Accenture Life Sciences

Patient Inspired. Outcomes Driven.

NEW SCIENCE

Biopharma's New Growth Machine

There is a quiet force in the biopharmaceutical industry that could have damaging implications.

Called **compressive disruption**, it often happens slowly and stealthily when a series of innovations, macroeconomic factors and other changes combine to squeeze profits over a decade or more.[1,2]

It is unlike "big bang" disruptions where companies are out-innovated by a competitor or new entrant that can quickly create products and services that are better and cheaper. But it's no less destructive.

In the past, compressive disruption has eroded asset-intensive industries such as automotive, utilities and energy. It happens when executives believe high barriers to entry and conventional business models will assure industry stability.

Today, there are clear signs that the biopharmaceutical industry faces a similar situation.

However, some biopharma companies have found a way to deliver exceptional growth amidst this compressive disruption. These companies are embracing **New Science**—an evolving, unique combination of the best in science and health technology (e.g., genomics, biomarkers, companion technologies, delivery methods, etc.) that is filling an unmet need and raising the standard of care. They are also broadening their horizontal strategy of dropping newly acquired molecules or companies into existing operating models. Instead, they are starting to embrace a type of vertical integration that is reaching into adjacent healthcare and technology segments to build new business models and approaches.

These companies are building biopharma value chains that integrate different capabilities and patient insights made possible by digital, data and genomics. In doing so, they are able to create new revenue streams, better patient outcomes and deeper partnerships with payers and providers.

New Science offers opportunities for biopharma growth while disruptive forces threaten to squeeze more traditional approaches.

THREE SIGNALS OF COMPRESSION

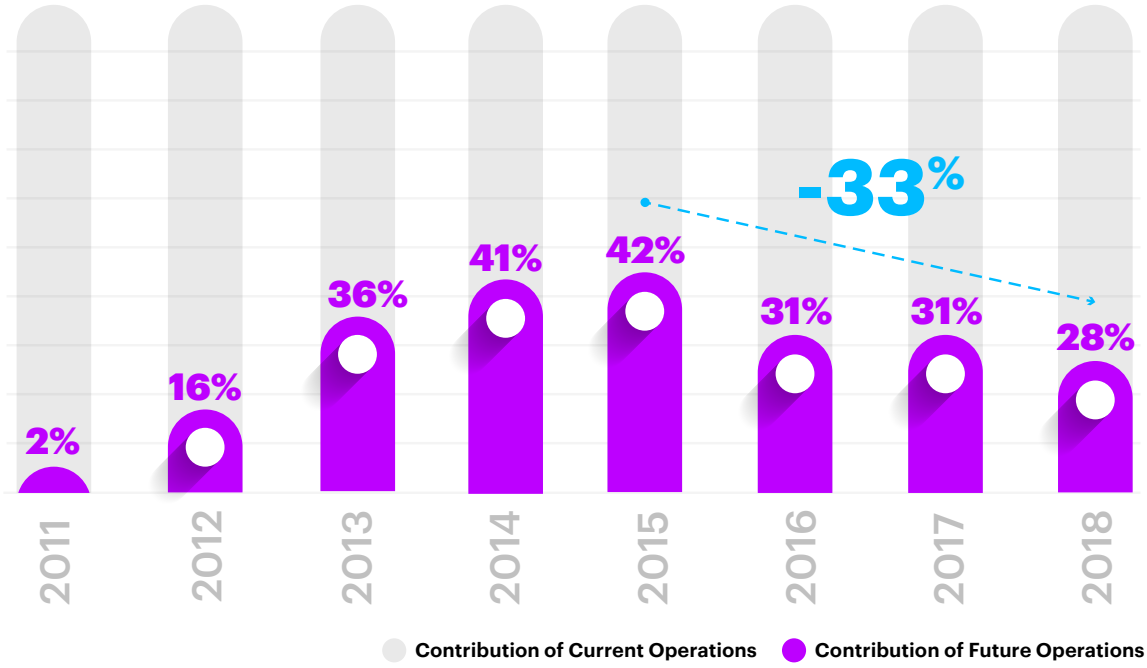
01 The first red flag indicating compressive disruption in biopharma is a decline in future value.

As a percentage of enterprise value, the future value of the industry shrank for three consecutive years. It slipped from 42% in 2015 to 28% in 2018 (see Figure 1).

This indicates that investor confidence in future earnings in the biopharma is diminishing—fueled by uncertainty about pricing policies, importation and other important healthcare policies. Meanwhile, other healthcare sectors are attracting greater investor confidence such as medical software and IT as well as provider and outpatient services.[3]

FIGURE 1: Investor confidence in future earnings is declining.

FUTURE VALUE AS % OF ENTERPRISE VALUE (2011-2018)

