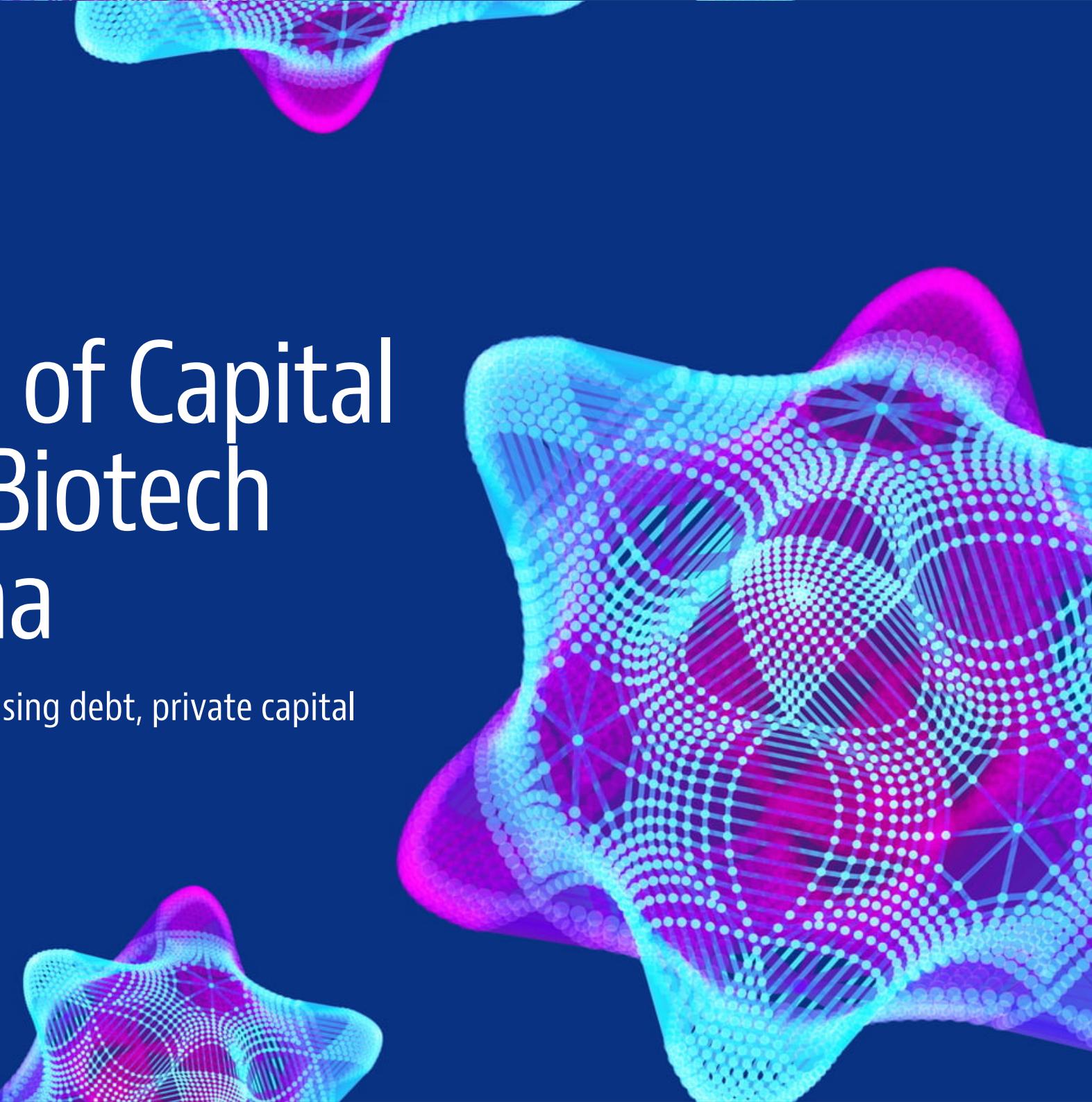


The Future of Capital Raising in Biotech and Pharma

Wave of opportunities with rising debt, private capital
and VC funding

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Foreword



Despite a decline in overall global activity and a wariness from investors towards pre-profit companies in some industries, the biopharma sector continues to see significant levels of interest and investment.

This is being driven by a number of factors, including:

- a strong pipeline of innovative technology and new drugs in advanced R&D stages
- robust demand from investors, who seek to leverage the higher returns on investment associated with the industry
- the need for pharma companies to replenish their pipeline to secure future revenue

Alongside these drivers, there has been a shift in the rationale behind why companies are raising funds and how they are choosing to raise those funds. Pharma, for example, has seen an exponential increase in debt capital raising — as it seeks to fund expensive acquisitions in an effort to replenish their pipeline and secure future revenue, as patents on blockbuster drugs are set to expire. In fact, more than 50% of blockbuster drugs coming to market in recent years are said to be as a result of both M&A and in-licensing, rather than direct R&D by pharma companies.

VC investment and equity capital raising remains popular with biotechs, but licensing deals between biotech and pharma companies continue to increase, as the appetite for mutually beneficial risk-sharing and cost-sharing increases. The scale of innovation, coupled with the use of AI, has seen biotechs disrupt the industry, gaining an increasing level of control of their development and more options for funding product development.

While the US remains the most active jurisdiction for biopharma activity, there is an impressive level of innovation coming from Asia, and China in particular, as governments are significantly investing in biotech R&D — as well as making regulatory changes to encourage biotech activity.

Alongside strong pharma activity in Europe, investment in biotech firms has grown significantly, more than doubling over the past few years, particularly in Belgium, Switzerland and the UK. The development of European VC funds has also seen VC investment increase three-fold. When it comes to raising growth capital via IPO, around a third of European biotechs are opting to raise capital on US exchanges, as IPOs tend to bigger on the US market.

Although geopolitical factors are expected to impact the overall global market in 2020, the underlying strength of this sector will continue to promote deal making. With the rate of advancement in the AI space facilitating speedier drug and tech development, we expect to see a continued whet of appetite in the biotech and pharma space.

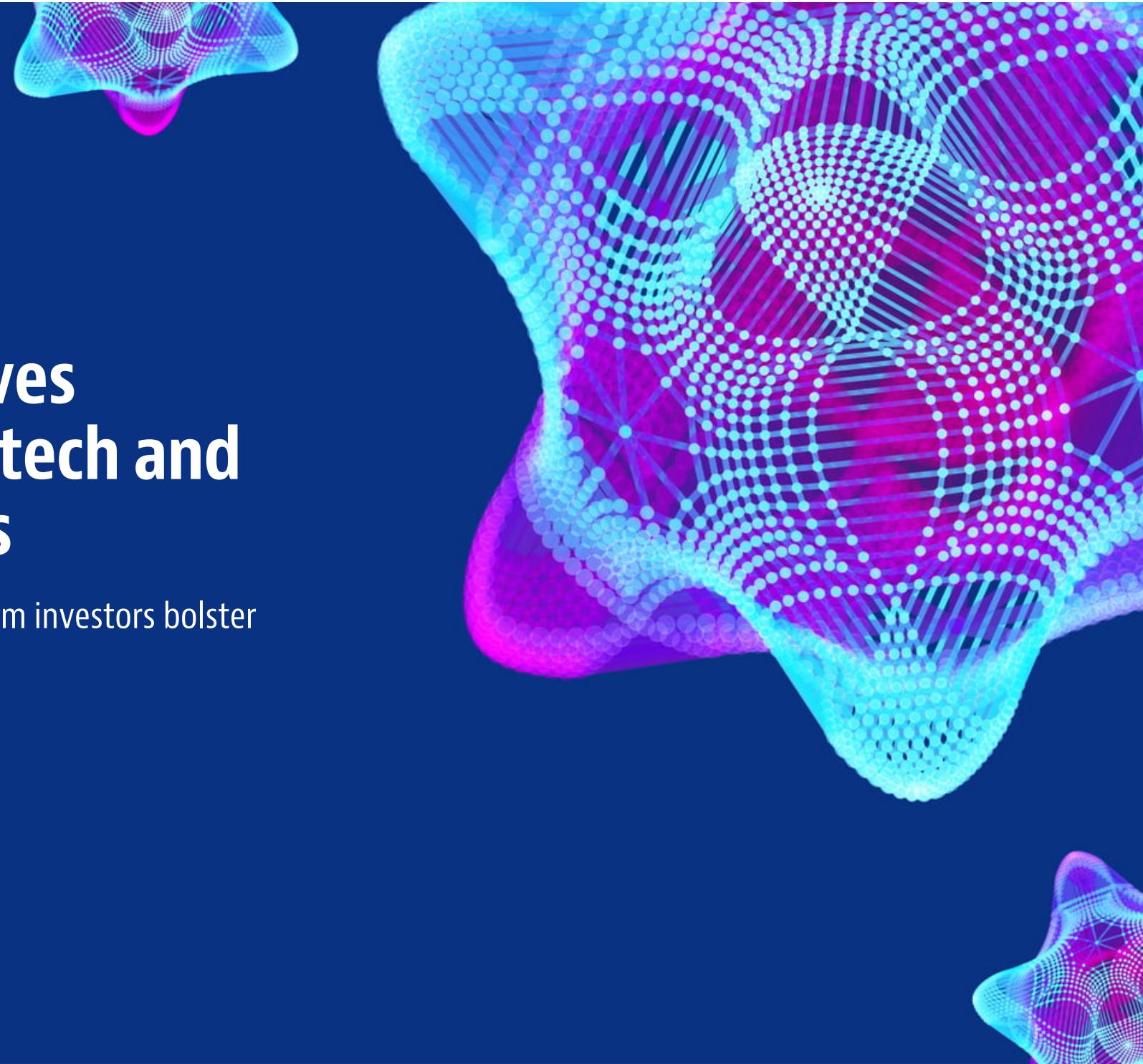


Koen Vanhaerents

Global Chair, Capital Markets

Innovation Drives Activity for Biotech and Pharma Sectors

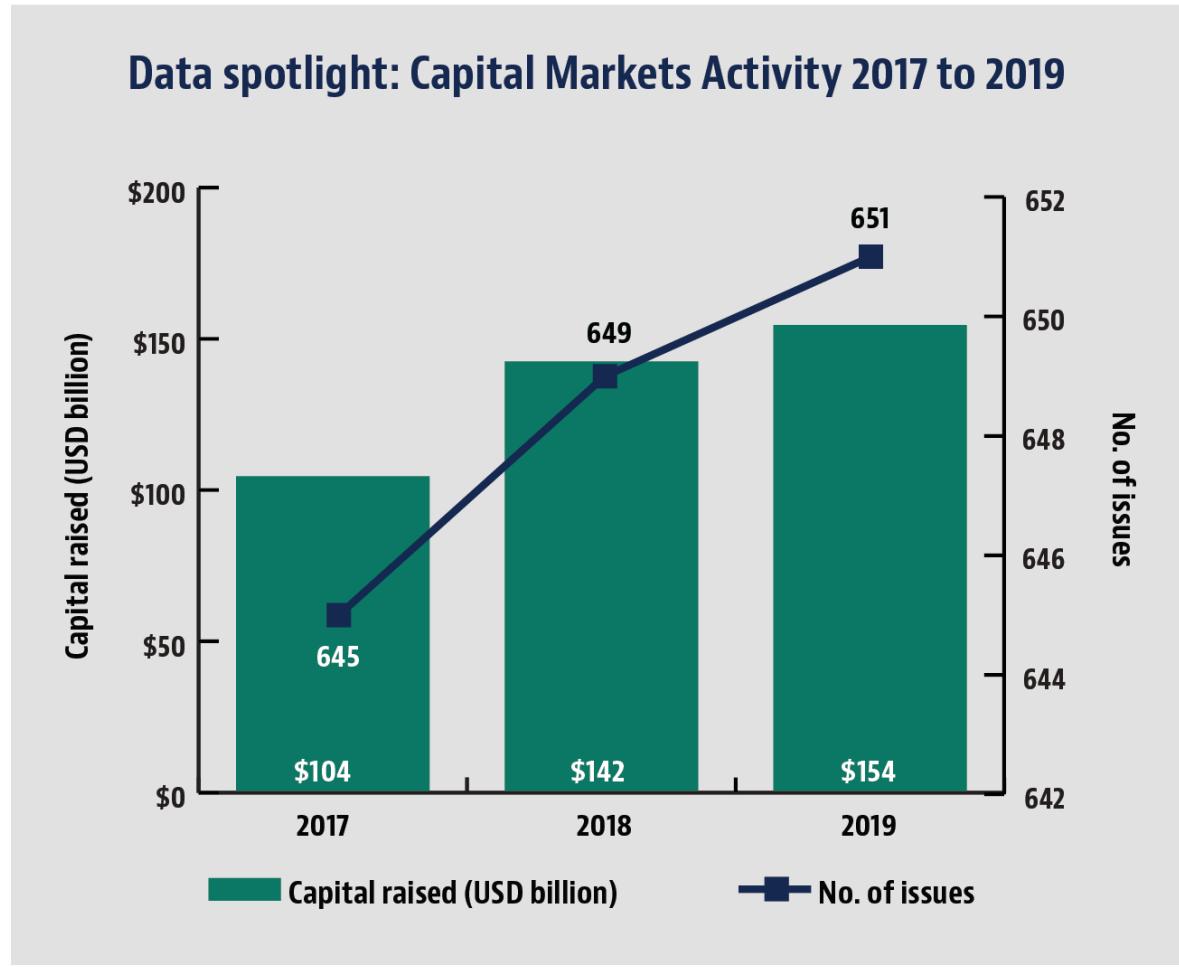
Robust pipeline and demand from investors bolster
activity



Despite a decline in overall global activity, the biotech and pharma (biopharma) sectors continue to perform strongly, bolstered by several factors including:

- a strong pipeline of innovative technology and new drugs in advanced research and development (R&D) stages
- robust demand from investors, who seek to leverage the higher returns on investment associated with the industry
- the need for pharma companies to replenish their pipeline to secure future revenue

2019 proved to be particularly affluent year, despite the marginal increase in offerings, raising USD 154 billion from 651 equity and debt offerings. Average deal value for 2019 showed an increase of almost 50% when compared to 2017, as bigger transactions are coming to market.



