



Novasecta



THE NOVASECTA EUROPEAN MIDPHARMA REPORT 2021

Novasecta: Strategic Partners for
Pharmaceutical Leaders

Europe is home to 85 'MidPharmas' that invest in developing and commercialising pharmaceutical products. They each generate €100m-€3bn in annual revenue. In our sixth annual report into this sector, we look at this microcosm of the global industry and examine how its companies survive and thrive. Ambitious pharma and biotech leaders can learn a lot from them.

Executive Summary

MidPharmas are both a microcosm and exemplar of what it takes to be successful in the pharmaceutical industry. In this report we examine the roots of this sector's success, which primarily lie in two dimensions: product innovation and commercial innovation.

We first cover **ownership** - three quarters of MidPharmas are privately controlled, which creates its own dynamics and requirements.

For **product innovators**, we explore the companies that rely on R&D to define their future. We look at how a clear focus on a technology platform or therapeutic area can drive growth and profitability, so long as the operating model is fit for purpose.

For **commercial innovators**, we delve into the diverse world of those creating value from on-market medicines, often past their patent expiries. In this case with the focus on finding product portfolio, geographical and patient journey niches that lend themselves to an innovative operating model.

We conclude with optimism. Since we started working with and tracking MidPharmas many years ago, we've seen big improvements in both growth and EBIT margins. This isn't yet universal but it shows what is possible at this scale, and demonstrates that necessity is indeed the mother of invention.

Novasecta analysed public domain data for European-headquartered companies that invest in developing and commercialising pharmaceutical products and generate €100m-€3bn in annual revenue. This definition excludes service companies, distributors, and US companies that domicile in Ireland or UK. Companies are also excluded from relevant sample sets where there are insufficient public domain data available. We analysed data for the years 2013 – 2020 (calendar years or nearest published business year) sourced from Global Data, company websites, and other public domain sources. Data analysed includes revenue, R&D spend, number of R&D employees, profits (using operating income as a proxy for Earnings Before Interest and Tax), and number of deals. All data reported in local currencies has been converted to Euros at the average exchange rate for the calendar year analysed. In each graphic, 2019 or 2018 data has been used for companies where more recent data was not published. For R&D investment as a percentage of revenue, of the 85 MidPharmas identified, 50 have sufficient recent public domain data on both revenue and R&D spend. Of those 50, Galapagos (R&D investment 110%), Basilea (67%) and Valneva (77%) are not displayed as they are outliers. Other companies are included in the remainder of the report where some data (such as revenue trends) are available. Compound Annual Growth Rates (CAGRs) are based on 2015 – 2020 data, or 2014-2019 where 2020 data are unavailable (four-year revenue CAGRs are used for Indivior, Pharma Mar, and Reig Joffre). For EBIT trend, companies where EBIT margin (EBIT divided by revenue) for all 5 years was not available were excluded. Deal analyses examine data on mergers, 100% and majority acquisitions, and strategic alliances collected from the GlobalData deal database for years 2016 – 2020. For the performance ranking, 39 ranked companies were assigned to 5 equal groups with integer scores from 0 to 4 representing the number of quadrants of the Harvey balls. Total rank is based on the sum of all three sub-rankings (R&D, commercial, and business development), and the lowest sum is the highest total rank.



**OWNERSHIP
DRIVES
STRATEGIC
FOCUS**



Aside from scale, the key feature that sets MidPharmas apart from pre-revenue biotechs and Big Pharma is ownership. Three quarters of the 85 European MidPharmas we track are privately held or controlled, with 68% being fully private, and 9% with both a dominant private shareholder (>50%) and a public listing.

In MidPharmas, private ownership traditionally means families or foundations, with a more recent trend towards Private Equity funds. Fully listed ownership is predominant in both larger commercially-focused companies - such as Hikma, Gedeon Richter and Vifor - and successful biotechs with added commercial capabilities that have joined the MidPharma space, like Genmab, GW Pharmaceuticals, MorphoSys and Valneva.

