin-offs specifically
  - Valuating early stage assets, for which the therapeutic efficacy is unknown and the risk to fail is high
  - Identifying private or public buyer
  - Defining how connected SpinCo and RemainCo should be after the separation (full separation vs. close collaboration)
  - Creating a new viable business

### Solutions proposed

<table>
<thead>
<tr>
<th>Spin-off Strategy Steps</th>
<th>Examples</th>
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</table>
| What is the TA strategy? What is the resulting R&D strategy? | Focus the portfolio
| | Enter into new TAs
| | Address blockbuster patent expiry
| What is the corresponding action plan? | Reorganize
| | Externalize (spin-off or outsource)
| | Acquire
| What is the strategic objective behind the spin-off ambitions? | Reduce operating cost
| | Divest non-performing units
| | Gain speed & agility, drive innovation
| Which capabilities / services to spin off? What is their value? | Low productivity / potential
| | Not in line with R&D strategy
| | In need for more entrepreneurship
| Who is the buyer? How should ownership structure look like? | Identify a public or private investor
| | Define RemainCo’s share in SpinCo
| | Negotiate deal conditions

### Benefits

- Robust mid- and long-term R&D strategy and corresponding action plan
- Spin-off strategy in line with overarching strategic objectives
- Independent valuation of the assets by externals
- Identification of a buyer for the assets to be sold
- Suitable ownership structure for SpinCo and appropriate connections to RemainCo’s infrastructure
Financial

Key complexities to be addressed
- Definition of carve-out business, preparation of financial statements and periods required
- Establishment of perimeter for baseline financial data
- Reduction of all assets, liabilities and other costs specifically identifiable and attributable to carve-out business
- Assessment of historical accounting policies, previously passed audit adjustments and historical business activity
- Identification of all corporate costs & related drivers for allocation to carve-out business
- Assessment of carve-out entity-specific accounting matters

Solutions proposed
- Structure Finance PMO
- Pro-forma financial information
- Assess carve-out entity-specific accounting matters
- Carve-out (auditable) financial statements
- Reporting and key performance indicators (KPI) development
- Audit support
- Financial Vendor Due Diligence (VDD)
- Define the equity story
- Day 1 accounting support

Benefits
- Clear view over standalone financials, carve-out financials
- Secured financial reporting structure on Day 1 & ensuring financial control is maintained
- Business plan supported by clarity over historic performance and future potential
- Reduction of risk of buyers calculating different costs, creating uncertainty in viability of operations and driving down purchase price

EY helps you become more informed and better prepared to negotiate. This enhances your ability to achieve maximum value in a minimum amount of time.
Key complexities to be addressed
- Identification of opportunities to reduce cash tax & enhance cash flow through alignment of business model and tax/transfer pricing model
- Ensuring local tax registrations to prevent significant negative cash flows impacts, e.g., inability to recover input VAT
- Limitation of incremental customs/duties and costs resulting from product flows under new operating model
- For private equity buying community - consideration of ability of buyer to utilize interest deduction on acquisition debt
- Pre-spin restructuring, development of new tax-efficient financing and holding structure including cash repatriation

Solutions proposed
- Input into organizational structure to ensure split of roles and responsibilities is aligned to target tax/transfer pricing model
- Input into legal entity structure and transaction flows to ensure requirements for local tax registrations are met
- Mapping of product flows, taking into account regional/global trade arrangements to identify optimal customs/duties
- Identifying opportunities to ‘de-atomize’ allocation of EBITDA across legal entities (e.g., input into organization structure design)

Benefits
- Reduced risk and enhanced cash flow likely to have positive impact on sale price
- Integrated approach minimizes disruption to the spin-off process
- Tax input to be tailored for trade or private equity buyers

Once the perimeter of the carve-out is defined, tax can play a significant role in defining each element of the asset’s future operating model:

Organization structure
- Input into the allocation of key roles and responsibilities in the new organization
- Ensure alignment to target transfer pricing/tax model to achieve cash flow benefits

Legal Entity structure
- Design of optimal legal entity structure, taking into account local regulatory requirements
- Ensuring tax registration requirements are met to avoid incremental tax costs

Transaction flows
- Mapping optimal product flows from customs/duties perspective
- Defining internal/external transaction flows to align to optimal transfer pricing model

IT / ERP framework
- Input into design of IT framework to ensure supportability of optimal transaction flows

TSAs
- Input into TSAs to minimize incremental tax risks and negative cash flow impacts due to VAT or customs

To achieve positive cash flow impacts, the tax workstream is part of an integrated approach to drive close collaboration with all other workstreams.
Depending on the current degree of integration in the overall organization, transitional services and potentially also long-term arrangements will have to be set up between SpinCo and RemainCo. Careful consideration will have to be given to the potentially diverging interests of the parties involved.

The statutory rules applicable to the transfer of contracts in a spin-off are ambiguous. Further, individual contracts may contain explicit or implicit transfer restrictions. It is therefore important to diligently analyze the relevant contracts and to appropriately design the transfer mechanisms.

The choice of legal entity form will be mainly tax-driven, but operational aspects also play a role. Consequently, close cooperation with all other workstreams is key.