There is a clear split between how biotech and pharma companies are choosing to raise funds, with biotech primarily raising capital through equity offerings and pharma through debt offerings.

Higher levels of venture capital (VC) backed investments, particularly for biotech companies focused on R&D funding, are partly accountable for the rise in value of private investments. VCs are now looking at a wider array of companies to fund and are becoming active in more rounds of funding.

Jurisdictionally, the US has historically dominated biopharma activity and continues to do so — home to some of the largest pharmaceutical firms in the world, with hotspots such as Silicon Valley supporting the pipeline of innovation and growth in younger biopharma companies.

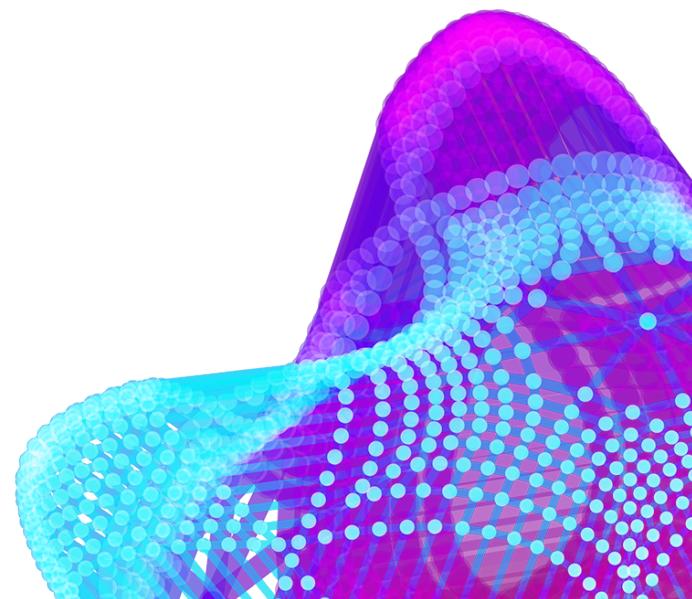
Coupled with its significant investor pool, the industry expertise of its stock exchanges and the fact that the US raised USD 93 billion on the capital markets (across equity and debt) in 2019, up 91% from 2018, we are unlikely to see a major shift in company or investor sentiment in the foreseeable future¹.

However, we can expect to see a number of changes in the coming years, with the compelling growth of Chinese biotech companies and Asian exchanges making key reforms to regulations to encourage these companies to remain domestic. Since 2017, capital raising by Chinese companies has grown by more than 40%. In 2019, USD 17 billion was raised, up from USD 12 billion in 2017.

According to the *Financial Times*², 2019 also saw Chinese authorities receive more than double the number of patent applications than in the US, suggesting that the next few years could see a wave of new Chinese activity that may challenge the monopoly that the US enjoys.

¹All data in this report is taken from Refinitiv or Pitchbook, correct as of 23 December 2019 and all values are rounded to the nearest USD billion, million or percentage point.

²Financial Times published an article "China plays catch-up with Europe and US in patents filing race", detailing the rush in patent applications in China and what it means for activity in biotech and pharma.

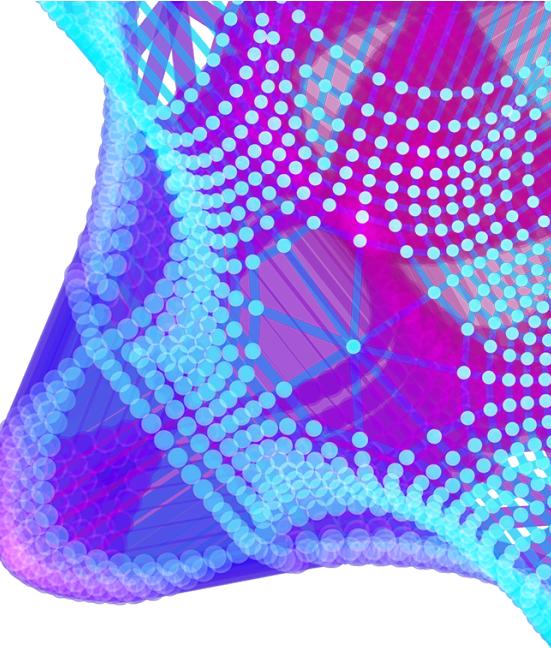


Europe has traditionally been a strong breeding ground for biopharma activity and in line with global trends, pharma debt dominates the European capital markets, raising USD 18.6 billion.

In total, Europe raised USD 27.5 billion on the capital markets in 2019, an increase of 26% upon the USD 20 billion raised in 2017 — driven largely by pharma debt and biotech follow-on offerings.

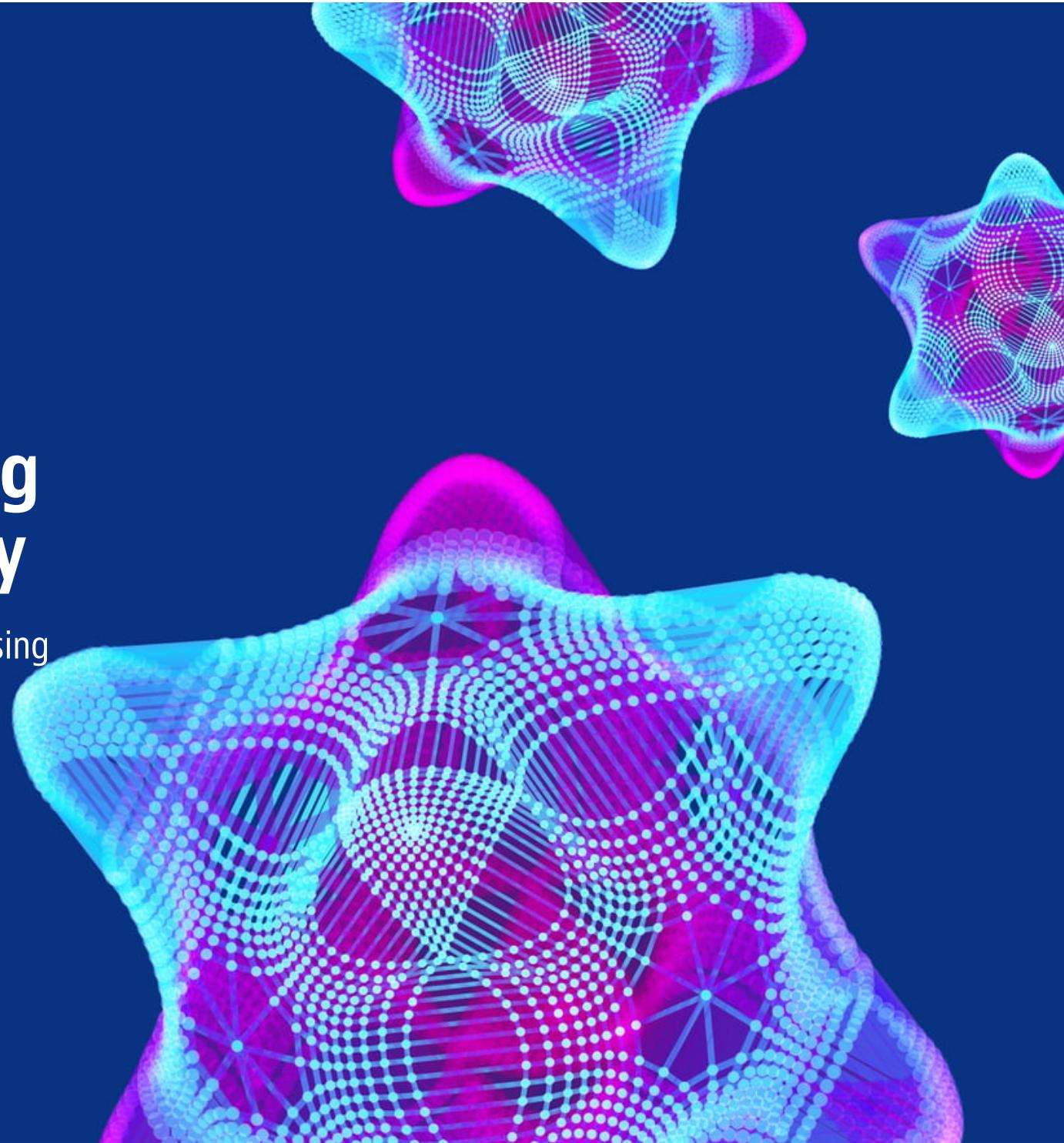
While these themes, among others, are explored further within this report, the most significant points of note we observed in the current biotech and pharma market include the following:

- The equity capital markets (ECM) have remained fairly steady over the last few years.
- Funds raised in the debt capital markets (DCM) space have shown significant increases, growing 80% from USD 57 billion in 2017 to USD 103 billion in 2019, driven by the pharma sector issuing large debt offerings to fund strategic and expensive acquisitions as they seek to secure their future pipeline and revenue stream.
- Deeper pools of VC are funding biotech development, with an increase in investment of 30% between 2017 and 2019.
- Private capital raising is on the rise as larger investments are being made — up 45% in 2019 when compared to 2017.
- Licensing and collaboration agreements continue to increase as the sentiment for risk-sharing and cost-sharing grows.
- The US continues to dominate the biopharma space, but competition from innovative Asian biotech companies is rising.
- Alongside strong pharma activity in Europe, investment in biotech firms has grown significantly, more than doubling over the past few years, particularly in Belgium, Switzerland and the UK. The development of European VC funds has also seen VC investment increase three-fold.



Equity Capital Raising Activity Holds Steady

A look at convertibles, VC activity and licensing

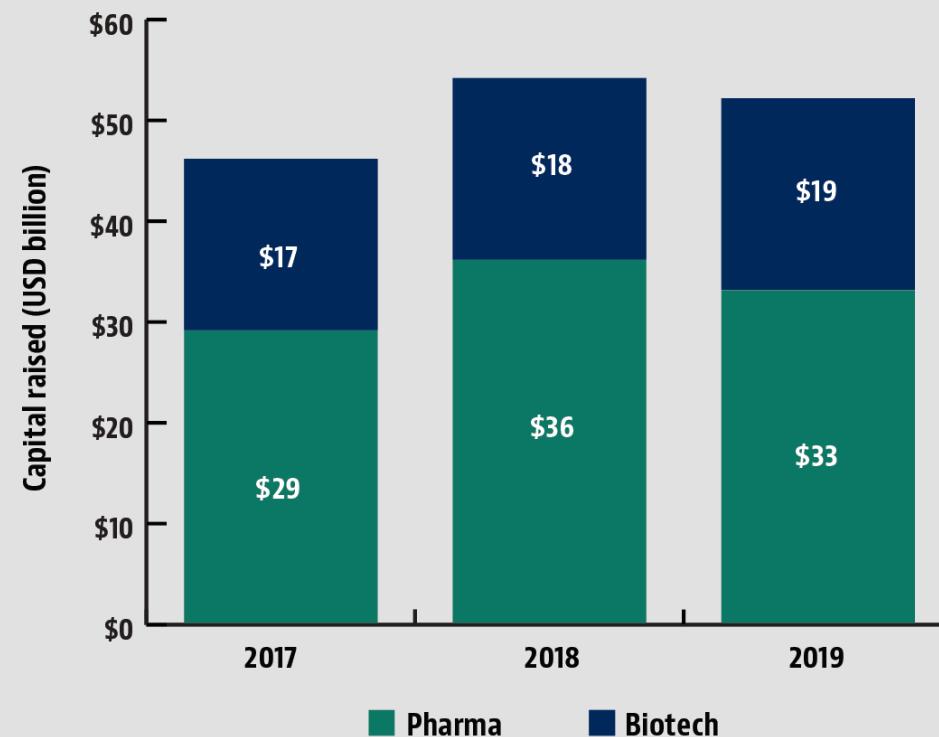


Equity activity shows continued interest in biotech and pharma

Overall, equity activity has remained relatively stable over the last three years as investor sentiment towards biotech and pharma companies remains peaked. In 2019, ECM activity across biopharma raised USD 52 billion, indicating only a 3% difference from 2018.

However, alternative fund raising options are becoming more popular, shifting the balance of ECM in the overall capital raising landscape. ECM accounted for just one-third of all capital raised for biopharma in 2019, down 45% when compared with 2017.

ECM: Capital Raised for Biotech and Pharma (USD billion)



Source: Refinitiv

Xiang Li, Head of Healthcare at China International Capital Corporation (Hong Kong) Limited³ observed an interesting trend in recent years in respect of the use of proceeds by listed pharmaceutical companies for equity investments in other pre-profits or developing biotech and pharmaceutical companies that are planning for their IPOs. "Very often, these listed biotech companies would acquire licenses from developing biotech or pharmaceutical companies in return, so that it would be a win-win arrangement for both parties", he states.

Moving forward, Li expects to see more M&A activity within the biopharma sector, particularly in China and especially for healthcare and drug companies, because there are stricter price controls for drugs which would in turn lead to more difficulties in valuation and market capitalization. As an alternative, these companies will look for M&A opportunities in the sector.

As discussed further in this report, both debt and VC funding have seen significant increases, accounting in part for this shift in balance, as the preference to remain private for longer becomes more popular, in line with overall global trends.

While IPOs continue to be a popular option, follow-on offerings unsurprisingly make up the lion's share of both value and volume, as biopharma companies continue to require capital to fund both R&D and the more expensive clinical trials.

Convertibles are also gaining popularity, becoming increasingly attractive to pre-revenue companies, as well as with companies with products ready to go to market (phase 3). Roel Meers, Partner, Baker McKenzie, Brussels states that convertibles "give shareholders and investors an opportunity to take an equity stake down the line. Because of their specialized nature, convertible instruments may not be useful for every type of company, but it can be very interesting for companies on the brink of a big breakthrough or on a path to break-even."

Some of the advantages to raising funds through convertible debt (which we consider an equity-linked product for the purposes of this report), include the lower costs and interest associated with convertible issues, the quicker process of issuing convertibles, and the delay on equity dilution that allows the company to retain control for longer.

"Pre-IPO convertible notes are particularly interesting, because they are a form of short-to mid-term debt that converts into equity, typically in conjunction with a future financing round. These convertible notes allow shareholders and/or investors to take on a form of equity stake and benefit from the increasing upside in the future. It also gives them a chance to benefit from the increasing potential gains going forward as future financing rounds occur."