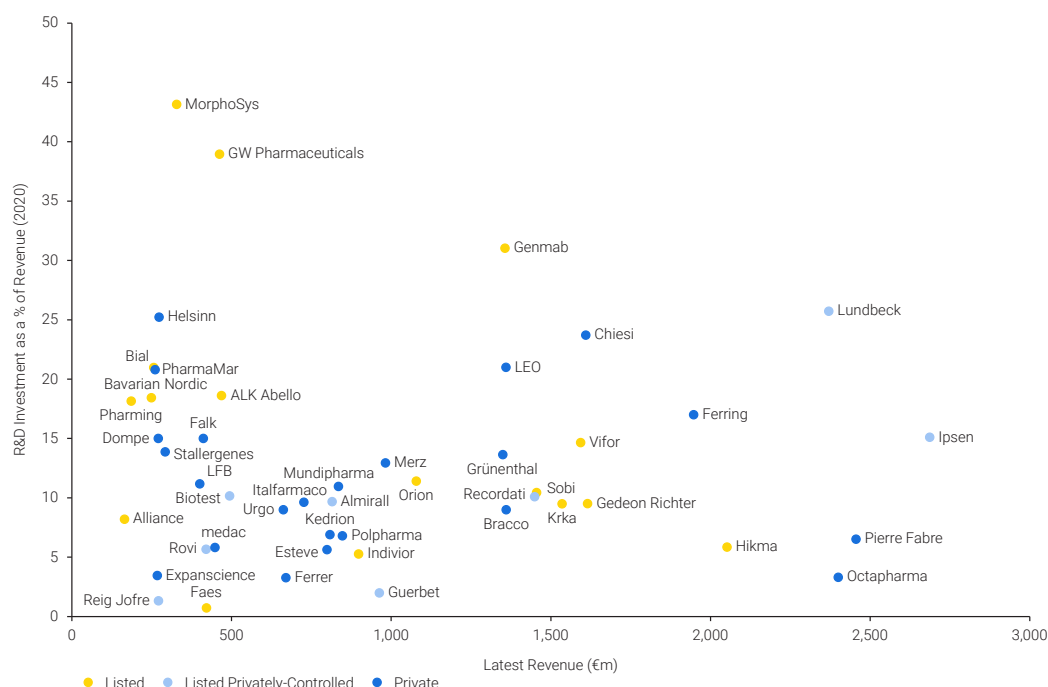
Because of their scale, MidPharmas need a clear sense of differentiation from both their well-funded Big Pharma competitors, and the increasingly well-capitalised pre-revenue biotech sector. More and more, they're choosing their basis of differentiation, either as product innovators or commercial innovators.

For the MidPharmas focusing on product innovation, the owners are usually families, foundations and investors seeking the upside of innovation, while accepting the associated risks. They hold a clear belief that value lies in the art of creating new medicines. Their companies often possess a core capability in either a platform technology or therapeutic area, maximising their chances of creating products that will create value and sustain their top-line growth.

By contrast, the owners of MidPharma commercial innovators (increasingly Private Equity funds) typically believe that value lies in EBITDA growth. They make the most of medicines that are already marketed through commercial innovation and cost discipline.

The distinction between a strategic focus on product innovation or commercial innovation is reflected in the different levels of R&D intensity amongst MidPharmas - the amount each invests in R&D in a year as a percentage of the annual revenue. Product innovators typically invest a significant proportion of their top-line revenue, while commercial innovators tend to see R&D as an annual cost to be kept as low as possible in order to boost EBITDA.

European MidPharmas have Highly Diverse Approaches to R&D Investment





**PRODUCT
INNOVATORS
FOCUS ON
PIPELINE
VALUE**



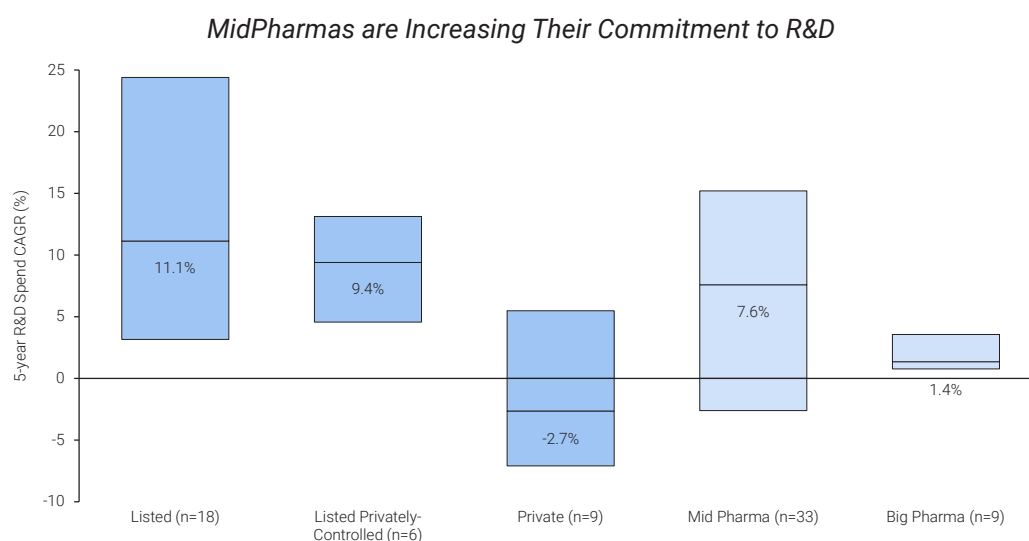


Product innovators focus on product-based R&D, often with a vertically integrated business model, incorporating discovery, development, marketing and sales of new pharmaceutical assets. The strategic focus of MidPharma product innovators is often driven by competencies in one or two therapeutic areas, or a multi-use technology platform. The intention being to create new products to replace those that no longer have patent protection or have been superseded by competition.