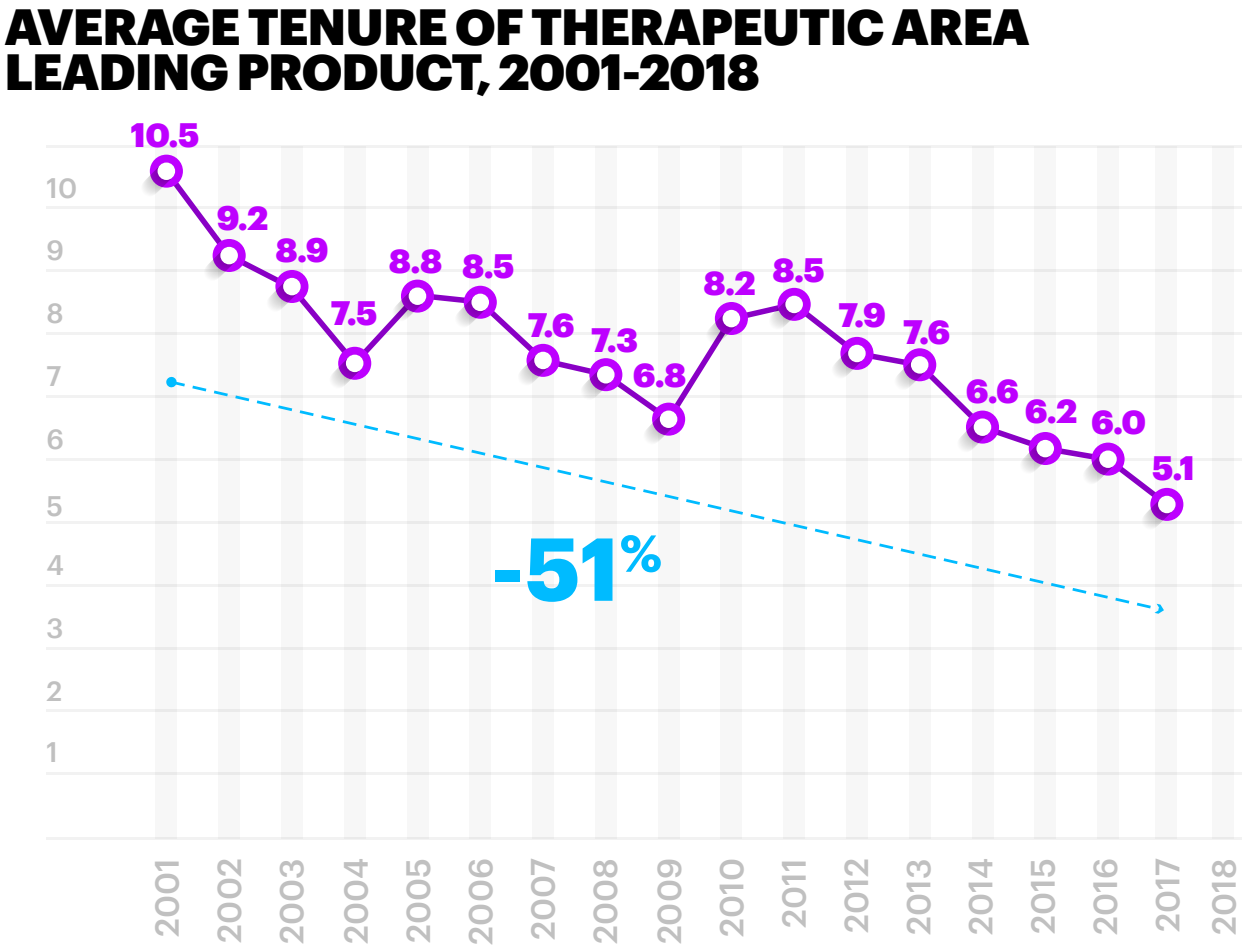


Sources: Capital IQ. Accenture Research Analysis. Calculations are the aggregated values for the pharmaceutical segment. Accenture High Performance Business Analysis 2018. Pharmaceutical & Biotechnology relative performance analysis of indicators including, growth profitability, and value indicators as reported by the market and monitored over 10 years. The HPB study identifies which companies are top performers within their industry and what distinguished them from their peers.

02 The second signal of compressive disruption is the gradual decline in the amount of time a treatment retains its leading position in the market.

The average tenure for a market leading treatment in a therapeutic area has dropped 51% from 10.5 years in 2000 to 5.1 years in 2017 (see Figure 2).

FIGURE 2: Tenure of leading treatments has been cut in half.