Roel Meers
Partner, Baker McKenzie, Brussels

³China International Capital Corporation (Hong Kong) Limited belongs to China International Capital Corporation Limited, which is one of China's leading investment banking firms that engages in investment banking, securities, investment management and other financial services primarily with institutional clients.

PE and VC-backed offerings on the decline

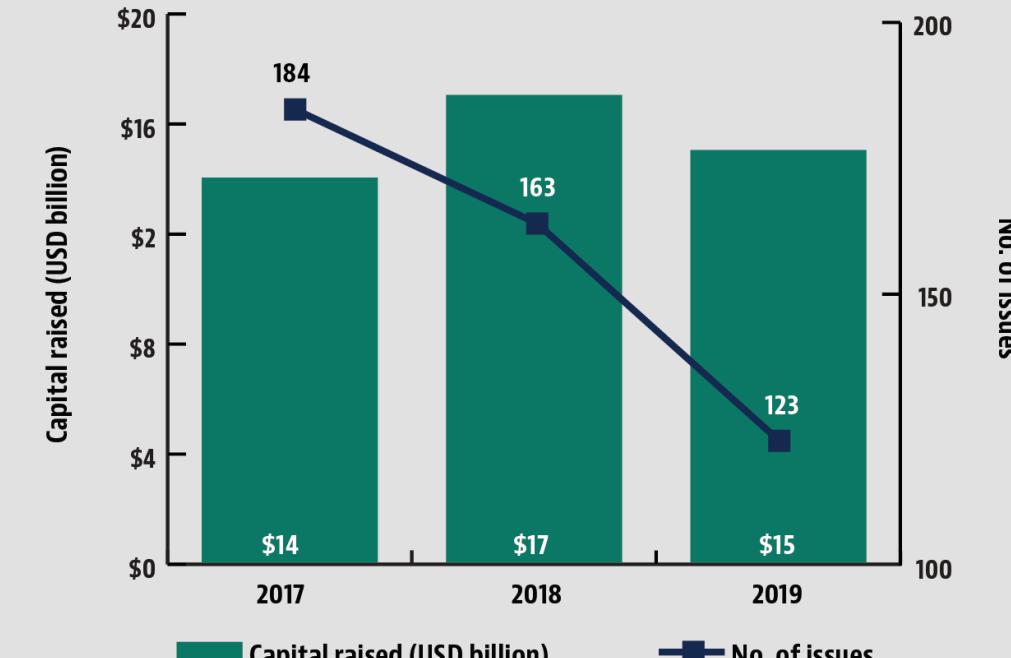
PE and VC-backed exits and offerings have been on the decline since 2017, as sentiment for staying private for longer has increased, allowing companies to gain higher valuations before going public.

The incentives for retaining control and eluding the complex regulatory and compliance requirements that come with being public, are also a big driver behind this decline. According to Pitchbook, from 2017 to 2019, there has been a 33% decrease in the volume of PE and VC-backed offerings.

"At this stage of our business, we are already actively planning for and exploring different funding options, including private equity funding and eventual listing in either Hong Kong or the US."

Dr. Wong Lap Yan
Chartered biologist in the UK and the Chief Scientific Officer and Principal Scientist of ALOM Intelligence Limited*

PE and VC-backed IPOs and Secondary Offerings



Source: Refinitiv

*ALOM Intelligence Limited is a start up business in Hong Kong that offers deep learning technology and analytical solutions relating to biomedical data.

Licensing Deals Powered by a Wave of Biotech Innovation

Mutually beneficial licensing and collaboration deals between biotech and pharma have always been core to the successful R&D and commercialization of new drugs and tech. As in-house R&D production in pharma declines, there is now more of a reliance on partnerships and collaborations with biotech companies to replenish the revenue and production pipeline.

In turn, biotech companies have an increasing advantage as their innovative drug and tech developments, and use of AI disrupt the market, bringing more diverse options on how to fund that development.

VC investment in this space has significantly increased, offering some biotechs the means to fund their own R&D and thus retaining rights and control of their own IP.

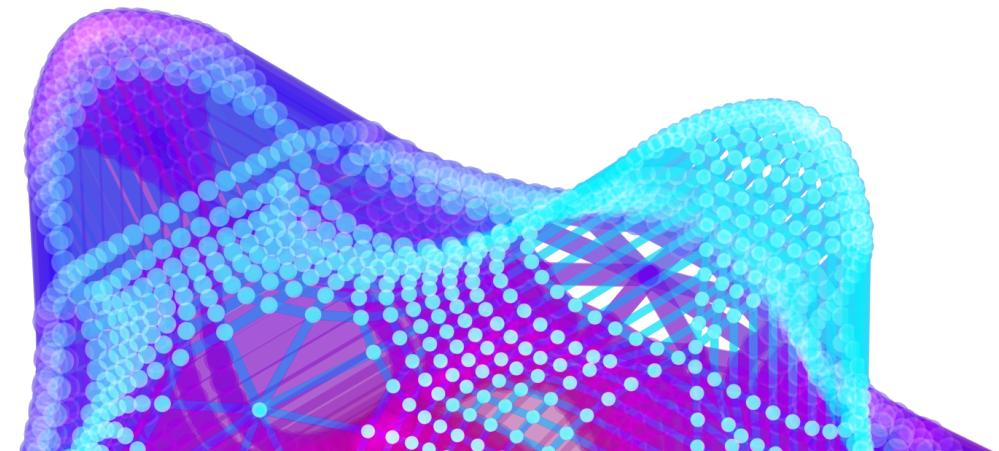
However, in a high cost, high risk environment, the popularity of licensing grows with both parties sharing both the financial burden and risks of failure, while remaining separate entities.

Thomas Stockman, Managing Director for European Healthcare at RBC Capital Markets, states that with ready access to capital and valuations relatively high, there is now less of an impetus for biotechs to sell or for pharma to buy, and the mutual benefits of cost-sharing and risk-sharing are a driving force behind the increase in licensing activity.

Stockman notes that with valuations of biotech companies and their products on the rise, we are seeing more licensing deals happening at the earlier stages of R&D when risk is higher, and so the cost of licensing and competition is lower.

"There has been a tremendous amount of growth and resources spent on AI capabilities and development in recent years, both in terms of capital allocation, data collection and analysis. AI development in this sector has facilitated a more streamlined and advanced process for screening and collecting data from the abundant pool of information available, providing meaningful observations and potential solutions to current health issues and offer preventative measures and treatments in a more timely manner."

Fu Yang
Managing Director and Head of Private Equity, BOCOM International Holdings Company Limited



Dr. Wong notes that AI is a particularly niche and new area. "Based on the feedback and opportunities we receive and see in the market, we are positive that there is exponential growth potential in the 'AI-Biomedica' sector and we believe that this marks only the beginning of an evolutionary new tech era in the sector", he says.

The rapid development of AI capability is also allowing biotech companies to expedite both the R&D and clinical trial stages. Fu Yang, Managing Director and Head of Private Equity of BOCOM International Holdings Company Limited⁴, who is responsible for identifying investment opportunities and making proprietary investments for BOCOM group, has expressed great interest and confidence in the development of biotech and biomed AI businesses.

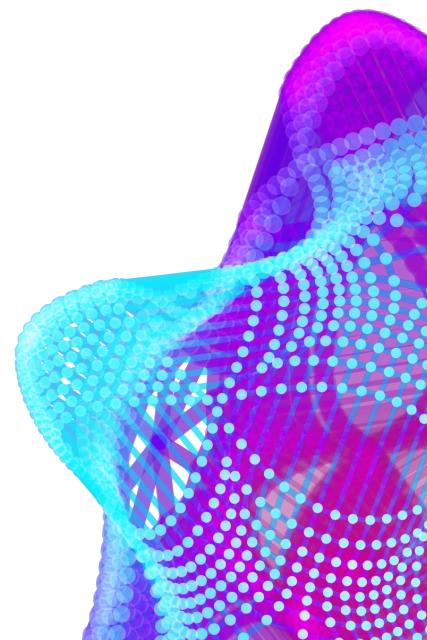
Denis Segota, Corporate & Securities and Life Sciences Partner at Baker McKenzie, New York/Princeton, states that increasingly, there are more licenses being issued at the pre-IND stage or for phase one assets, as the cost of acquiring late stage assets is extremely expensive.

Additionally, Randy Sunberg, North America Chair of Healthcare & Life Sciences at Baker McKenzie, shares that licensing and collaborations in the pharmaceutical and life sciences industry has really been a mainstay of how larger companies supplement their internal R&D and how biotech companies expand the reach of their technology.

"Licensing and collaboration has also become a route to capital raising or funding through upfront payments, milestones, royalties and profit splits. Often, licensing deals can morph into acquisitions. In many cases, when pharmaceutical companies acquire a biotech company, whether it's a privately-held or publicly-held biotech company, the M&A deal may have begun from initial licensing discussions."

Randy Sunberg
North America Chair, Healthcare & Life Sciences, New York/Princeton

⁴ BOCOM International Holdings Company Limited ("BOCOM International") is a subsidiary of Bank of Communications Co., Ltd. ("Bank of Communications") and it provides a wide range of financial services including securities brokerage, corporate finance and asset management to its domestic and international clients. Both BOCOM International and Bank of Communications are listed on the Hong Kong Stock Exchange.



Pharma Debt Capital Raising Activity on the Rise

Influence of megadeals, increased competition and
patent expiry

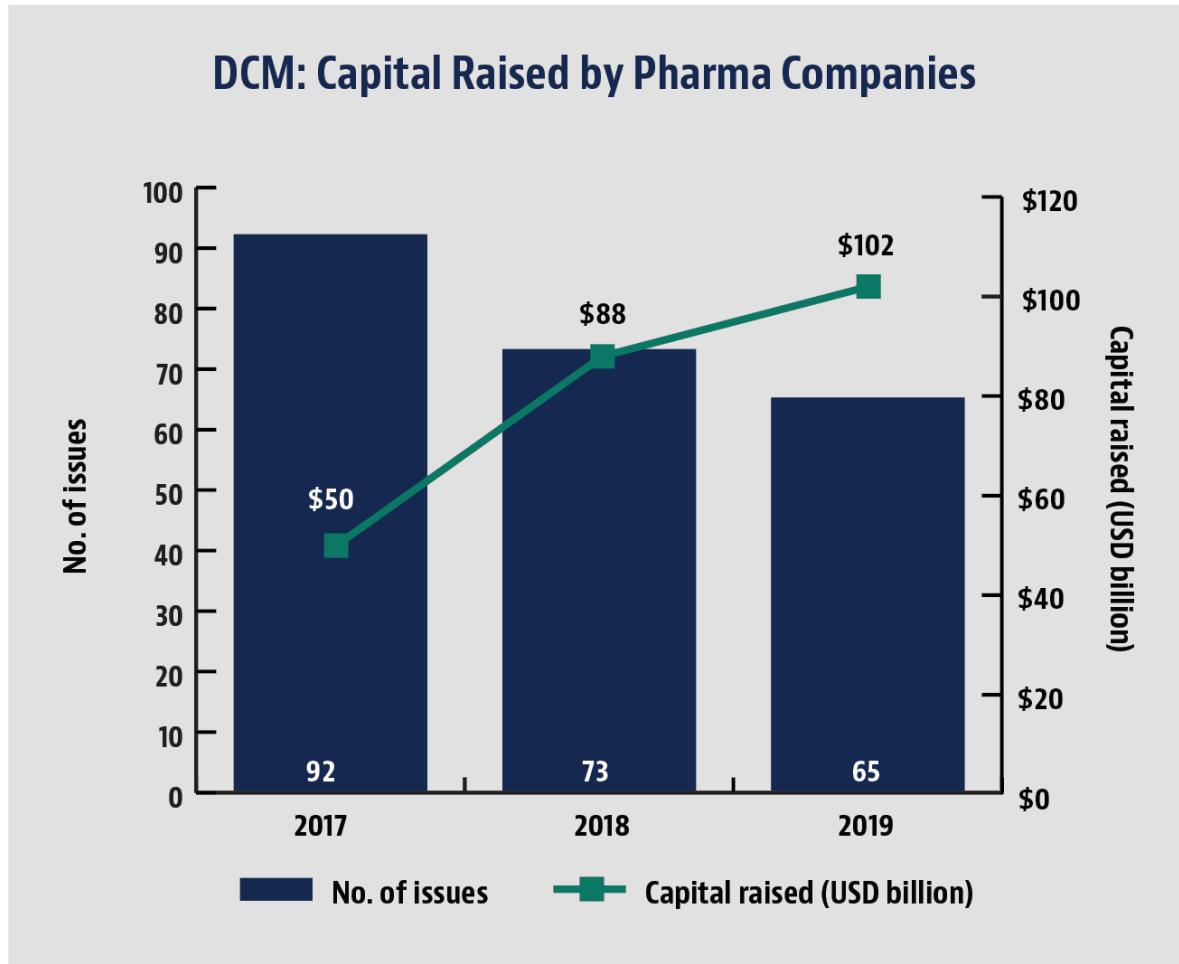


In contrast to the steady performance of the equity markets, debt capital markets have shown a significant increase in value.

This was driven mainly by pharma companies issuing larger debt offerings to fund mega acquisitions, such as AbbVie's proposed USD 63 billion acquisition of Allergan, and the USD 74 billion acquisition of Celgene by Bristol-Myers Squibb.

According to Refinitiv, biotech debt offerings have all but disappeared, with only four issuers raising USD 392 million in 2019, down from six issuers raising USD 7 billion in 2017.

Despite lower volumes of pharma issues, with 65 in 2019 down from 92 in 2017, total value raised more than doubled, with USD 102 billion raised in 2019 up from USD 50 billion in 2017.



Source: Refinitiv

This significant jump in debt capital raising is also driven in part by increased competition from generic manufacturers and rising drug development costs forcing pharmaceutical companies to engage in M&A as a defensive strategy to offset losses in market share and gain cost savings.

Debt financing has an important role to play (as borrowing rates are still relatively cheap) in enabling these transactions which, in turn, maximizes industry efficiency and delivers value for shareholders.

Patent expiry prompts big pharma to act quickly and strategically

Much of the expansive growth in pharma capital raising can be attributed to the increasing need for pharma companies to innovate and replenish their pipeline, as patents on blockbuster drugs near expiration.