There are different formal ways of achieving a spin-off, each with its pros and cons. The choice of the right form is important to ensure optimal transfer of all assets, liabilities and contracts and to minimize legacy effects.

Benefits
► New legal entity is optimized to operational and tax requirements
► Transfer of assets, liabilities and contracts is handled in the most efficient way, eliminating or minimizing legacy burden
► TSA/LTAs are ready and service delivery continuity is ensured on Day 1 for SpinCo spin-off
► A clear, efficient TSA exit plan for SpinCo to be fully standalone

Solutions proposed
► Analyze output from other workstreams
► Analyze pros/cons of available forms (formal or functional demerger, asset transfer)
► Contract review and transfer
► Identify transfer restrictions
► Analyze shared customer and supplier contracts between SpinCo and RemainCo
► TSA/LTA preparation (joint effort between business and legal)
► Analysis of relevant legal framework

Key complexities to be addressed
► SpinCo legal entity setup
► Identification of appropriate form of spin-off
► Management of contract transfer or split
► Understand SpinCo dedicated contracts
► Understand Day 1 business-critical contracts
► Transition service agreements/long-term agreements setup
► Transfer of permits, licenses, certificates, etc.
Key complexities to be addressed

- Identification of all entanglements between SpinCo and RemainCo: shared processes, people, systems, contracts and assets
- Definition/level of separation on Day 1
- Prepare people transition (employee allocation, compensation & benefits scheme)
- Asset transfer to SpinCo (tangible and intangible assets - patents/trademarks, etc.)
- IT entanglements and separation concept definition for Day 1 and beyond => major separation complexities
- Process/procedures transition (quality documents (e.g., SOPs))
- Shared facilities separation

Solutions proposed

- Define scope of transfer and identify gaps
- Define right-sized SpinCo organization, employee allocation, knowledge transfer
- Identify required tangible and intangible assets to be transferred
- Early planning and execution of IT separation activities: clarity on system landscape, access and data segregation, separation of IT system architectures
- Review and transfer in a timely manner quality documents for ongoing and new trials
- Define Day 1 must-haves, conduct Day 1 Readiness workshop including cutover plans
- TSA / SLA requirements definition (scope and pricing)

Benefits

- Achieve independent SpinCo on Day 1 (first day when SpinCo is operational)
- Smooth transition to a SpinCo (successful Day 1 experience for all stakeholders)

Shared processes

Analysis of current shared processes with parent company and/or other business units within the country, region or at central, global level

Shared people

Identification of employees in shared processes/functions which are business critical for SpinCo post-Day 1

Shared systems

Analysis of IT applications, infrastructure & projects shared with parent company which are business-critical for SpinCo post-Day 1

Shared contracts

Analysis of shared customer and supplier contracts as well as permits, licenses and other legal documents required to run SpinCo post-Day 1

Shared assets

Identification of all required tangible and intangible assets that are not fully dedicated and shared with other seller entities (e.g., offices, laboratories, intellectual property)
The following are critical elements of a spin-off:

- **Prepare SpinCo financials** - Standalone company financials, reporting structure
- **Understand tax attributes and value** - Effective tax structuring should enable you to monetize a proportion of your investment in SpinCo prior to the spin-off
- **Understand legal implications** - The form chosen for the spin-off will have long-term implications both for SpinCo and RemainCo, and transfer of contracts will have to be carefully designed
- **Understand operational separation challenges** - Start early and don’t underestimate the lead time or resources needed to separate your business, especially in the finance and IT functions
- **Don’t underestimate the importance of good transaction governance to successfully execute operational spin-off** - Efficient SpinCo and project management contributes to an on-time, risk-free separation
- **Additionally, manage RemainCo and SpinCo conflicts of interest** - RemainCo, which has responsibility to shareholders and decision power until close, should make decisions that best enhance the long-term combined value of both future companies

Keeping these principles top-of-mind while managing the five critical workstreams will help enable control over the process and will drive toward a successful R&D spin-off

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<td>Define operating model changes and the impact on standalone cost structure; implement separation and TSA for Day 1</td>
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**Summary**

Financial reporting
- Manage the carve-out audit and processes; establish financial reporting function in SpinCo

Tax aspects
- Separate RemainCo and SpinCo in a tax-free manner

Legal
- Design the legal process with a view to the long-term implications

Operational Separation
- Define operating model changes and the impact on standalone cost structure; implement separation and TSA for Day 1
Why EY?

► **Connected team:** We have assembled a team that combines experts across borders, who are also accustomed to working together as an effective team.

► **Transaction experience:** Our team has a strong background in operations and IT, tax, financial, legal/accounting and a proven track record in advising our clients regularly on complex divestitures such as spin-offs.

► **Swiss experience:** We have all relevant capabilities covered in our Swiss team. Our Swiss professionals know the market and the specificities of transactions involving Swiss companies.

► **Market leadership:** We have the global critical mass to access niche expertise across the team.

► **Approach:** Our approach is flexible and practical, and our methodologies are built to drive high-quality results in time-pressured situations. We follow an issues-led approach that moves beyond a risk-based approach to diligence, toward opportunity identification and potential upsides for prospective buyers.
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