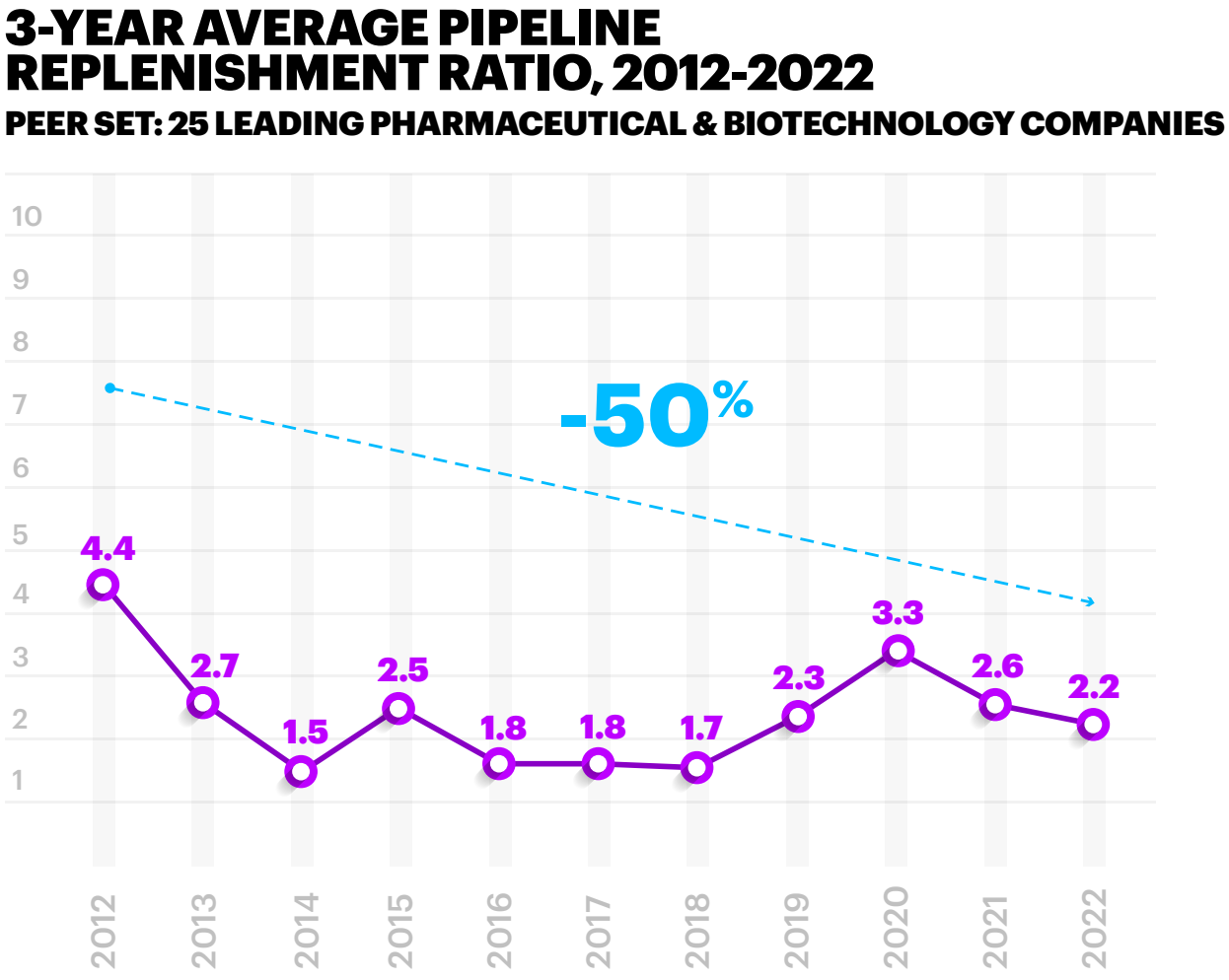


Source: Accenture analysis, data provided by Evaluate Pharma

03 The third sign of compressive disruption is the industry's struggle to compensate for lost revenue due to patent expiry.

It's true that more treatments are coming to market than in recent years (2018 was a record year with 59 new molecular entities approved by FDA[4]). However, many of these medicines are highly specialized and treat smaller patient populations. As a result, they often don't generate peak revenues for the duration that they used to which puts pipeline replacement ratios under pressure (see Figure 3).

FIGURE 3: Pipeline replacement ratios are declining.



Source: Accenture analysis, data provided by Evaluate Pharma

NEW SCIENCE— THE ANTIDOTE TO COMPRESSION

There is a new category emerging that is driving industry growth. We call this category New Science. Those companies who are leading in New Science are escaping the disruptive forces of compression and building the capabilities for exceptional growth.

NEW SCIENCE:

Solves for a clear unmet need through a new mechanism, modality, or health technology, as documented or approved by a regulatory agency (see Research Methodology). Examples include new cell therapies like CAR-T (Kymriah, Yescarta) and curative gene therapies (Luxturna, Zolgensma).

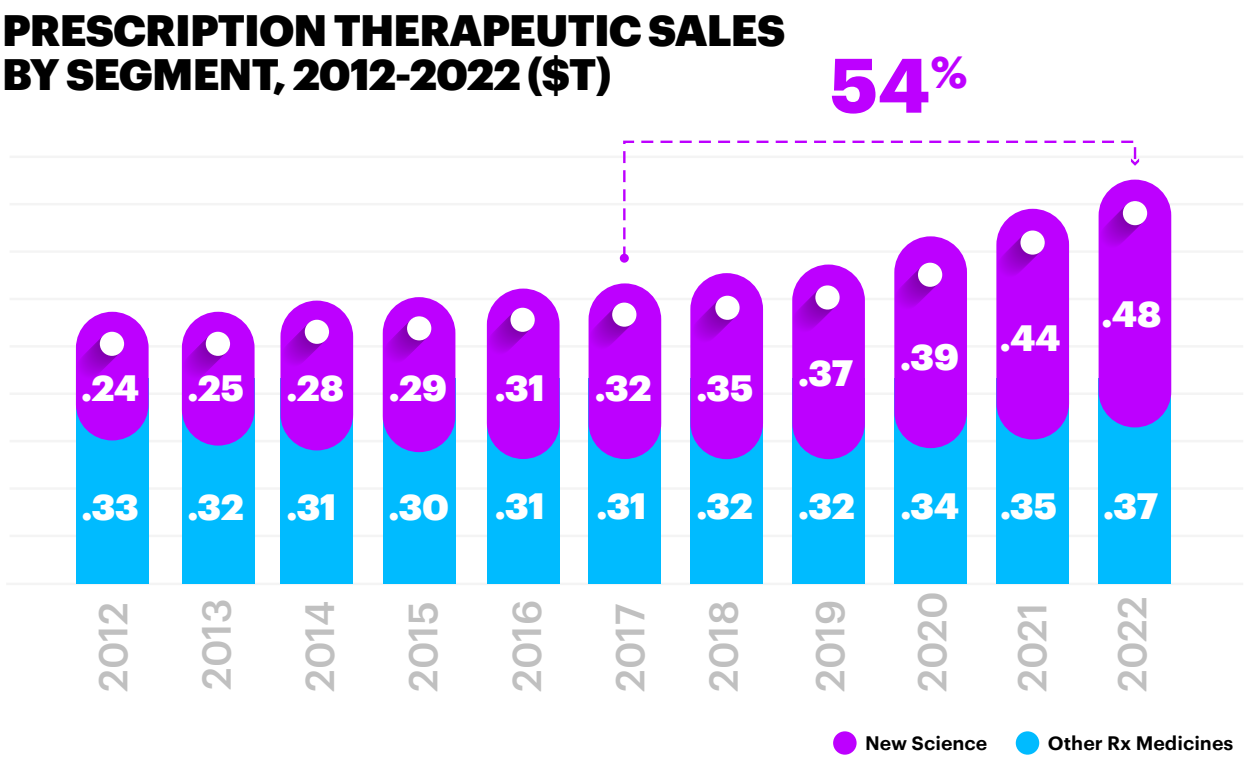
Often requires a new technology device or diagnostics for development or as a companion to treatment. Think of Bayer's Betaseron and associated Betaconnect injector and myBetaApp companion.