Increasing R&D Investment Year-on-Year

There are numerous ways to measure pipeline value and the return that pharma companies make on R&D – all of which require assumptions, and unfortunately many of those are neither soundly based nor unbiased. Yet, most can agree that if a corporate leadership team commits more funds to R&D year-on-year, and is supported by its shareholders, it's engaging in "productive" R&D. Increased R&D investment suggests that either projects are advancing to the more expensive stages of development, or that there is more belief in the value that R&D will bring to shareholders. Or both.

By the measure of increasing R&D investment year-on-year, MidPharmas are apparently more "productive" in R&D than their Big Pharma counterparts, with the listed MidPharmas also much more productive than their fully private counterparts:

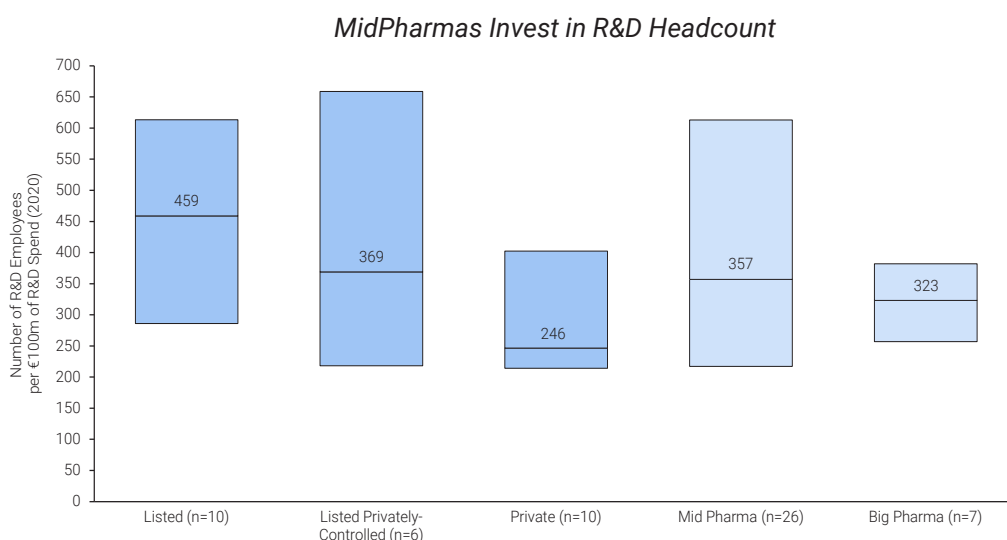


The 9-11% annual increase in R&D investment for listed MidPharmas is impressive. Clearly, public ownership drives management discipline through the need to constantly prove to shareholders and stock market analysts that value is being created. Ownership also influences corporate behaviour - with growing listed MidPharmas, analysts and boards focused on rewarding increased pipeline value, which requires more R&D investment. Meanwhile, Big Pharmas' R&D investment median increase of only 1.4% annually demonstrates that capital is going into other companies that investors trust more to create new innovative medicines.



The stark contrast of the median 2.7% decline in R&D investment in private MidPharmas highlights a change in the R&D approach of many of these companies. In some cases, this represents an ongoing long-term commitment despite setbacks. In others, it's because of a strategic shift of the business model. For example, Grünenthal has reduced its commitment to R&D, while increasing its commitment to commercialising established brands. It first acquired the European rights to the off-patent acid reflux drug Nexium, and later acquired other established medicines. Similarly, Esteve spun out its discovery activities and acquired Riemser, which commercialised and distributed established medicines in Europe, as well as other established brands further down the line.

Building Internal R&D Capabilities



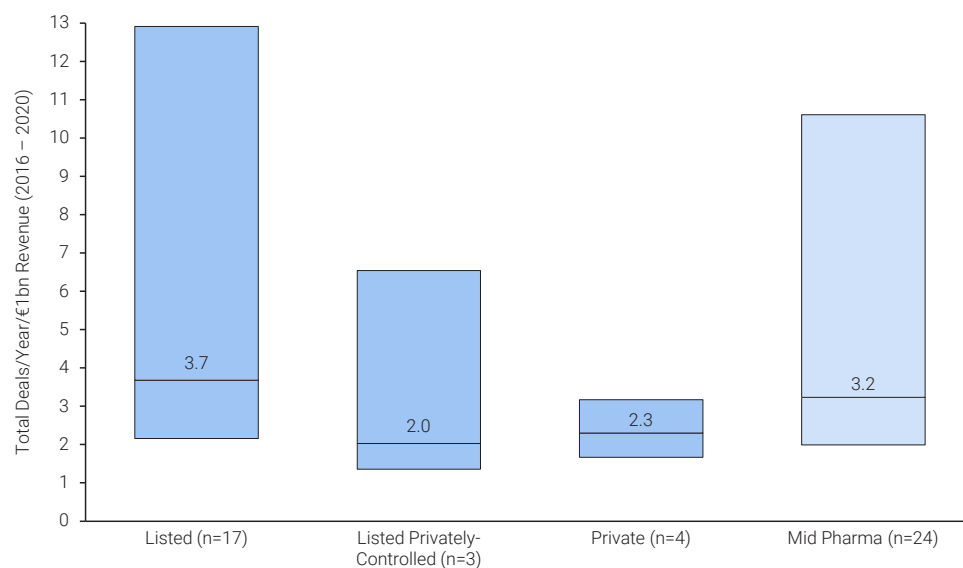
It's encouraging that, as well as demonstrating the highest growth in annual R&D spend of MidPharmas and Big Pharmas, the listed MidPharmas also have the highest number of R&D heads per €100m R&D spend. While increased headcount doesn't always mean increased quality, it is generally correlated. It shows the benefits of being willing to access and utilise capital to invest in R&D capabilities, and highlights a big contrast against the leaner R&D models of the fully privately held MidPharmas.