Acquisitions of biotechs by pharma companies — many of which are funded through debt issuances — remain strong with total deal value recorded at USD 20 billion in 2019 compared to USD 5 billion in 2017.

Rudy Dekeyser, Managing Partner of LSP, a specialized European healthcare VC investment firm focused on life sciences, emphasizes that patent expirations on blockbuster drugs are a very real concern to many of the big pharma companies. "As big pharma continues to spend billions of dollars on their own R&D, they need the support of a continual pipeline of revenue. Pharma companies are increasingly building their pipeline by combining their internal R&D efforts with the acquisition of assets from biotechs and academic institutes. As biotech firms are fully focused on R&D, having both scientific expertise and patents, they are the ideal target for pharma. In fact, more than 50% of blockbuster drugs are now coming from pharma companies as a result of M&A and in-licensing, rather than from their own R&D", he says.

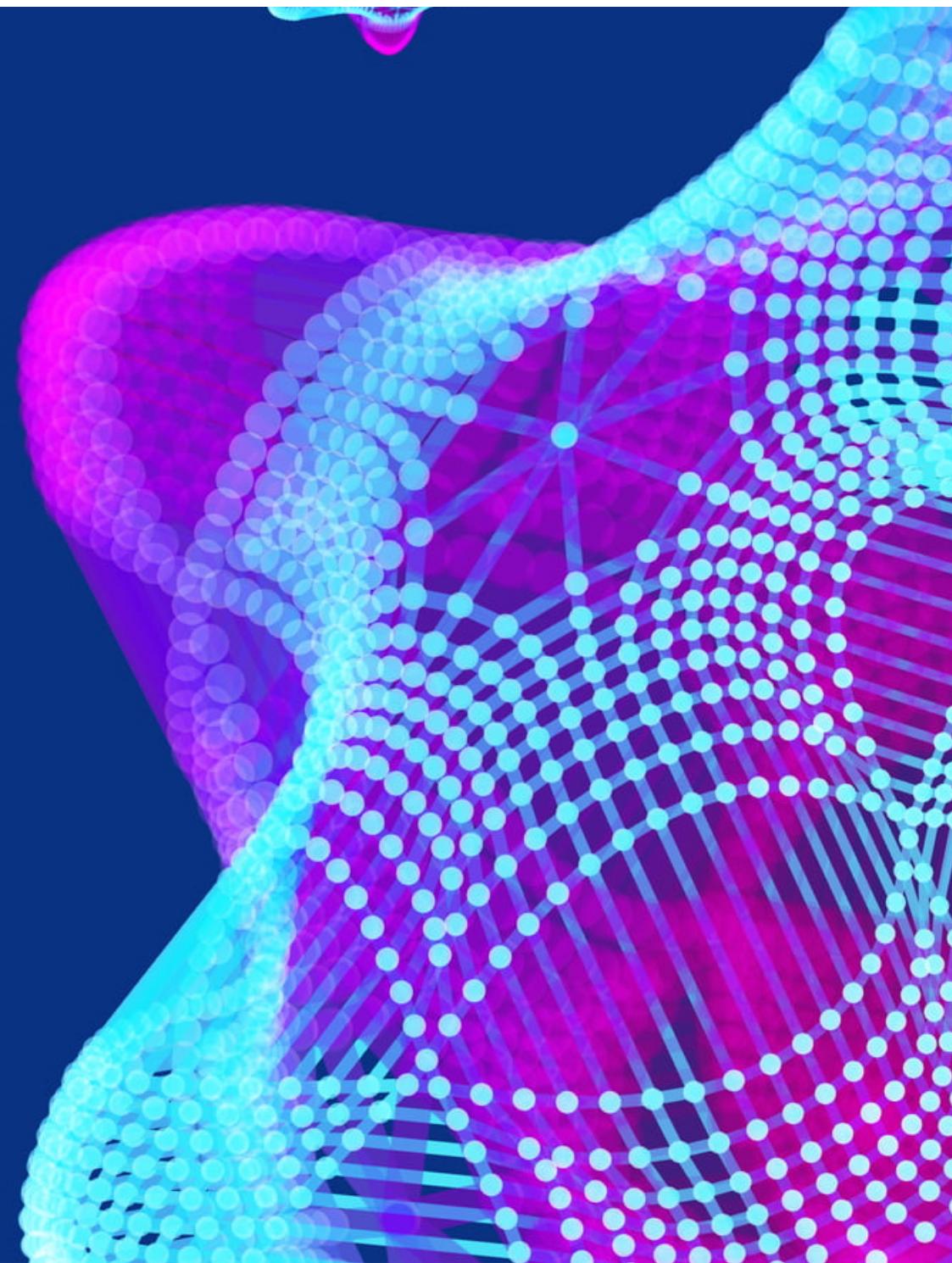
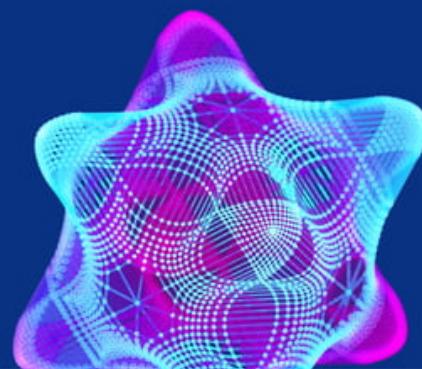
Segota also recognizes a shift of mindset, which is causing "strategic positioning that impacts deal activity or capital raising". Segota adds that "companies are keen to make up for the potential loss of revenue on sales and develop new core competencies through major acquisitions. Some bigger pharma companies are reacting to growing shareholder pressure. Through M&A deals, bigger and potentially less agile companies can reduce the increasing liability of single-drug revenue."

"For biotechs, engaging with pharma companies offers the R&D funds they require, along with the crucial experience that pharma companies have in bringing a drug or product to market and its commercialization. Today's biotech/pharma ecosystem creates a win-win situation for all involved. It is the engine providing society with a continual pipeline of new and highly innovative treatments."

**Rudy Dekeyser
Managing Partner, LSP**

Abundance of Private Funding Sees Companies Staying Private for Longer

The power of dry powder, PE and VC-backed funds



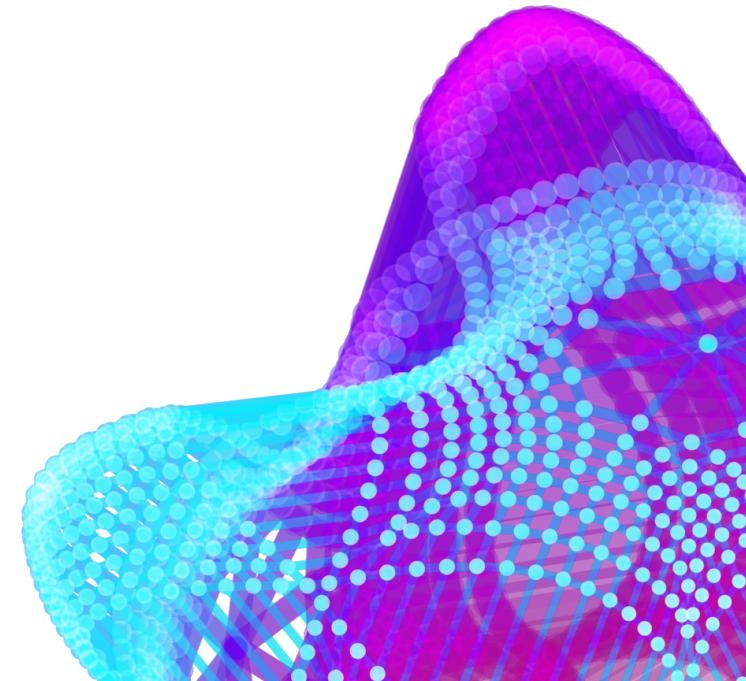
Companies staying private for longer, buoyed by abundance of dry powder

Dekeyser believes that more companies are opting to stay private at least until they reach the more advanced clinical stages. He notes that the availability of larger private funds allow for companies to remain private for longer and there is a strong incentive to raise capital through the private route in order to retain control. "This alternative avoids some of the stringent requirements that come with being public, and the answerability to stakeholders. It's a big driver for companies considering private funding over public capital raising routes", Dekeyser adds.

However, on the flip side of that, the availability of private funding through institutions or private funds can potentially alter the attractiveness of different opportunities within the sector causing valuations in other therapeutic areas such as oncology, to change. It may drive activity to other areas or other stages of funding, particularly in the pharma space.

Segota states that in the US, "the abundance of private funding available through traditional venture capital and family offices has caused increased valuations, especially in oncology. As a result of the increased competition in the oncology space, life science investors are focusing on other therapeutic areas where the competition is not as intense."

Ivy Wong, Asia Pacific Chair for Capital Markets at Baker McKenzie concurs that an increasing availability of private funding is changing the landscape for capital raising. Wong notes that, "private entities may be keen to participate not only in later rounds of the financing, but also at the very early inception round. The latter could be due to what these private funders observe in the market with strong performances, which incentivizes them to tap into the growing opportunities in biotech and pharma. This optimism has to do with seeing the positive post-offer valuations of some of the younger biotech companies. This could possibly be a mid-term trend in the biotech and pharma capital raising landscape."



PE and VC-backed investments shape R&D funding

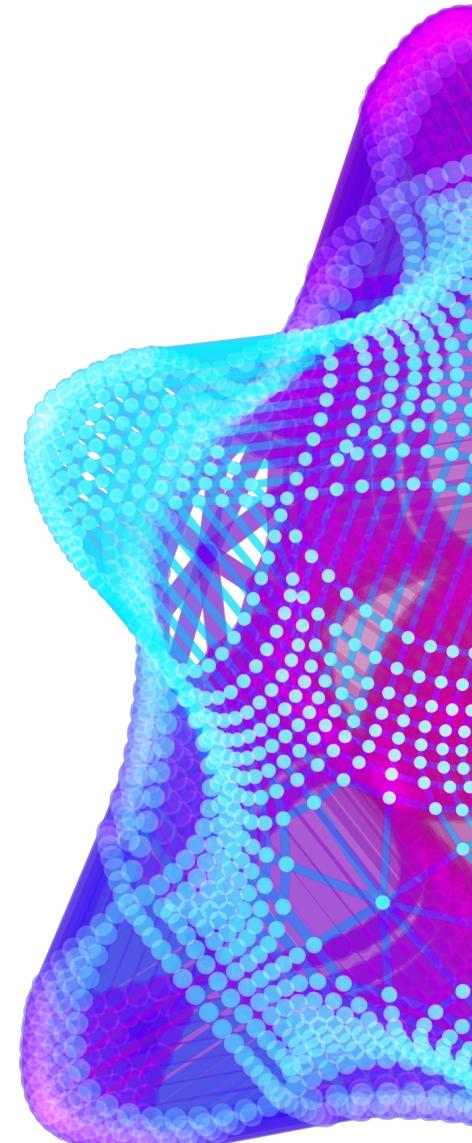
Investment funds backed by private equity and venture capital firms are becoming more influential, according to Sunberg. Funds such as SOSV III, ARCH Venture Fund VIII Overage and the Connecticut Innovations Bioscience Research Fund made over 130 investments in 2019.

Additionally, Europe-based Dekeyser noted that LSP received well over 1,000 VC investment applications in 2019.

The existence of more specialized biotech developing funds offer more opportunities in the private market to fund R&D. According to Pitchbook, there was a 20% increase in the number of biotech and pharma focused funds that closed in 2019 (133 funds), compared to 2018 (111 funds). Some such specialized funds, Sunberg observed, "have aligned and formed entities with the clinical development expertise, and the financial ability, to both fund late-stage clinical development trials, which can be in the range of USD 100 million, USD 200 million or more, and to conduct those trials."

This is an attractive option for pharma companies to move a program forward with external funding, as well as for the funding entities, as returns can reach between five to seven times the original investment, according to Sunberg. In such deal structures, he notes, "negotiation of success criteria for each stage of the clinical development program to launch is crucial. These arrangements also should lay out the respective obligations of both the funding entity, typically to fund and conduct the late-stage trials, and the pharmaceutical company, typically to file for regulatory approval and to commercialize the product."

Sunberg also shares that these specialized development funding groups provide "a way for companies to fund clinical trials for products that they might not have otherwise pursued. It is like a hybrid between capital raising and licensing but allows the company to maintain control of product commercialization."



VC investment continues to grow due to biotech rush

Venture capital investment is playing an increasingly significant role in the growth of the biotech sector.

According to Pitchbook, there was a 29% increase in funding from VC entities, moving from USD 21 billion in 2017 to USD 27 billion in 2019.

One reason for this increase could be a change in investor attitudes and behaviours. Segota cites that change is afoot as VCs expand their focus to include biotech companies that focus on multiple products or programs.

"Biotech investments tend to generate a larger ROI than in other industries. This is why we see huge chunk of VC investment coming from a growing number of limited partners, who tend to have deep enough pockets to balance the risk against the reward."

Rudy Dekeyser
Managing Partner, LSP

Aligned with the belief that the biotech sector is fairly cyclical, Segota sees a change in VC-backed activity from what it was a decade ago.

"10 years ago, a lot of VCs were funding specific, single asset companies. The trend now has been to invest in platform technology that has multiple paths to commercialization. This potentially diversifies risks but also increases the amount of investment funds needed to support the portfolio companies", he states.

Higher risk, higher reward

Considerable levels of investment from VC entities into seed funds and early stage Series A funding shows that investor attitude to risk is more positive than seen in other industries globally.

Across 2017 to 2019, there were 668 VC investments classified as seed funding and 892 classified as Series A. Combined, they account for 60% of total activity for the same period.