Could be the technology alone (a small but rapidly growing segment). For instance, Omada Health in diabetes management.

New science goes beyond industry definitions of personalized or precision medicine. It includes a spectrum of treatments including those developed with precision techniques such as Luxterna, a targeted gene therapy, and small molecules like Lyrica, a novel way to treat a select class of Central Nervous System diseases (See Research Methodology).

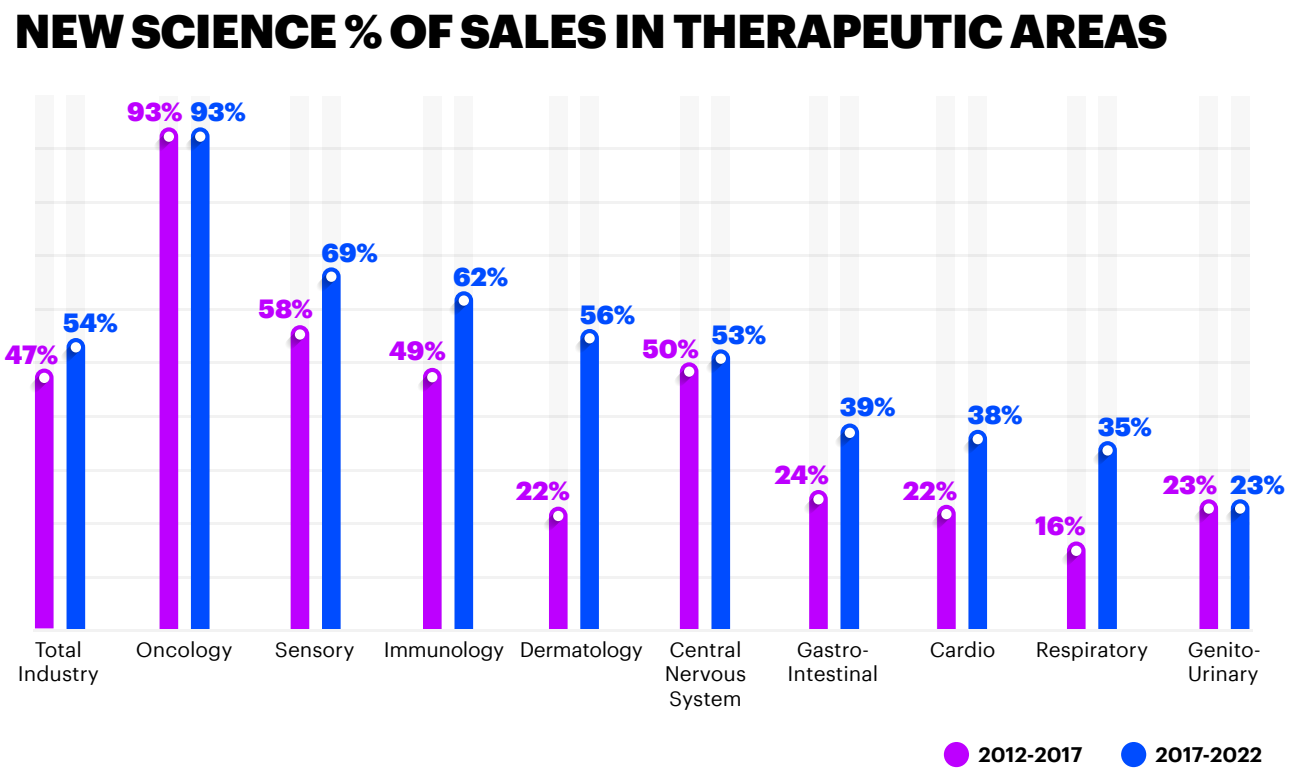
New Science is expected to drive 54% of sales between 2017 and 2022 (see Figure 4).

FIGURE 4: New science is a major driver of industry growth.



While New Science is prevalent in oncology, it is expected to drive significant growth across multiple therapeutic areas, including gastro-intestinal and immunology treatments (see Figure 5). We see several pioneering treatments in these areas that show great promise. For example, Teprotumumab is a non-oncology immune medicine which treats active thyroid eye disease (TED) using a monoclonal antibody and a targeted inhibitor of the insulin-like growth factor 1 receptor. It recently demonstrated a dramatic reduction in eye bulging, the main cause of morbidity in TED in its Phase 3 clinical trial. There are currently no FDA approved treatments available for this disease that affects 15,000-20,000 people each year in the United States.[5]

FIGURE 5: New Science is driving growth across multiple therapeutic areas.



Source: Accenture analysis, data provided by Evaluate Pharma

New Science is more likely to succeed—and in some cases, get to market quicker.

Like many highly specialized treatments, New Science can carry a higher price tag – sometimes as much as three to five times more than traditional medicines. The upside, however, is forecasted to be substantial.

New Science has a higher Probability of Technical and Regulatory Success. Accenture analysis revealed a 10.8% success rate for New Science compared to 7.2% for other new molecular entities (NMEs) and new biologic entities (NBEs) (see Figure 6).