The relatively low R&D headcount of the private MidPharmas reflects both a hesitancy to invest heavily in internal R&D, and a more recent inclination to remove costs from the business. There's no doubt that a lean headcount does provide flexibility to cope with setbacks – in fact, it's the preferred biotech model. But in private MidPharmas it can suggest an inability or unwillingness to invest in (or attract) the high-quality hires who will catalyse great science. This creates a vicious circle - drip-feeding R&D can lead to poor pipeline progress, which in turn can result in a more drastic strategic shift to remove it entirely and completely change the company business model.



Collaborating Externally

Listed MidPharmas Execute More External Deals Than Their Peers



Effective external innovation – accessing great people and science from around the world – is one of the hallmarks of the successful MidPharmas focusing on product innovation. Science moves too fast to keep it all internally.

Listed MidPharmas lead the way in terms of deal execution, which is most likely down to having greater funds to participate in mergers, acquisitions and collaborations, and added motivation to create news flow which may impact valuations. Regardless of ownership, however, MidPharmas have been conducting a median of 2-4 deals/year per €1bn of revenue over the last five years, demonstrating a universal understanding that they can't 'go it alone' to be successful in R&D.





Focus and Stand for Something

The MidPharmas focusing on product innovation are almost always focused on either 1-2 therapeutic areas or a technology platform. This is no accident – building differentiated capability is tough and, at this scale, to attract talent MidPharmas have to stand for something.

The larger MidPharmas with a long heritage of specialising in product innovation will usually focus on a therapeutic area (TA), and usually it's a single area – though sometimes with (or building) an additional complementary one. Examples of globally renowned TA-focused MidPharmas are: Lundbeck in CNS, Chiesi in Respiratory, Ferring in Women's Health, LEO and Almirall in Dermatology. As with Big Pharma, this is often down to having a single great product, one that forms the basis of physician-relationships and disease-understanding that mark out the most successful TA-focused players. Such in-depth pharmacological and medical disease-understanding increases the likelihood of identifying and progressing successful assets. It can also act as a magnet for the world's most innovative clinician scientists, to either join or collaborate with the company.

By contrast, the newer MidPharmas specialising in product innovation often have a technology platform focus. A frequent characteristic of pre-revenue biotechs, this kind of focus creates a deep scientific understanding of technology that can create multiple products. The challenge is to create multiple products that span multiple disease areas, which makes end-to-end therapeutic focus much trickier to achieve. That said, it is possible - GW Pharmaceuticals (more recently acquired by Jazz Pharmaceuticals for \$7.2bn) is an excellent example of an organisation sustaining an innovative edge in a technology, in their case synthetic cannabinoids. As is often the case, the exception is oncology, where a platform focus - for example, in antibodies like Genmab and MorphoSys - can be leveraged into multiple indications in a single TA.

A further area that has become popular with some MidPharmas is Rare Diseases. In reality, this is neither therapeutically nor platform-focused. Rare diseases cover thousands of diverse indications and lend themselves to multiple technology modalities, including Cell and Gene Therapy as well as small molecules and biologics. The appeal of potentially shorter development timelines, higher prices, and fewer patients (meaning cheaper clinical trials), all suggest promising profit margins for MidPharmas. The niche patient populations and small, centralised treatment networks of rare disease indications also lend themselves to smaller and more focused commercial organisations - though these are very different to traditional primary of specialty commercial capabilities, so are not an easy "bolt on". As such, some MidPharmas are creating special integrated units to focus on this area - notably Chiesi and Recordati, who have both pursued this path alongside their core businesses.



Create and Sustain a Fit-for-Purpose Internal Operating Model

Success in R&D comes from people. Great science and medicines are created by great people working together, standing on the shoulders of the giants that came before them, and inspiring investors to back them. Attracting and motivating the right people from multiple disciplines (both inside and outside the organisation) to work together effectively is the central R&D challenge for the entire industry. It's this 'operating model' that distinguishes the winners from the losers in R&D. Capital is always available for organisations with amazing operating models.