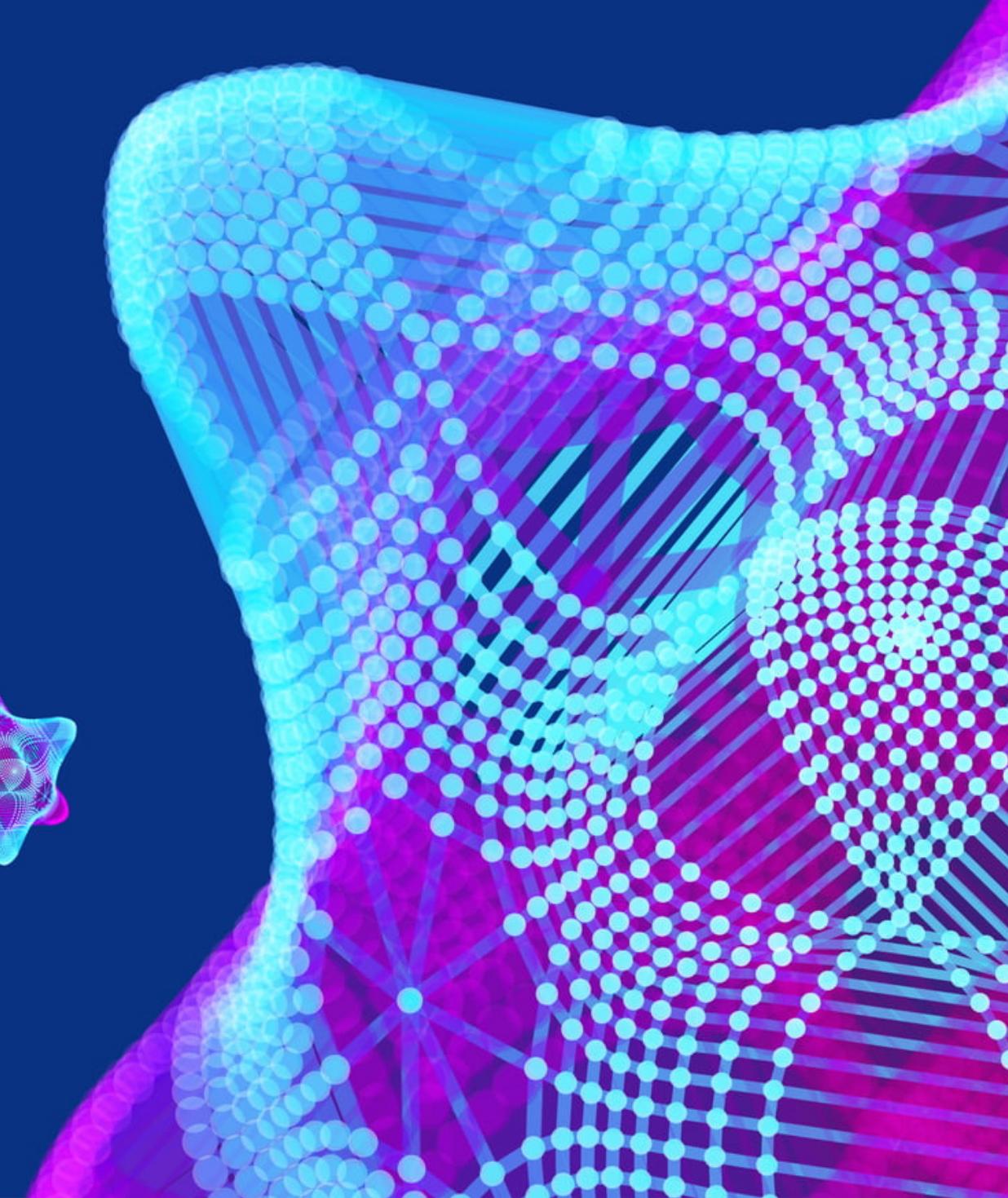
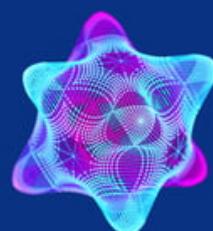
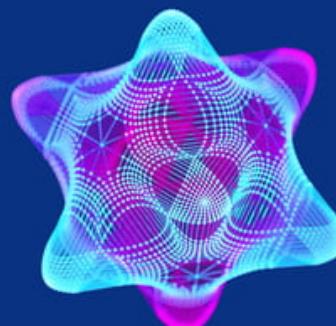
When we consider the rate of product failure in this sector, it becomes apparent how much riskier these types of investment are. Drug Patent Watch⁵ estimates that 36% of drugs fail to pass the preliminary stage of drug development, while 68% do not make it beyond the intermediate stage, and 40% do not pass the final stage.

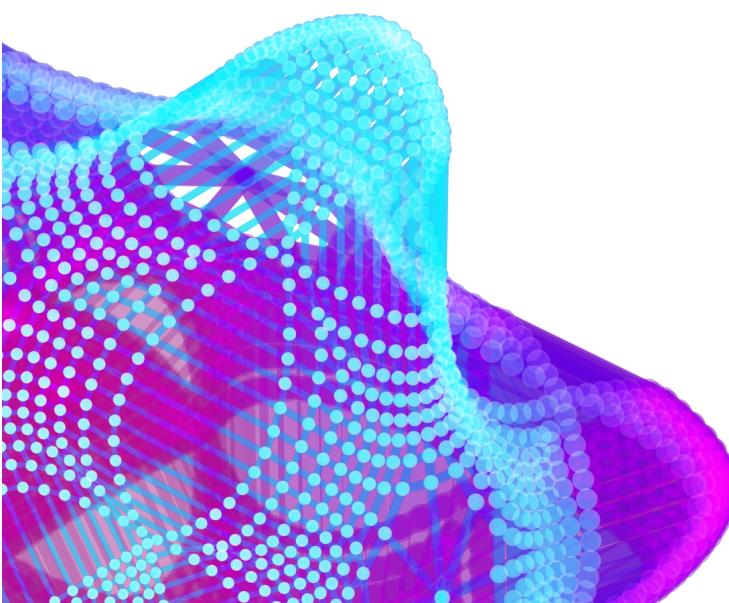
However, the higher rewards that come from successful development and market commercialization of new drugs and innovative tech generate such rich returns that investors are willing to take the risk.

⁵ Statistics on drug development failure were taken from an article published on Drug Patent Watch's website

Alternative funding: Venture Lending and Corporate Capital

Younger companies now have more options





The heightened interest in venture lending is part of a bigger trend — the rise of private funding for biotech companies. It is part of the increasing corporate VC activity by standalone VC firms, as well as the VC arms of bigger pharma companies.

Venture lending presents opportunities to younger companies

Matthias Courvoisier, Partner at Baker McKenzie, Zurich states that venture debt or venture lending is interesting because it has an element of equity.

"It is a form of capital raising that is made increasingly available to younger companies — those in earlier stages of development that may not have the cash flows or assets to put up as collateral," he says.

Ben McLaughlin, Global Chair of Healthcare & Life Sciences at Baker McKenzie also notes the ongoing trend of venture lending in biotech. McLaughlin states that "VC firms or VC arms (corporate venture capital) of larger and more established pharmaceutical companies are lending money at incredibly low interest rates.

Venture lending is unique as it is quasi-equity and quasi-debt. It is something we might see instead of equity purchases, acquisitions or traditional VC deals.

"Venture lending will give companies that do not have access to capital via traditional routes, the ability to do draw-downs and possibly also have shares placed in the market. This would then mitigate the liquidity problem, enabling them to continue with R&D or innovation."

Matthias Courvoisier
Partner, Baker McKenzie, Zurich

This gives smaller biotech companies the chance to develop a piece of technology or a drug, in order to reach a point where they can get FDI approval or other relevant governmental approvals."

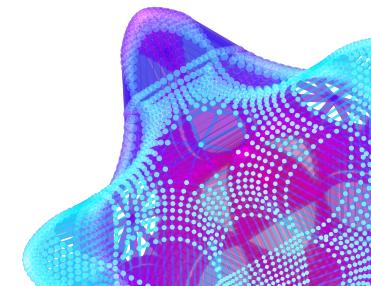
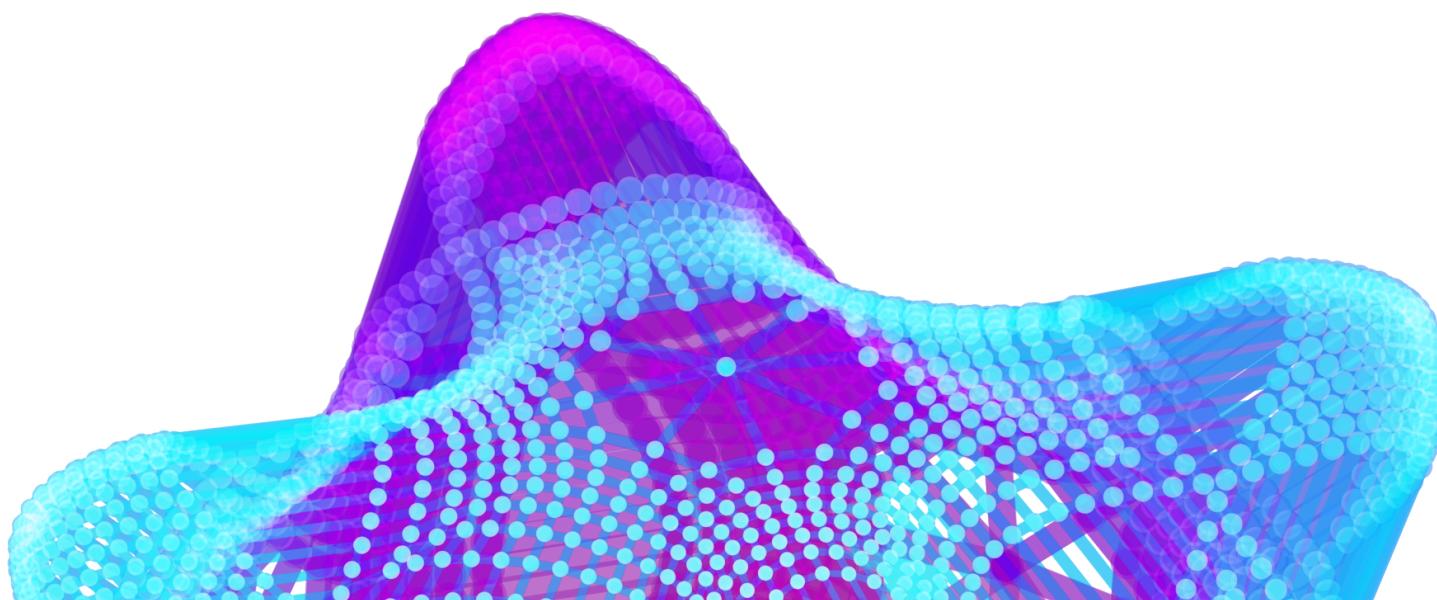
Venture lending is becoming more popular as it combines debt with a right to equity. This combination makes venture lending a viable alternative to smaller companies, who are unable to raise debt via more traditional methods.

Corporate capital raising through VC arms

Bigger and more established players in the pharma sector are often restricted by extensive and complicated financing structures.

Corporate venture funding plays the role of replacing in-house R&D in larger pharma companies. In the interest of keeping pace with innovation in the industry, some VC arms are pouring funds into strategic investments and acquisitions that allows them to either gain access to the technologies and/or expertise of younger biotech companies, or to reap the rewards of the new technologies or innovation being developed.

VC arms such as the Novartis Venture Fund, GlaxoSmithKline and Celgene have been particularly active in the biopharma space. Though VC arms traditionally extend funding to earlier stage companies, they are now spending more, and leading later rounds of funding as well, pointing towards a growth of corporate capital raising across more stages of financing in the sector.



Mapping Global Activity in Key Regions

US remains the epicentre of biopharma activity



US remains the epicentre of biopharma activity

The US continues to lead the way in terms of biopharma activity, both by volume and value. With its deep investor pools, its innovation hotspots, investors with specialized sector knowledge and its history of successful commercialization of drugs, it is by far the leading jurisdiction in terms of activity, experience and development.

"As a highly concentrated market, the US remains the capital raising location of choice, globally. It remains a stronghold for capital raising in the pharmaceuticals industry and accounts for up to 70% of global sales", states McLaughlin.

Capital raising in the US across both debt and equity raised USD 92.7 billion in 2019, accounting for 60% of total capital raised and 40% of issues for the biopharma sector.

"The US is still a key jurisdiction for raising capital and the sector will continue to see direct listings on NASDAQ. Companies are less dependent on market sentiment when they engage in a direct listing. The US has a wealth of knowledge in this area and there are a lot of specialized investors for biotech and pharma in this region."

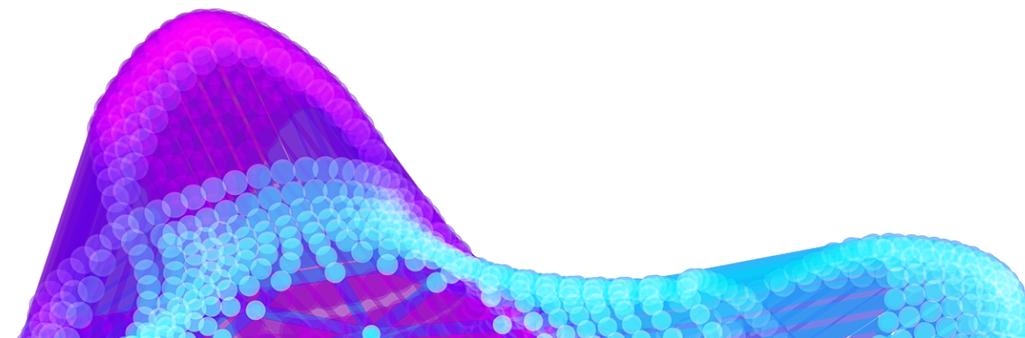
Chris Bartoli
North America Chair, Capital Markets

FDA approvals are boosting activity

Rising valuations and follow-on activity have also been fuelled by the upward trend in drug approvals by the FDA. In 2019, the FDA's Center for Drug Evaluation and Research's (CDER) approved 48 novel drugs, which follows the highest-record in 2018 at 59.

The rush of FDA approvals are important because they indicate the pipeline to commercialization and the capital raising needs to do so.

According to the FDA, CDER classified more than one-third of the 48 approved novel drugs under the Fast Track designation, which aims to shorten the runway for drug development and review. Out of these 17, 13 of the novel drugs were also listed as "Breakthrough Therapies", which allows companies to shorten the development time (and hence commercialization timeline) for drugs that exhibit significant improvement on patient function, survival or quality of life.