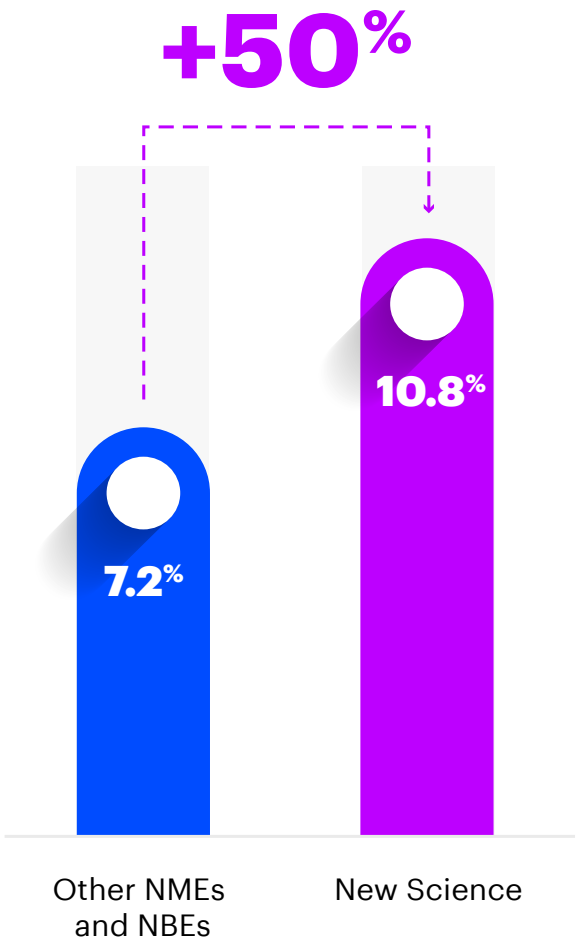
While conventional thinking suggests that these more innovative treatments are more risky to develop, it turns out they are more likely to reach the market.

Many regulatory bodies are recognizing the impact of these more specialized treatment and changing their approval processes. For example, the FDA has multiple designations for new products to qualify ones as “breakthrough” and “fast track” them through approval. The European Medicines Agency (EMA) introduced its PRIME (Priority Medicines) program of accelerated approval and priority review in 2016. And there are several other examples around the world. Many regulatory bodies are also applying technology and process improvements to update their guidance to biopharma on how to run clinical trials and improve the patient experience.

FIGURE 6: New Science is more likely to pass regulatory scrutiny.

PROBABILITY OF TECHNICAL AND REGULATORY SUCCESS

(PHASE 1 THROUGH APPROVAL, CLINICAL TRIALS 2012-2017)