European MidPharmas are typically committed to retaining people, particularly in family firms, which ensures they maintain the right level of knowledge through the long process of idea-to-product. However, such commitment becomes a risk in terms of losing scientific edge and sustaining an inward focus that doesn't accept new ideas and capabilities from external sources. Managing this balance is tough. And unsurprisingly, top management teams who are disappointed with their R&D organisations are naturally attracted to the allure of external innovation and acquiring successful biotechs. Yet, they need great internal capabilities to decide what is good externally. And without a healthy internal R&D organisation and a pipeline that attracts great people, they're stuck.

Adopt an External Innovation Mindset

Product innovation in pharmaceuticals is notoriously expensive and risky, so it demands a certain amount of fortitude and resilience. It's testament to the owner-entrepreneurs and families who have undertaken such innovation that they've often used mostly their own money for an uncertain return, and continue to do so. Yet, the reality of product innovation now is that no single organisation can control and own all of the factors required to create a rich pipeline of potential products. Accepting and sharing risk with outside parties, such as other companies or new investors, is an essential element of any MidPharma (or indeed Big Pharma) business model, particularly in R&D.

When it comes to sourcing expertise, bolt-on acquisitions, strategic partnerships and raising capital, successful MidPharma product innovators need to be very externally wired. This mindset shift manifests itself in companies actively building relationships with high quality expert scientists and physicians. Again, it's about people – the right experts can often provide access to wider expert networks that ultimately guide portfolio and project decision-making. MidPharmas, therefore, need to develop and leverage a network of innovators in numerous areas - academia, biotech, pharma companies, venture funds, tech transfer offices - to access new project ideas and opportunities.



**COMMERCIAL
INNOVATORS
FOCUS ON
SCALE AND
EBIT GROWTH**

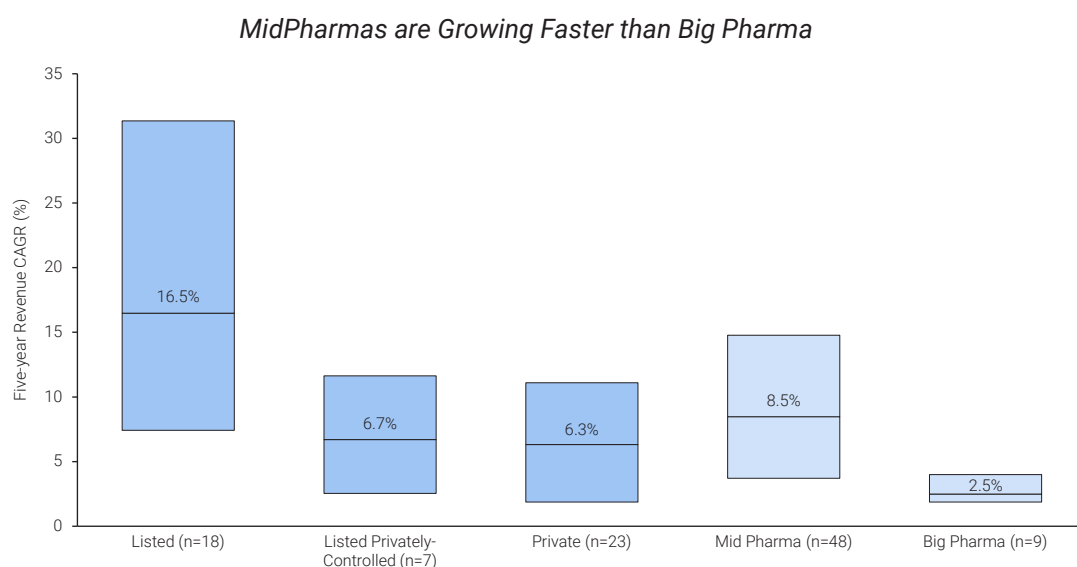


Commercial innovators realise that great products can still generate revenue and margin after their patents have expired. Some of these innovators choose brands that require very little promotional spend, some find patient-journey niches where reliable drug supply is limited - such as unlicensed medicines - and others create new business models to drive margin growth. With Big Pharmas often wishing to divest established products to fund innovation or cut costs, there are opportunities for MidPharmas to buy assets and find more profitable paths for non-innovative medicines.

Some commercial innovators also invest in lower-risk R&D activities, including reformulating and enhancing off-patent medicines, to expand and find underserved markets for established products.

Although tough to achieve anything above the generic price, this low-risk development can be more easily outsourced or partnered, meaning companies don't need to invest in significant in-house R&D to improve top-line performance and profitability.