"Principally, the US has been the main location for biotech companies. Valuations are more sophisticated there, and both investors and the market are much more familiar with the biotech industry, although it is interesting to see how Asian markets are also gradually growing and developing their knowledge and expertise in this area."

Ivy Wong
Asia Pacific Chair, Capital Markets,
Baker McKenzie

Li noted the substantial and rapid growth of the China biotech market over the last few years, which he considers to have been mainly attributable to an improved system and infrastructure for approving biomed, biotech and pharmaceutical products in China. "The National Medical Products Administration formerly known as the China Food and Drug Administration or CFDA) is becoming much more efficient and sophisticated in its approval process and it has also taken note of the relevant international standards adopted by other authorities, including the food and drug administrations in the US, Europe and Japan", he states.

Geo-political factors of influence

The 2020 US Presidential elections could have significant impact on the global biopharma sector, as generally the state of the US market has a resounding effect on the wider market, given the volume of activity and capital raising that occurs there. Potential legal action on reducing prescription drug prices in the US could place intense pressure on share prices, with a potential for a market correction.

Additionally, in line with the continued Sino-US trade war, tightened US scrutiny of overseas investment may pose a challenge to Chinese investors in the biotech and pharma sector. Mirroring those restrictions, US-based start-ups may also struggle to raise capital from the significant pool of investors in mainland China.

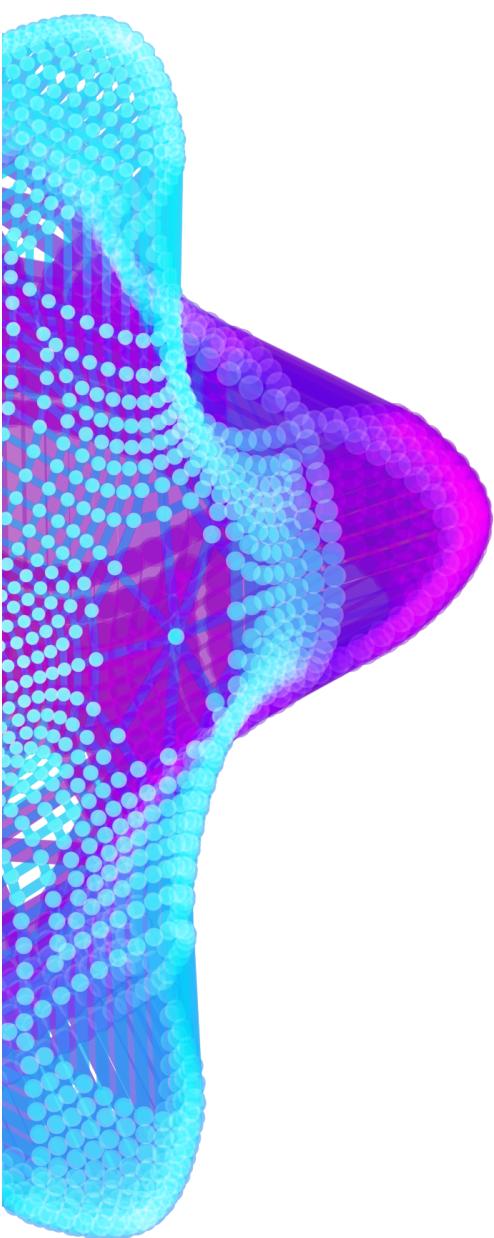
China set to become a more influential player

China follows the US in terms of value and volume of biopharma activity

In 2019, China raised USD 16.5 billion across 90 deals, a 17% increase in volume and 13% increase in value from 2018 — as China's government continues to heavily invest in its biotech R&D particularly. In 2018 alone, The Financial Times⁶ reports that scientific R&D spending in China topped USD 291 billion,

with further plans to increase investment in this space. Such large levels of investment mean that China is able to grow at a more rapid and innovative pace than many other jurisdictions. Regulation changes intended to bring down the cost of common drugs, coupled with looser restrictions on the sharing of medical information gives Chinese companies more access to patient data and a more competitive edge in pricing.

Lv Hongbin, Head of the Healthcare Division/Investment Banking of Huatai United Securities Co., Ltd., echoes the growth potential of biotech companies in China.⁷ Lv states that "there is an increasing interest in funds among biotech and innovative companies, and venture capital and private equity funds play an important role in fund-raising exercises. These biotech and innovative companies still prefer equity over debt financing — efficiency and long term expected return in fund raising activities are often key factors for consideration by Chinese issuers and investors alike. So in China, there does not seem to be a trend of biotech companies staying private for a longer time than before as it may have been the case for some other jurisdictions."



"The continuous growth in specialized knowledge among bankers and investors in the industry in Asia will definitely contribute to positive investor sentiments both privately and publicly in the capital market in China."

Mr. Lv Hongbin
Head of the Healthcare Division/Investment Banking
Huatai United Securities Co., Ltd.

⁶ According to the Financial Times article "Chinese biotech: from copycat to innovator ", Chinese spending on R&D topped USD 291 billion in 2018.

⁷ Huatai United Securities Co., Ltd. belongs to Huatai Securities Co., Ltd., which is an integrated securities group in China that provides full life-cycle integrated financial services, securities brokerage services, asset management services, investment banking and M&A advisory services with a leading e-platform, and whose securities are listed on the Shanghai Stock Exchange, the Hong Kong Stock Exchange and the London Stock Exchange.

STAR Market brings promise of more domestic capital raising

Launched in 2018, Shanghai's Science and Technology Innovation Board (STAR Market) was part of the Chinese government's strategy to encourage biotech and pharma companies to raise capital on home ground.

Wong shares that "as the Chinese government introduces policies and subsidies for companies in the biotech space, investors are encouraged to engage in capital raising activity, triggering new opportunities for business and collaboration."

Key STAR Market incentives for biotech and pharma capital raising

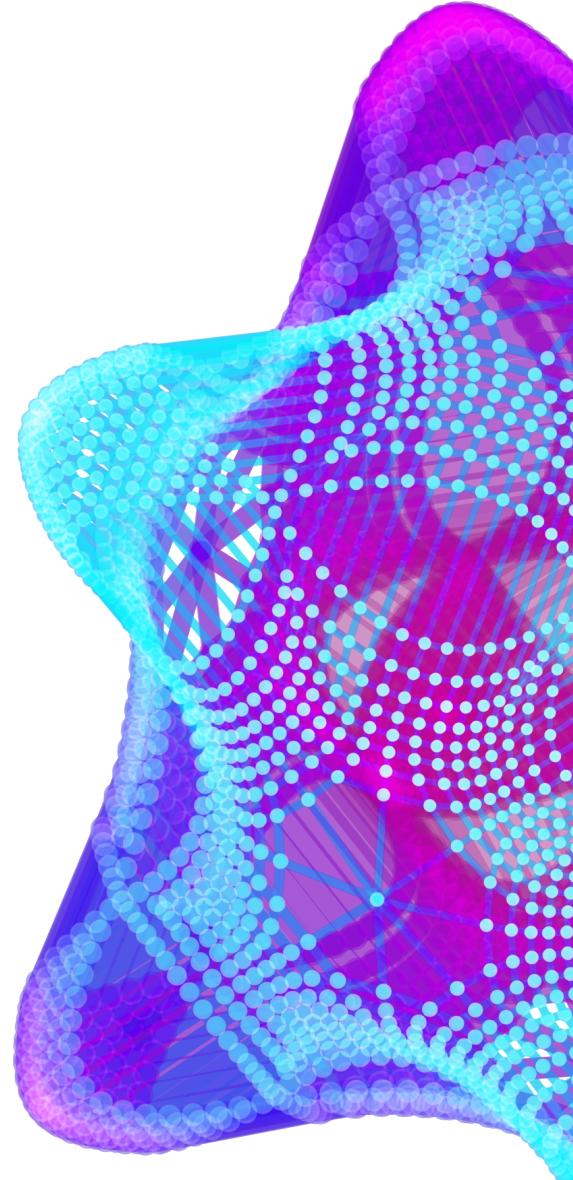
1. Preferential policies for high-tech and strategic emerging industries, including pre-profit tech companies (including biotech companies).
2. Availability of Chinese depositary receipts (CDR) gives foreign-funded mainland companies an added incentive to list on the STAR market.
3. Dual-class shareholding structure companies are also sanctioned to conduct fundraising on the STAR market.

Dr. Lou Jing, the Chairman and founder of 3SBio Inc⁸, also shares a positive outlook for biotech and pharma in China, stating that "as part of international expansion plans and strategies, there is great incentive to seek investment and collaboration opportunities in both domestic and international markets."

He notes that "with a booming and growing market and investor base in the biotech and pharma industry, coupled with the different new listing regimes and initiatives launched by regulators in different jurisdictions (for example, the new biotech listing regime in Hong Kong and the STAR Market in Shanghai), we see both debt and equity financing set to remain popular means of fund raising by market players in the sector."

This sets the tone for Chinese venture capital firms and other primary market investors, as the STAR Market represents a viable alternative to NASDAQ that could allow them to exit investments more easily at high valuations.

⁸3SBio Inc. is a fully integrated biotechnology company in China with market-leading biopharmaceutical franchises that had made a successful strategic move from a listing on NASDAQ to a listing on the Hong Kong Stock Exchange in 2015.



Hong Kong also strives to entice biotech activity to its shores

In April 2018, Hong Kong Stock Exchange (HKEX) implemented changes to allow pre-revenue biotech companies to list on its exchange. This widening of market access for early stage companies allows emerging biotech and pharma entities to seek crucial funding to carry on with innovation and R&D activities. Additionally, intentions to shift to a fully electronic subscription process for IPOs will lead to a paperless bourse system that will further simplify the process of listing on HKEX.

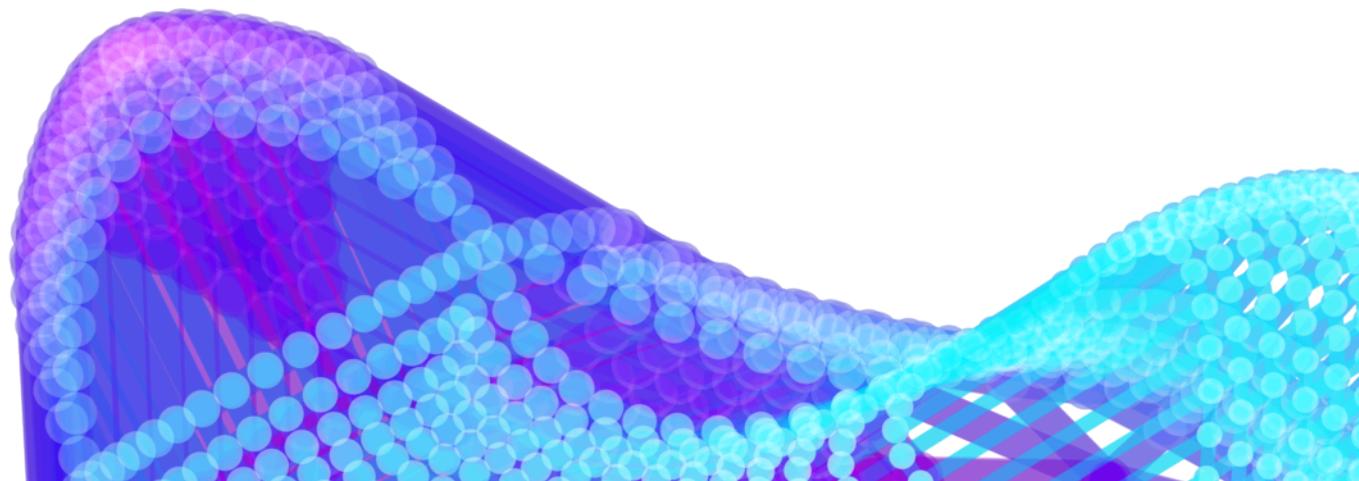
This move to modernize regulations and provide a credible, alternative listing location to rival the NASDAQ-dominant landscape, helps to shape investor interest in the biotech and pharma sector.

So far these changes have triggered a good flow of applications, as well as a stable number of listed companies in the pre-profit biotech space in Hong Kong.

Wong notes that pre-profit biotech companies are becoming more active in Hong Kong, adding that "this heightened activity is something that is expected to continue across the Asian side in China, Hong Kong and Singapore. This is partly because there is obviously a proven record of appetite on the buy side, as market players recognize the huge growth potential for biotech and pharma."

Looking to the future, Wong also states that "some of these pre-profit companies are getting listed and observe that the market cap could actually get even higher. Seeing successful launches and post-launch valuations where companies exceed the offer price, can trigger activity and further interest for investors."

However, due to market conditions, valuations remain diverse both in Hong Kong and generally across the globe. Wong observes that high growth potential remains for companies who may not reach market cap or max out their financing value.



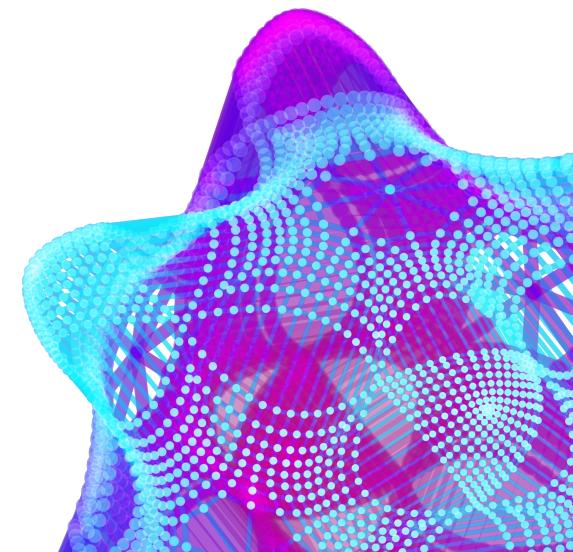
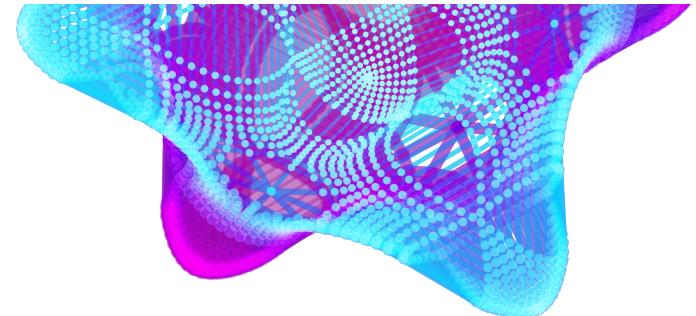
Since the implementation of HKEX reforms to the listing regime, Hong Kong has become the world's second largest funding hub for biotech companies.