Source: Accenture analysis, data provided by Informa Pharmapremia

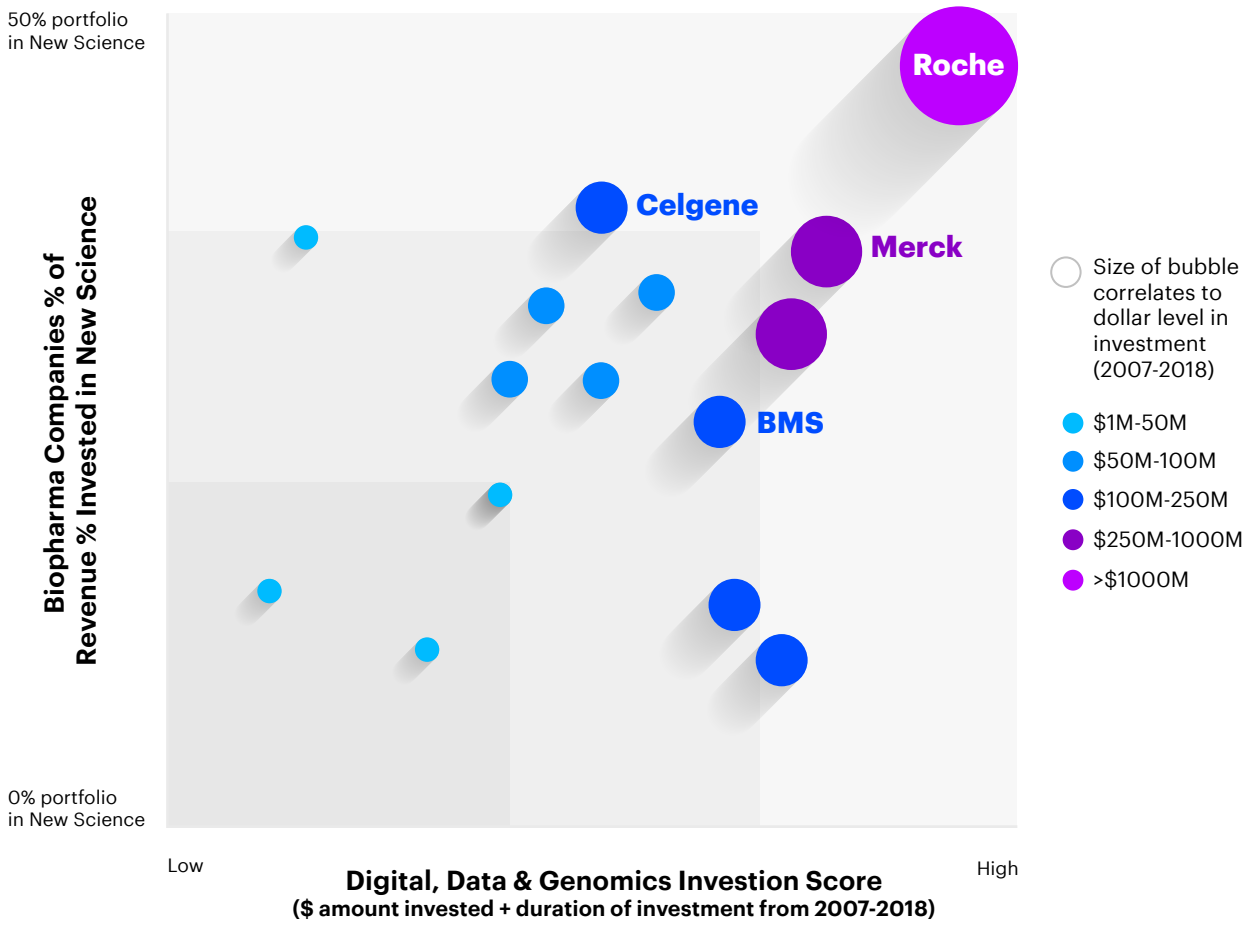
LEADERS IN NEW SCIENCE

INVEST HEAVILY IN DIGITAL, DATA AND GENOMICS.

New methods and technologies, such as biomarker-based development and companion diagnostics are helping fuel this R&D success. These approaches inject more precision into the traditional development process and support real-world evidence (RWE) of an improved patient outcome, helping regulators reach positive conclusions more rapidly.

Companies at the forefront of New Science are investing heavily in emerging technology to improve R&D and clinical outcomes, as well as the patient experience. Leaders in New Science are investing six to seven times as much on digital, data and genomics compared to their peers (see Figure 7).[6]

FIGURE 7: Leaders in New Science invest 6-7 times more in digital, data and genomics.



Source: See Research Methodology

Their investments are strategic, sizeable and meaningful. Examples include:

ROCHE

- **Acquired FlatIron providing real-world evidence to support oncology trials.**
- **Merged with Foundation Medicine to expand expertise in genomics and molecular information to enhance the development of personalized medicines and care for cancer patients.**

CELGENE

- **Signed a licensing agreement with Human Longevity which provides genomic data analysis to improve understanding of the connection between genomic/ genetic factors and health (and other physical traits).**

BMS, CELGENE AND MERCK

- **Invested in Grail providing them access to genomic and RWE analysis to expand their understanding of cancer biology.**

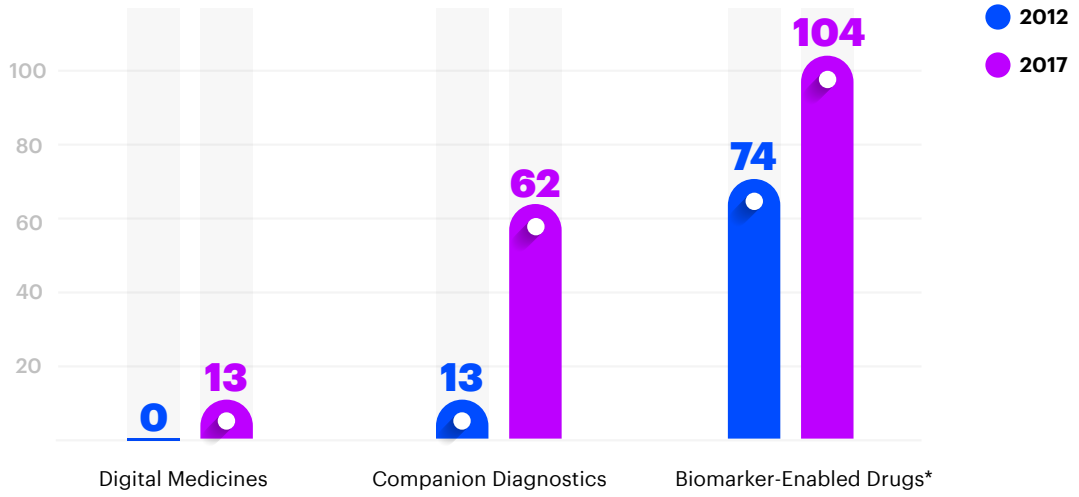
Source: Accenture investment and emerging technology database

The rise in New Science is also evident in the number of FDA-approved therapies that used at least one biomarker or specific combination of biomarkers for either patient identification or an endpoint. The number of these biomarker-enabled medicines grew from 74 in 2012 to 104 in 2017.

Over the same period, the number of approved companion diagnostics jumped from 13 to 62 and digital medicines went from zero in 2012 to 13 in 2017 (see Figure 8). In addition, 42% of all FDA approved NME's were personalized medicines requiring biomarkers for diagnosis up from 35% in 2017.[7]

FIGURE 8: Technology is fast becoming part of the treatment—in some cases, the entire treatment.

GROWTH IN SCIENCE & TECHNOLOGY CONVERGENCE (2012-2017)



*Active drugs that used at least one biomarker or specific combination of biomarkers in R&D for either patient identification or measurement of success