Driving Top-line Growth

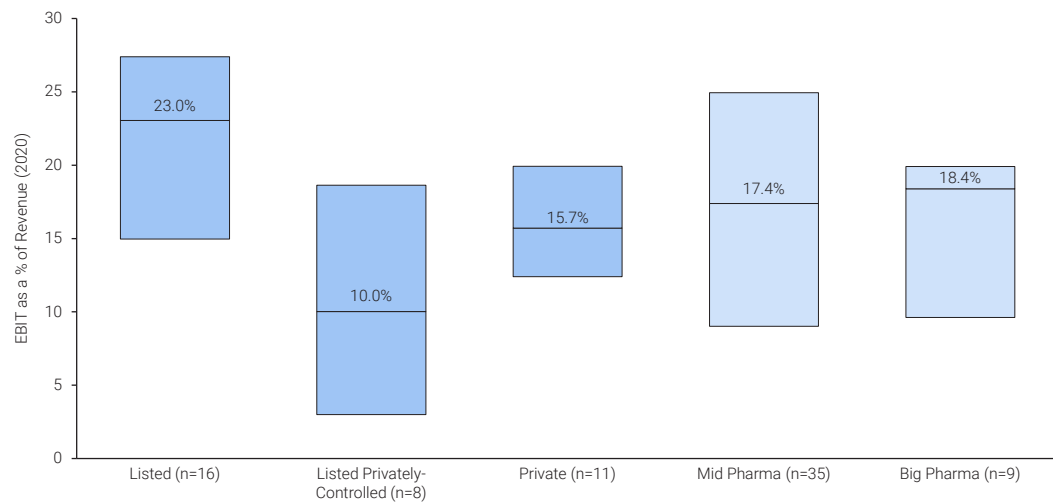


MidPharmas' impressive median 5-year revenue CAGR of 8.5% contrasts sharply with the 2.5% CAGR achieved by Big Pharma. While it's admittedly easier to post such growth rates when a company is smaller - particularly when the cohort includes newly emerging pre-revenue biotechs such as Genmab - the growth performance still spans all MidPharmas and ownership types. This performance hasn't gone un-noticed by Private Equity funds seeking opportunities to invest capital for medium-term growth - as illustrated by controlling investments or acquisitions in multiple MidPharmas, such as Acino, Advanz, Alvogen, Ethypharm, Galderma, Neuraxpharm, Nordic Pharma Group, Recordati, Sobi, and Stallergenes Greer.

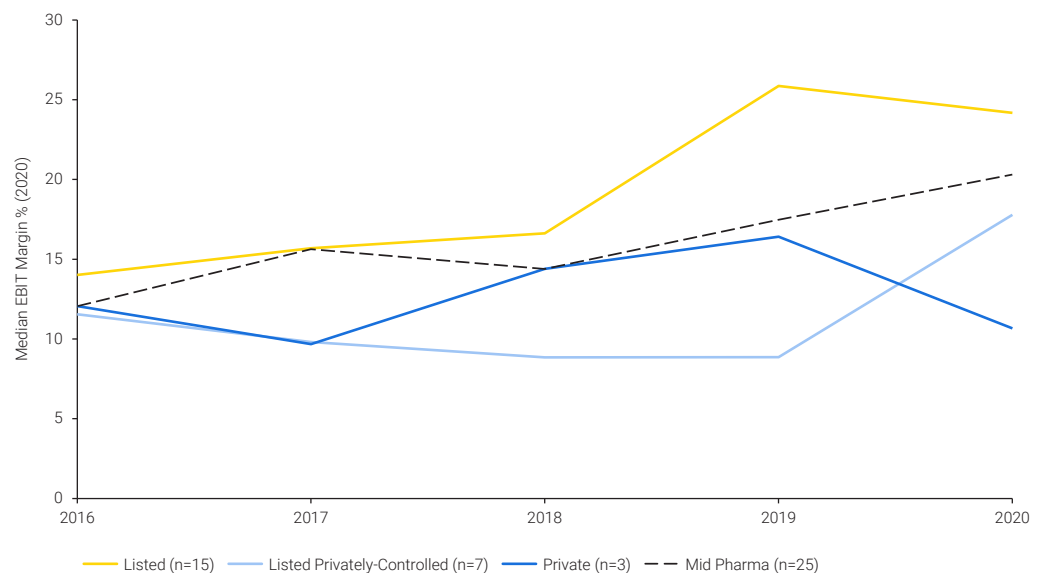


Relentlessly Seeking EBIT

MidPharmas Have Comparable EBIT Margins to Big Pharma



EBIT Margins Have Trended Upwards, with Listed MidPharmas Leading the Way



The impressive top-line growth of the MidPharma sector hasn't been at the expense of profitability, with EBIT margins now comparable to those of Big Pharma. This is indicative of strong leadership with the discipline to maintain operational efficiency while growing. With sustained revenue growth, the attractiveness to potential investors and follow-up funding from existing investors may yet contribute to a virtuous growth cycle for listed MidPharmas.