To date, 23 biotech companies have listed on the Main Board, raising USD 8.7 billion. This includes 14 pre-revenue biotech companies which raised USD 4.4 billion. Overall, Hong Kong's healthcare sector has enjoyed strong growth with more diversified issuers.

However, increased competition and activity requires regulators to protect investors by ensuring the suitability and quality of biotech and pharma issuers. HKEX's biotech chapter (Chapter 18A) includes listing rules and guidance letters to protect investors. Given the specialized nature of the biotech sector, HKEX has also established a biotech advisory panel of international practitioners.

Hong Kong is well on its way to becoming one of the world's major healthcare and biotech centres. Looking forward, the biotech IPO pipeline remains robust and continued growth will stem from developing a sustainable biotech ecosystem; one that brings global and regional issuers, investors, policy experts and professionals together.

This commentary has been shared by Michael Chan, Head of International Issuer Services at Hong Kong Exchanges and Clearing Limited



Alan Fu, a Managing Director in the Corporate Finance team of Haitong International Capital Limited⁹ in Hong Kong, focusing on the biotech and pharmaceutical sector, sees strong sentiments among investors in Asia in biotech companies. Fu believes that IPOs remain the primary type of fund raising activities for these companies that are seeking to expand their R&D capabilities and fund their business developments.

"The pipeline of biotech companies, whether pre-revenue or post-revenue, seeking to list on the Hong Kong Stock Exchange remains strong and the exchange has remained a popular listing venue for biotech and healthcare companies with a strong business presence in China. Even though the recent launch of the STAR Market in Shanghai has posed some competition between the two stock exchanges, the Hong Kong Stock Exchange remains a popular venue for Chinese biotech companies with offshore shareholding structures, founders with overseas background and international business expansion plans that require offshore funding," he says.

"Biotech companies with AI capabilities or AI companies facilitating biotech analysis may well be the next generation of listed issuers emerging on these tech boards over the next few years."

Alan Fu
Managing Director, Corporate Finance
Haitong International Capital Limited

This is further backed by Li, who is also of the view that IPOs will remain a popular means of fund raising for pre-revenue biotech companies. NASDAQ in the US, the Star Market in Shanghai and the new biotech listing regime in Hong Kong offer a good variety of listing venues for different issuers with differing needs. Li sees such variety of listing venues as complementary rather than competing among each other and these three exchanges will continue to dominate listings of companies in the biotech and pharmaceutical sector.

⁹ Haitong International Capital Limited belongs to Haitong International Securities Group Limited, which is a stock brokerage firm and investment bank based in Hong Kong and whose securities are listed on the Hong Kong Stock Exchange.

European biotech investment doubles in recent years

European capital raising activity for biopharma largely follows similar global trends, with DCM activity raising USD 19 billion of the total USD 28 billion raised in 2019. The bulk of total capital raising activity, unsurprisingly, came from pharma issues, which raised USD 25 billion of the total USD 28 billion raised in Europe.

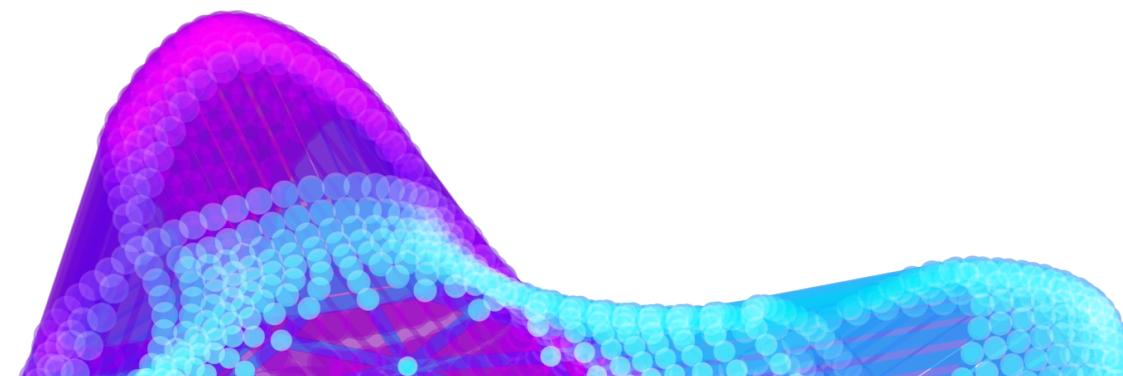
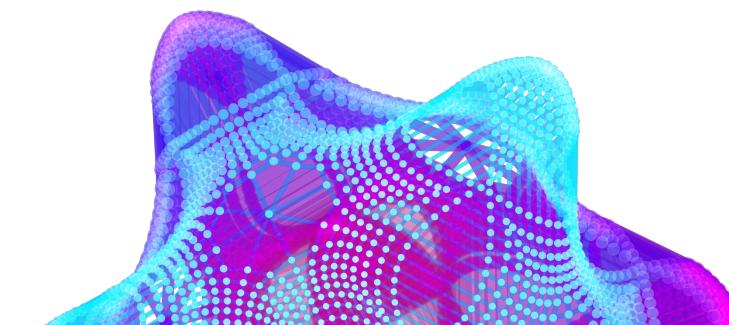
Alongside strong pharma activity in Europe, investment in biotech firms has grown significantly, more than doubling over the past few years, particularly in Belgium, Germany, Switzerland and the UK. The development of European VC funds has also seen VC investment increase three-fold. When it comes to raising growth capital via IPO, around a third of European biotechs are opting to raise capital on US exchanges, as IPOs tend to bigger on the US market.

Stockman notes that there are a number of factors that could potentially impact European biopharma activity and that "macro-trends have created a more challenging market for capital raising by pre-revenue companies in Europe. Where five years ago, we regularly saw activity across Euronext, London and the Swiss and Nordic exchanges, we are now increasingly seeing European biotechs heading to the US to raise capital and IPO — drawn to its sophisticated market and its well-capitalized investor base."

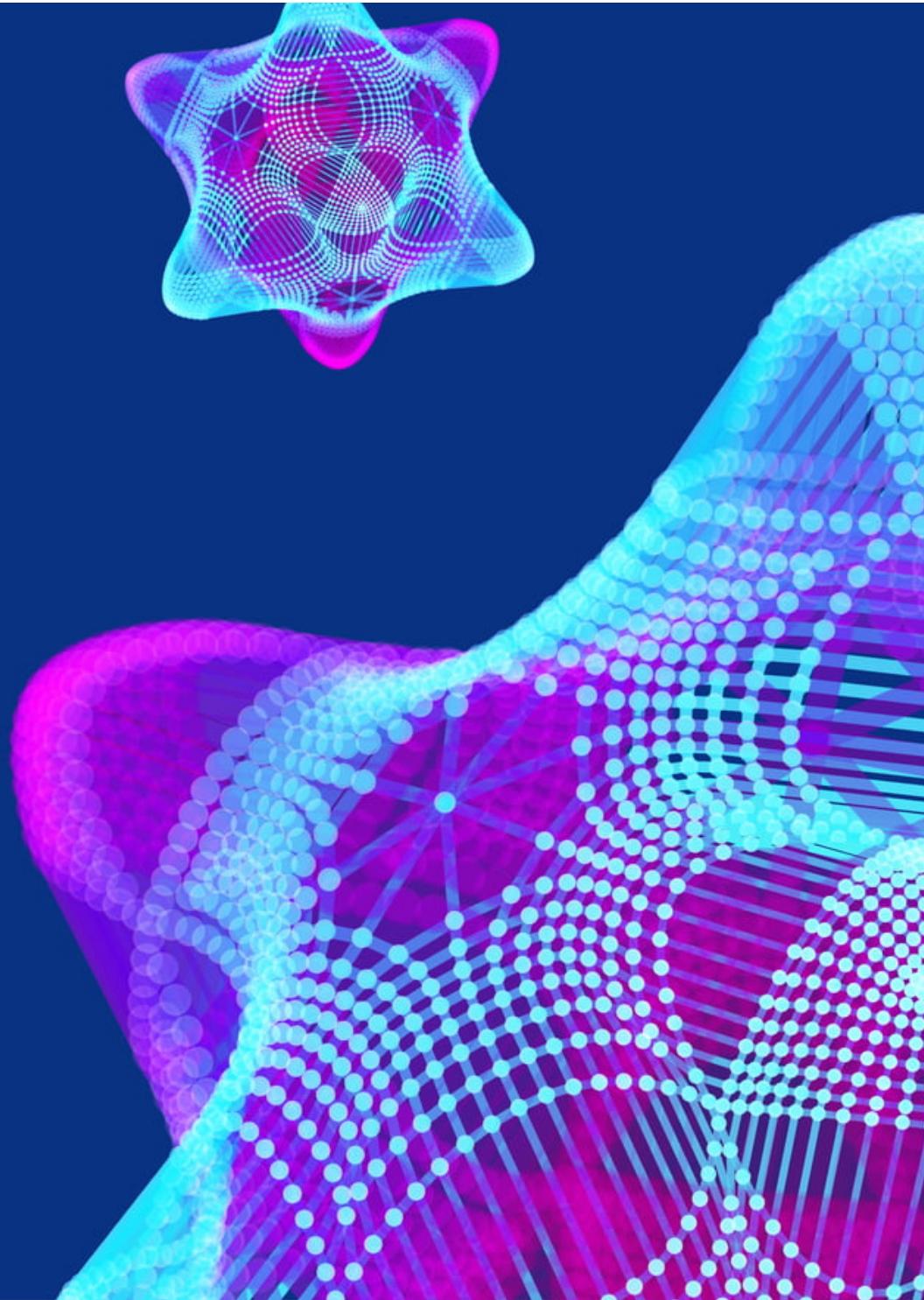
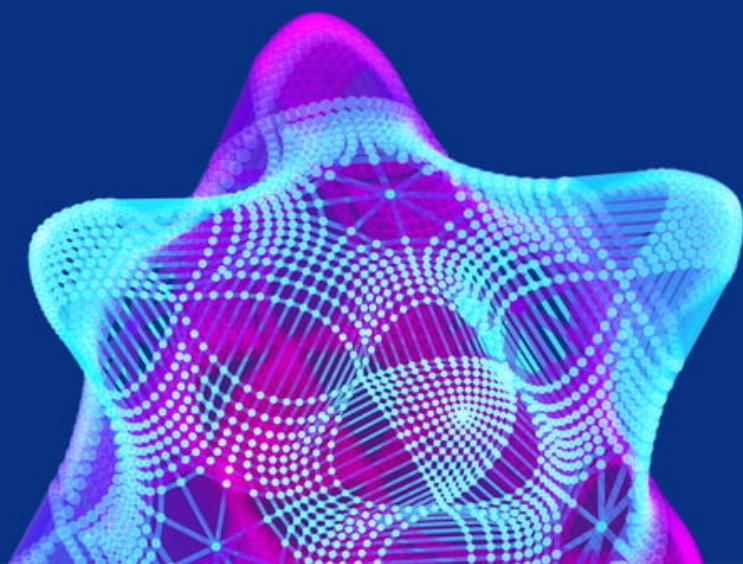
As biopharma activity in Europe slows down in line with global trends, Stockman notes that we are "seeing a reduction in the ecosystem of specialist investors, research and sales locally, and global banks with transatlantic capabilities are tapping into cross-border activity from European biopharma companies, leveraging the specialized industry knowledge and investor access we are able to offer."

One area of activity that Europe continues to perform strongly in is that of biosimilars. Since the first biosimilar medicine was approved by the EU in 2006 (Omnitrope®), Europe has been considered a pioneer in the regulation of these medicines — and continues to drive innovation in this space, having approved the highest number of biosimilars globally with 56 approvals in Europe ahead of the US on 19.

Market forecasts have suggested that the biosimilar market is set to grow three-fold over the next three years, driven largely by the more cost-effective nature of biosimilar production, with almost half of that growth expected to come from Europe. This, coupled with the fact that there are currently over 1,000 biosimilar products in the biopharma pipeline, suggests that we could see increased levels of investment in the European market.



Conclusion



Conclusion

Robust activity in the biotech and pharma sectors looks set to continue, though the changing needs of companies at different stages of development are impacting on how companies are choosing to finance that development and growth, along with influencing factors such as sophistication of the market, patent expiry pressure, regulatory changes and new listing incentives.

While biotech companies continue to favour ECM over DCM and IPOs remain a popular choice, overall activity is heavily dominated by pharma, which accounts for over 86% of total capital raised in 2019. This was driven by large debt offerings to finance strategic acquisitions, in the face of patent expirations impacting on revenue streams and the need to innovate to replenish pipeline.

While the US continues to lead the biopharma sector in terms of financing, Asian markets are making concerted efforts to grow their presence in the space, particularly in China, Hong Kong and Singapore. Record investments made by the Chinese government, relaxation of listing rules by the Hong Kong Stock Exchange, the launch of Shanghai's STAR Market, as well as other regulatory changes such as dual-share structures and the Monetary Authority of Singapore (MAS)'s new Grant for Equity Market Singapore (GEMS), will incentivize activity in the market.

European biotech companies saw a banner year for equity funding (public markets and private equity), raising over USD 7.7 billion in the region, slightly ahead of the previous high in 2018. In terms of offerings, and in line with global trends, follow-on offerings dominated and were particularly affluent for European firms listed on NASDAQ. Coupled with the robust R&D pipeline and strong pharma investor sentiment, the European biopharma market appears to have avoided some of the impact that a slower economy has had on other sectors in the region.