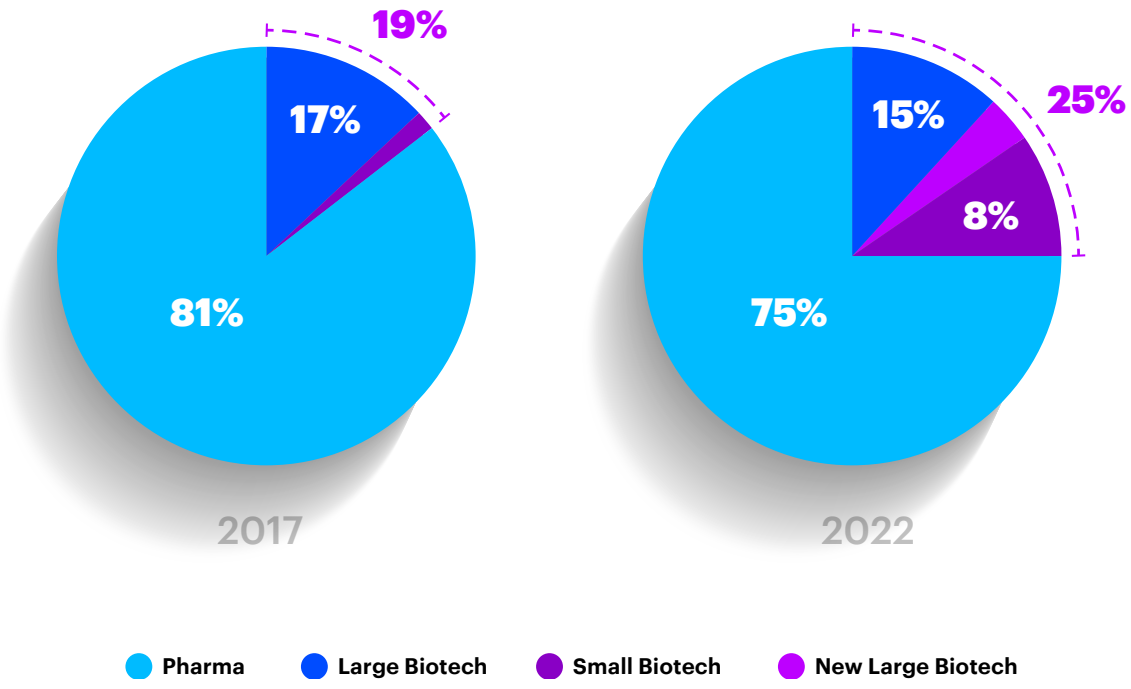
NEW SCIENCE IS CHANGING THE M&A PLAYING FIELD

Biopharma companies that lead in New Science are reshaping the value chain with more investment in non-traditional areas reaching outside the pharma market and into others. While horizontal mergers and acquisitions will still take place, the playing field on which they do is changing.

Biotech companies are an important source of New Science. Their market share is expected to grow from 19% in 2017 to 25% in 2022. This growth will be driven almost entirely by smaller biotech companies (<$1 billion in revenue) who are expected to grow from 2% market share to 8% market share. Meanwhile, large biotech companies will stay roughly the same at 17% in total (see Figure 9).

FIGURE 9: Biotech's market share is rising, driving by smaller biotech companies.

ESTIMATE RISE IN BIOTECH MARKET SHARE (2017-2022)



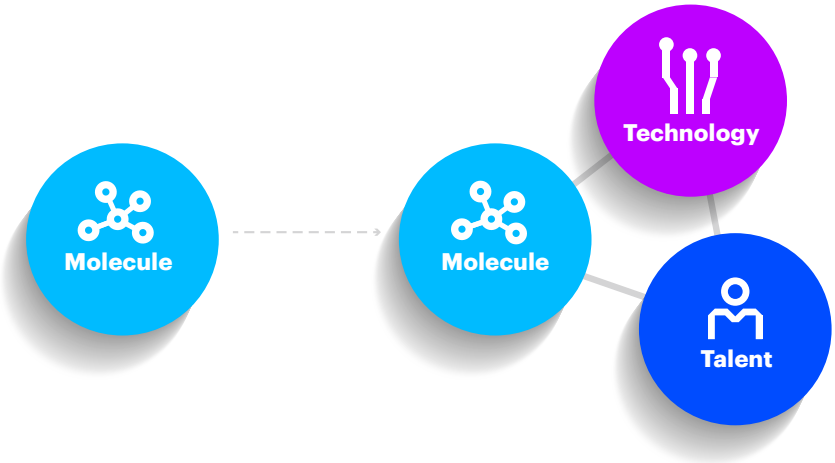
Source: Accenture analysis, data provided by Evaluate Pharma

Major biopharma companies have traditionally invested in large biotech companies as they have more mature assets and pipelines with stronger indications of market success. Roche's acquisition of Genentech and BMS's proposed acquisition of Celgene are good examples of this practice. However, to lead in and acquire New Science, executives will need to consider investing in an ecosystem of smaller, less proven biotechs as they will become more prevalent and drive biotech growth. To accommodate this shift, they will need to reconfigure investment and R&D sourcing models to consider not just acquiring a molecule, but the opportunity to acquire technology and talent as well.

FOR INSTANCE:

- **If the talent and technologies acquired do not exist internally, what are the most effective ways to source, integrate and leverage them within the organization?**
- **Is it possible or even advisable for new teams to operate like a start-up while inside large pharma?**
- **What's the best way to develop and sell software and services along with medicines?**

SHIFT IN ACQUISITION AND ECOSYSTEM STRATEGY



The emergence of vertical integration

Vertical integration—where companies acquire or partner with companies outside of their traditional industry—is on the rise with exciting, new relationships forming. For example, CVS acquired Aetna to build an innovative health care model that is local, easier to use, less expensive and put consumers at the center of their care.

Biopharma is just starting to catch on. Healthcare mega-deals (acquisitions >$10 billion), such as CVS-Aetna, totalled $238 billion since 2007—of which 85% involved entering or expanding outside of their traditional business. Meanwhile, biopharma companies have invested $790 billion since 2007 but with the vast majority invested in biotech and pharmaceuticals. As mentioned earlier, New Science leaders are breaking out of this mold. We expect future leaders in New Science to continue to push the boundaries with more M&A, partnerships and collaborations across the healthcare spectrum—and with companies outside the traditional healthcare market.