The listed MidPharmas are outperforming both private and privately-controlled peers as well as Big Pharma – both in EBIT margin, and as a trend over five years. For both Big Pharma and the private MidPharmas, this may be explained by timing – notably the impact of reduced prices (and therefore margins) in primary care diseases and established brands, together with a lag in reaping rewards from highly specialised innovation. Time will tell, and MidPharmas are increasingly acknowledging that they cannot rely solely on physician loyalty to branded generics and co-marketing innovative products sourced from Big Pharma.



IMPLICATIONS FOR COMMERCIAL INNOVATORS



Focus the Product Portfolio and Geographic Footprint

The first mental step for commercial innovators is to remove the expectation that R&D will deliver the next big thing that will keep the salesforce busy. Some have taken longer than others to do this, and many have found it very hard to take the next step of letting go of the loyal R&D employees who've been trying unsuccessfully to create the products they need.

Importantly, some R&D capability must remain to maintain dossiers and deal with regulatory changes, particularly related to manufacturing. In some cases, MidPharmas use R&D more creatively to add incremental low-risk formulations and label extensions to existing products – always relying on an existing product to leverage.

Once the corporate focus has moved solely to commercialising an on-market product portfolio, the real work of creating a strategic focus can begin. This requires the dedication of leadership to portfolio profitability analysis, price modulation, and the creative management of a diverse range of on-market products.

MidPharmas have always been creative in how they commercially innovate. Some, like Cheplapharm, purchase established brands (usually from Big Pharma) and apply a lean and ultra-low-cost approach to sales and marketing – allowing them to make margins that Big Pharmas couldn't achieve with heavy legacy fixed-cost burdens. Some have chosen to supply in profitable niches, such as Clinigen in unlicensed medicines. While others have opted to sustain low-risk incremental R&D in legacy therapeutic areas, such as Stallergenes Greer in allergy. It's the diversity of approaches to commercial growth that characterises the MidPharmas choosing a commercial patch to success, rather than relying on the classic Big Pharma product innovation model. There are niches and opportunities which entrepreneurial management teams can exploit – in all cases, the foundation is a clear strategic focus to galvanise action.

Re-imagine the Commercial Operating Model

Some of the commercially innovative MidPharmas focus on operational innovation to achieve success, where incremental product innovation (such as reformulations and branded generics) often only achieves marginal price premiums. To create and sustain value, these companies depend on key value drivers, such as a lean commercial footprint in tactical geographies, strong regulatory competencies, and efficient outsourcing models. This is exemplified by Advanz Pharma and its unique India Centre of Excellence, specialising in quality, regulatory and medical. This allows it the efficiencies of 'outsourcing', while retaining the benefits of being 'internal' - such as improving its technology, and training its own people.

Commercial innovators are also taking advantage of investment in technology-based commercial innovation, reversing the traditional thinking that 'innovation' should always belong in R&D. One example is the technology-enabled tools



that optimise customer segmentation and provide actionable insights to sales teams to be used for call planning, navigation, and pre-call insights. However, one common pitfall when using these tools is moving from a pilot phase to true industrialisation. Companies need to take time to understand what works for their businesses, so it's important to ensure robust implementation of those value-creating technologies, and to ensure capabilities are truly embedded rather than just added as 'extra' functions within the organisation.

The classic line-by-line cost-cutting approach can be useful for MidPharmas that are focusing on commercial innovation. The creative MidPharmas take this one step further – essentially using the strategic focus on specific on-market medicines to re-imagine the entire operating model. Thus investing in world-class capabilities in selected areas, creating simple and dynamic governance, stripping out activities that don't add value, and outsourcing to low-cost providers.

A clear and effective commercial operating model is also required to ensure that any acquired brands or companies are quickly and profitably integrated into the company. Again, MidPharmas that have developed these capabilities can drive profitable growth more quickly than the ones that are slower to adapt.

Aggressively Acquire Companies and On-market Products

Without any source of new products from internal R&D, it's imperative for commercial innovators to acquire products from external sources - which usually means the company acquisitions, product/portfolio acquisitions, and roll-ups that are typically favoured by cash-rich Private Equity funds. Correspondingly, Big Pharmas wanting to divest portions of their established portfolios can create bidding wars to secure a significant premium for their assets. While capital is plentiful, Private Equity funded MidPharmas can afford this. And as a result, family-owned and listed companies with less appetite for leveraging up their balance sheets can find it hard to compete.

For some privately held and long-established MidPharmas, acquiring to build has been a legacy strength. Over decades, the entrepreneurial (and often acquisitive geographical) expansion of companies such as Recordati and Menarini has transformed them from local pharmacies to successful global pharmaceutical companies. The challenge now lies in the limited supply of small companies to acquire at reasonable prices. Those that wish to play in the established brand space now find many competitors for products, and companies that are already generating EBITDA. This has resulted in the price to acquire or license them going up exponentially.