CONCLUSION

Looking ahead, the biopharma industry has a tremendous opportunity to overcome compression and drive growth with New Science.

Executives will need to reconsider their calculations of value and remain open to the different ways it will be reimbursed. Life Sciences companies must pivot wisely to realize the promises of New Science—novel ways of treating patients and using technology to augment the delivery of those treatments and an understanding of how patients are using them.

New Science offers a better way to treat and care for patients in ways not previously attainable.

The business case is clear—New Science will drive the majority of industry growth and continually reshape the landscape.

How will you reshape your current business to lead in this new environment?

What new businesses could you create that solve for patients in new ways?

References

[1]Accenture Research. Traditional asset-heavy organizations: Are they safe from disruption? Accessed February 11, 2019.

[2]Paul Nunes, Accenture Research. The flip side of Big Bang Disruption: It's slow and deadly, yet avoidable. March 02, 2018.

[3]Accenture Research: Healthcare's Future Winners and Losers, June 2018. www.accenture.com/us-en/insights/health/healthcare-future-winner

[4]www.accessdata.fda.gov/scripts/cder/daf. January 2019

[5]Horizon Pharmaceuticals. News Release. Horizon Pharma plc Announces Phase 3 Confirmatory Trial Evaluating Teprotumumab (OPTIC) for the Treatment of Active Thyroid Eye Disease (TED) Met Primary and All Secondary Endpoints. February 2019

[6]Accenture research based on analysis of investments in digital, data and genomics from 1998-Present (see Research Methodology)

[7]Fda.gov and Personalizemedicinecoalition.org., February 2019

Research Methodology

NEW SCIENCE:

Accenture conducted pipeline and commercial product analysis for approximately 60,000 total products covered by our data partners, of which 4000 are currently in-market. R&D and regulatory approvals analysis conducted on all clinical programs with phases ending after Jan 1, 2000. Technology investments analysis covered all digital health investments made since 2007.

Approximately 4,000 unique assets were segmented across three dimensions. The first is scientific novelty as determined by regulatory designations, date of discovery, application of innovative methods for development and characteristics beyond being a new molecular entity. The second is unmet need, as determined by regulatory bodies, or treatment of previously unaddressed indications. The third is technology convergence as determined by the assets reliance on technology either to be prescribed or delivered to a patient. (See Figure below) Expanded approvals and additional regulatory designations were considered only within 3 years of first launch. An asset achieved classification as "new" if it qualified into one or more of the dimensions.

The total segment was evaluated for its ability to generate revenue today and over the next five years. This analysis was calculated using the 2012-2018 sales revenue of each asset and forecasting the future sales into 2022. This analysis is possible through our syndicated data partners and verified against multiple data sets.

DIMENSION	HYPOTHESIS	MEASURE
Scientific Novelty	Measuring scientific novelty in specific terms will enable us to better under future areas of growth in disease and overall therapeutic areas, and better manage portfolio risk.	**New Mechanism/Mode of Action**
		New Treatment Modality
		New Scientific Platform
Unmet Need	Measuring products that quality as achieving current unmet need ensures devolpment of medicines for patient impact.	**Previously-Untreated Population**
		Significant Improvement in Effectiveness
		Significant Reduction in Complications
Technology Convergence	Given recent policy shifts and technology impact on product development, measuring medicines that coexist with technology in the near-term and future ensures a better understanding of science's growing dependence on tech.	**Digital Medicine***
		Reliant on Companion Diagnostic
		Joint Approvals of Treatment and Tech
		Availability of Direct-to-Consumer Testing

*Digital Medicine—digital software/hardware that augments or directly provides treatment for a disease, and improves clinical outcomes. The improved outcome must be clinically demonstrated.

PROBABILITY OF TECHNICAL & REGULATORY SUCCESS

The probability of success analysis of this segment versus other assets was curated by assessing probability of technical and regulatory success for each asset across each phase of development, through comparative analysis across all assets in clinical trials. This analysis is also made possible by our syndicated data partners and verified against benchmarks.

The technology convergence analysis was conducted by reviews of FDA approvals of companion device, diagnostic, software as a medical device and digital health filings.

EMERGING TECHNOLOGY: DIGITAL/DATA/GENOMICS

The emerging technology investment analysis comparison was conducted by evaluating leading biopharma company percentage of portfolio that represents "new science." Each company's portfolio was split into assets which were classified as "new" or "not new." The company's percentage of their portfolio that represents the New Science segment was determined.

In addition, each company in the Biopharma segment was evaluated for their digital, data, genomic investments, based on publicly available data. Total dollar investments in these categories were collected from 2007-2018, with approximately 1500 assets evaluated, across the years representing the analysis of this research. Duration of the investment was also considered. The New Science portfolio analysis was superset on the digital, data and genomic investment analysis to understand the relationship between New Science and the emerging health technologies.

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Accenture's Life Sciences group is committed to helping our clients make a meaningful impact on patients' lives by combining new science with leading edge technology to revolutionize how medical treatments are discovered, developed and delivered to people around the world. We provide end-to-end business services as well as individual strategy, consulting, digital, technology and operations projects around the globe in all strategic and functional areas—with a strong focus on R&D, Sales & Marketing, Patient Services and the Supply Chain.

We have decades of experiences working with the world's most successful companies to innovate and improve their performance across the entire Life Sciences value chain. Accenture's Life Sciences group connects more than 15,000 skilled professionals in over 50 countries who are personally committed to helping our clients achieve their business objectives and deliver better health and economic outcomes.

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