OUR MIDPHARMA PERFORMANCE RANKING



Since most MidPharmas are not listed, market capitalisation is an insufficient measure of success in this sector. So we've created a proxy ranking of performance to identify the MidPharmas that've been doing well, and those that are still on the journey. This year, we've ranked the MidPharmas in terms of top-line and bottom-line, using three metrics: 5-year revenue CAGR, absolute revenue, and EBIT margin. These three allow a comprehensive view of growth, current size, and profitability. We've taken public domain data on each of these three attributes for the companies that disclose such data (39 out of 85), and have ranked the companies based on the combination of the three.

Novasecta's European MidPharma Performance Ranking 2021

Rank	Company	Revenue CAGR	Absolute Revenue	EBIT Margin
1	Genmab	●	●	●
2	Sobi	●	●	●
3	Ipsen	●	●	●
4	Hikma	●	●	●
5	Octapharma	●	●	●
6	Vifor	●	●	●
7	Recordati	●	●	●
8	Clinigen	●	●	●
9	Chiesi	●	●	●
10	Lundbeck	●	●	●
11=	Gedeon Richter	●	●	●
11=	Krka	●	●	●
13	Pharming	●	○	●
14	Guerbet	●	●	○
15=	Faes	●	●	●
15=	Dermapharm	●	●	●
17=	GW Pharmaceuticals	●	●	○
17=	Galapagos	●	●	○
19	medac	●	●	●
20=	Alliance	●	○	●
20=	MorphoSys	●	●	●
22=	PharmaMar	●	○	●
22=	Rovi	●	●	●
24=	Abiogen	●	○	●
24=	Orion	○	●	●
26	Bavarian Nordic	●	○	●
27	Ferring	○	●	●
28	LEO	●	●	●
29	Reig Jofre	●	○	○
30	Kedrion	○	●	●
31	ALK Abello	●	●	○
32	Indivior	○	●	●
33	Zambon	○	●	●
34	Basilea	●	○	○
35	Almirall	○	●	●
36	Valneva	●	○	●
37	Merz	○	●	○
38	Stallergenes	●	●	●
39	Biotest	○	●	○

Key: Listed Listed Privately Controlled Private

The top three in our ranking perfectly demonstrate the strength and diversity of the MidPharma space. Genmab's antibody platform and product innovation has served it and its investors very well over the last five years. Sobi's focus on rare diseases resulted in an offer from a Private Equity consortium for \$8bn in 2021.



And privately controlled (also listed) Ipsen has sustained its growth from its long-established products by investing in commercial entry into the USA.

Notably, fully private family ownership isn't an obstacle to outstanding performance. Family-owned Chiesi and Octapharma have each performed well, owing to their dominance in a clear focus area - in Chiesi's case respiratory, and in Octapharma's plasma fractionation. Private control (more than 50% of shareholding) with a stock market listing has also served companies well, such as Recordati (family, then more recently Private Equity) and Lundbeck (foundation), as well as Ipsen (family).

Lower down the list, we see companies that have transformed their businesses and will need more than five years to see the results in revenue and profitability – notably Almirall which pivoted from respiratory to dermatology, and Merz which pivoted from CNS to aesthetics. Investing in product innovation requires a long-term mind-set and resilience, which is why many MidPharmas have chosen the commercial innovator route. Sadly, many of these (often Private Equity funded) players don't disclose any revenue or profitability data, so how well they're doing can only be judged by the premiums they achieve when they are sold to a company or another investor. Sometimes even this isn't disclosed. That said, we interpret the significant increase in Private Equity interest in these kinds of MidPharmas as evidence that strong profitability and growth is indeed possible.

Conclusion

MidPharmas are both a microcosm and exemplar of what it takes to be successful in the pharmaceutical industry - a clear strategic focus, a fit-for-purpose operating model, and an appetite for external collaboration. Change is the norm, as without the scale of Big Pharmas which are able absorb setbacks, MidPharmas have to both consistently choose the right path for their companies and adjust rapidly to competitive and market developments. This keeps management on its toes.

Is there a choice between investing primarily in product innovation or commercial innovation? In most cases we see MidPharmas inexorably choosing one or the other. Some companies feel they can do both, keeping the commercial focus to drive EBITDA, while limiting R&D investment to a level where it is affordable, even if it doesn't deliver new products. With the right operating model this is feasible, but by no means easy. Boards and management teams can find it hard to invest in scientific risk if the dominant part of the business lies in commercial growth. Time will tell - either way it behoves management teams to ask themselves the question strategically.

Novasecta is proud to have supported many MidPharma pharmaceutical leaders with empowering their organisations to deliver improved performance. Our work with biotechs and Big Pharmas also draws on this experience of operating under constraints, after all necessity is the mother of invention. Successful MidPharmas have demonstrated the value of creating and cascading an unambiguous strategic focus, while evolving to a fit-for-purpose operating model that is both internally and externally effective. We will continue to help them to both create and provide access to medicines for patients that need them.



Novasecta

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