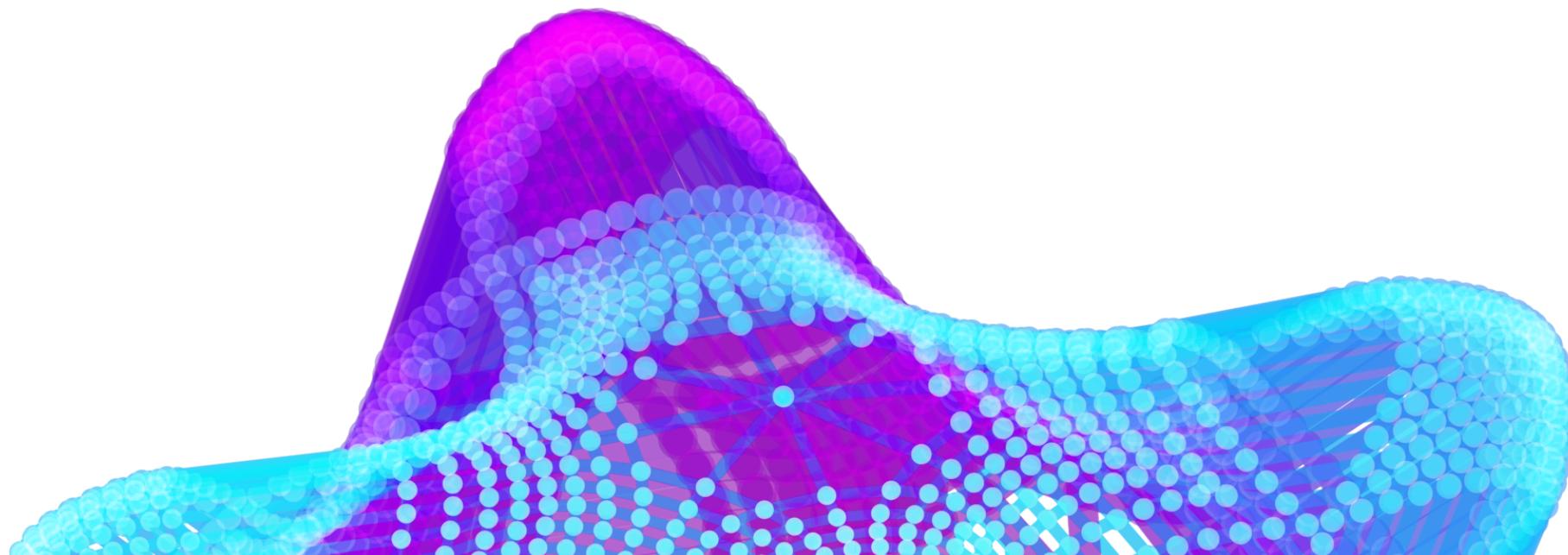
Licensing and M&A activity will continue to account for much of the innovative growth and strategy of firms, particularly licensing and collaborative deals. The mutually beneficial advantages that come with licensing and collaboration such as cost-sharing, risk-sharing and control retention, coupled with the fact that assets sourced through licensing are more likely to be successful due to less disruption during the R&D phase, suggests that this will continue to hold major appeal for companies and investors.

Rise of pharma debt, biotech VC and convertibles

Due to the growth of private funding for early-stage companies in the biotech and pharma industries, we expect the trend of increasing debt activity to continue – with companies preferring to leverage the advantages that come with remaining private for longer, such as retention of control.

Similarly, we expect this increase in debt capital to be driven by the pharma sector, as they battle that pressure to innovate, replenish R&D pipelines and retain high levels of revenue.

Given the overall desire among companies to remain private for longer, we foresee both convertibles and venture capital funding playing a significant role in shaping how companies finance their growth in the future. Equally, the positive investor sentiment in this space continues to drive demand for biopharma offerings and funding, as the return on investment tends to be significantly more impressive than in other industries.



Early-stage investment becomes more attractive

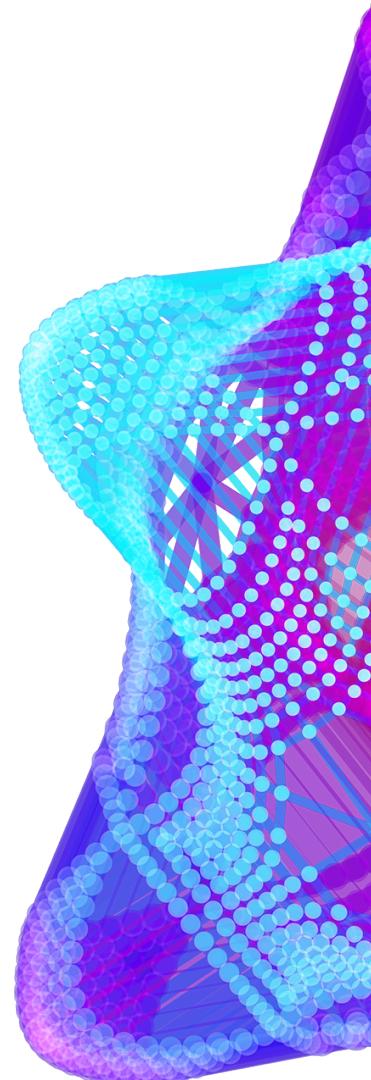
Segota expects that the sector will see "more established companies moving to acquire smaller biotechs, even those still in the pre-finance or pre-profit stages." Segota anticipates that the biotech and pharma sector will continue to be a capital intensive area, where there will always be a need to conduct R&D in new areas.

This is in line with the observation of increasingly earlier VC-entry, where investors target companies in early or pre-R&D stages, in order to avoid the higher costs of acquiring a late stage asset. An earlier entry translates to a potentially richer exits down the road.

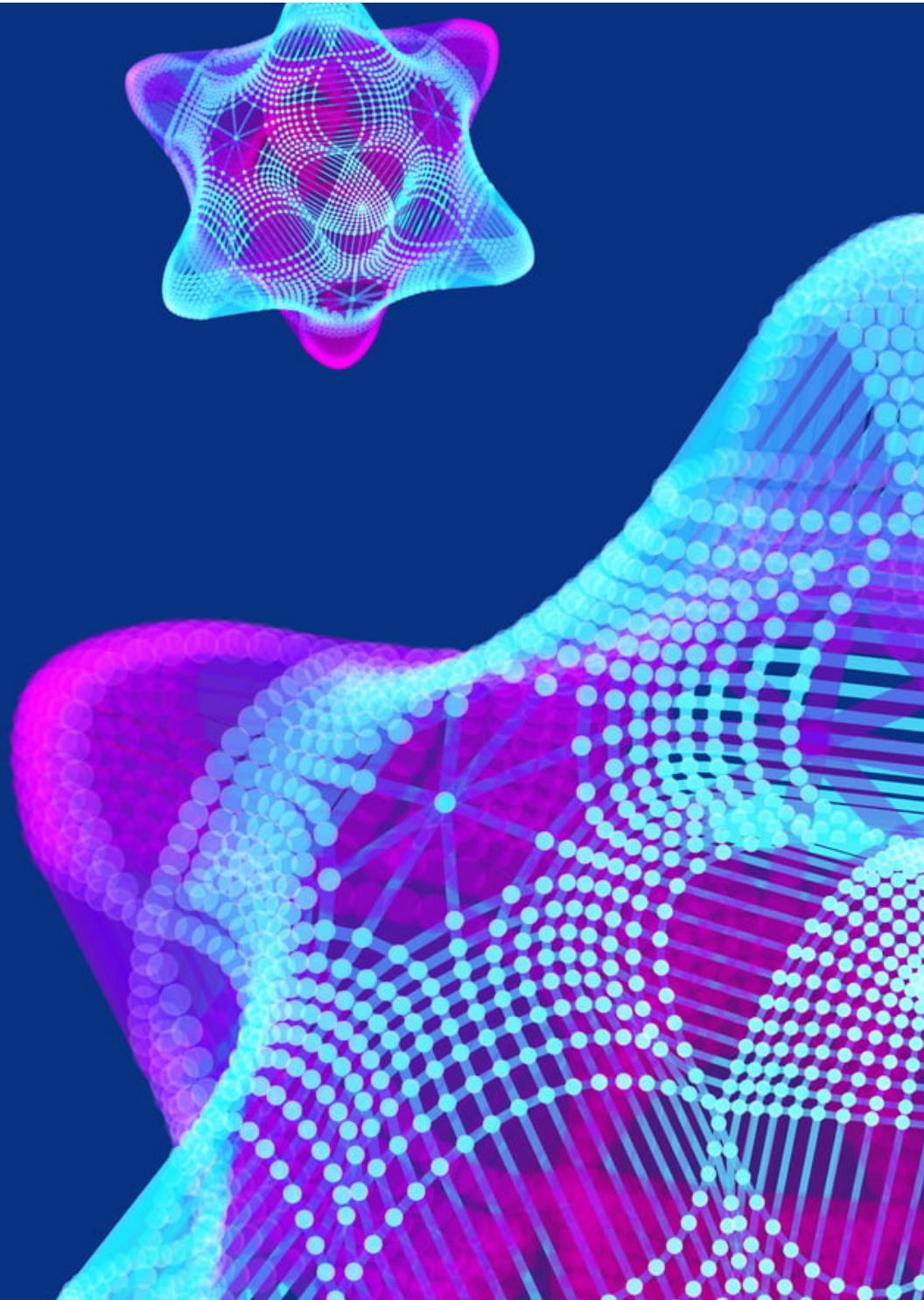
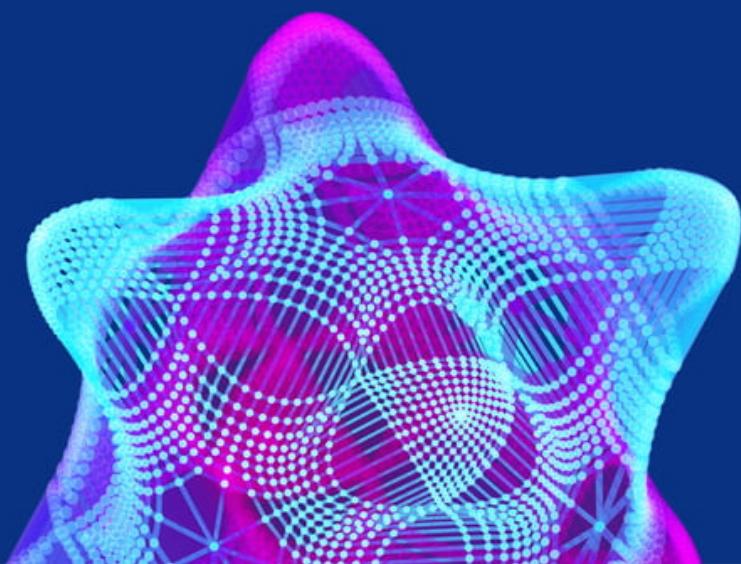
As biopharma companies battle investment headwinds and rising costs of drug and therapy development, the shift towards earlier stage deals has already begun in terms of licensing, collaboration and joint ventures.

Oren Livne, Corporate & Securities and Life Sciences Partner at Baker McKenzie, New York/Princeton, notes that the sector will "see continued deal activity in the cell and gene therapy space as larger companies seek to bolster their capabilities in this area. Given the platform nature of these technologies, this will likely take the form of field, indication or target-specific license and collaboration agreements, as well as M&A, and require significant capital raising for development activities."

Additionally, innovation within the sector also remains a key factor in the market. Pressure on pharma to attain high growth margins and to manage patent expiration means that pharma has to fill gaps by acquiring innovative technologies.



Case Studies



Galapagos NV

Deal Value: USD 5.1 billion

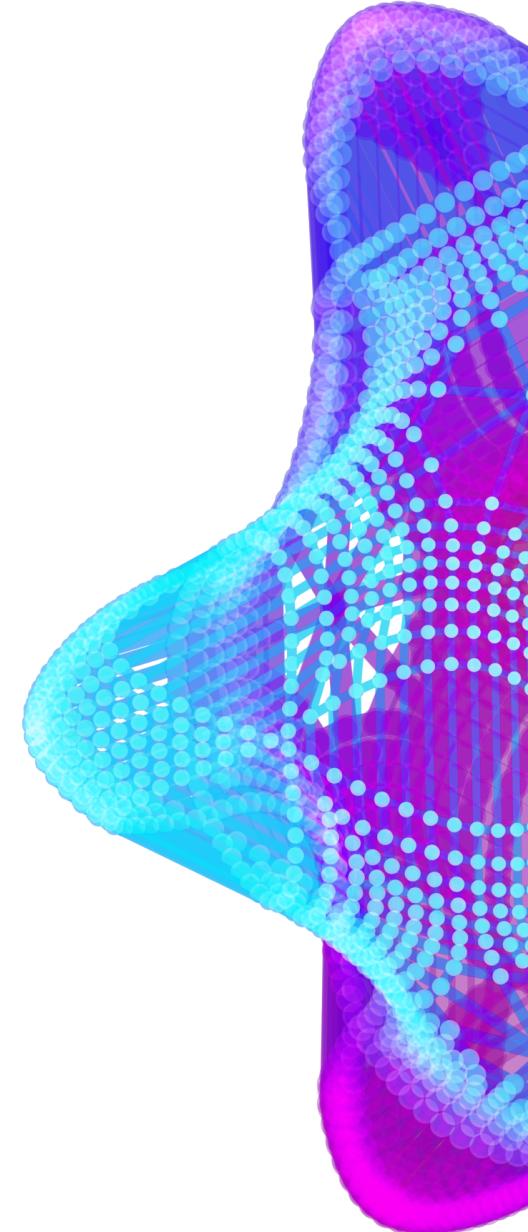
Jurisdiction: EMEA

Baker McKenzie acted as lead counsel to Galapagos NV on its USD 5.1 billion ten-year global R&D collaboration with Gilead Sciences Inc. This deal gives Gilead an exclusive license and option to develop and commercialize Galapagos' current and future programs beyond Europe.

Gilead Sciences Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. In 2019, it completed an equity deal with Galapagos NV, a Belgian company that discovers and develops small molecule medicines with novel modes of action. It is known as a pioneering force in the development of target and drug discovery platforms.

Deal Highlights:

- The agreement gives Gilead access to Galapagos' portfolio of six drugs currently in clinical trials, more than 20 preclinical programs and a proven drug discovery platform.
- Galapagos received an upfront payment of USD 3.95 billion to accelerate its R&D programs.
- In addition, Galapagos issued new shares at a premium totalling USD 1.1 billion, taking Gilead's shareholding from 12.3% to 22%, with two warrants allowing it to increase its shareholding to up to 29.9%.



Teva Pharmaceuticals

Deal Value: USD 2.1 billion

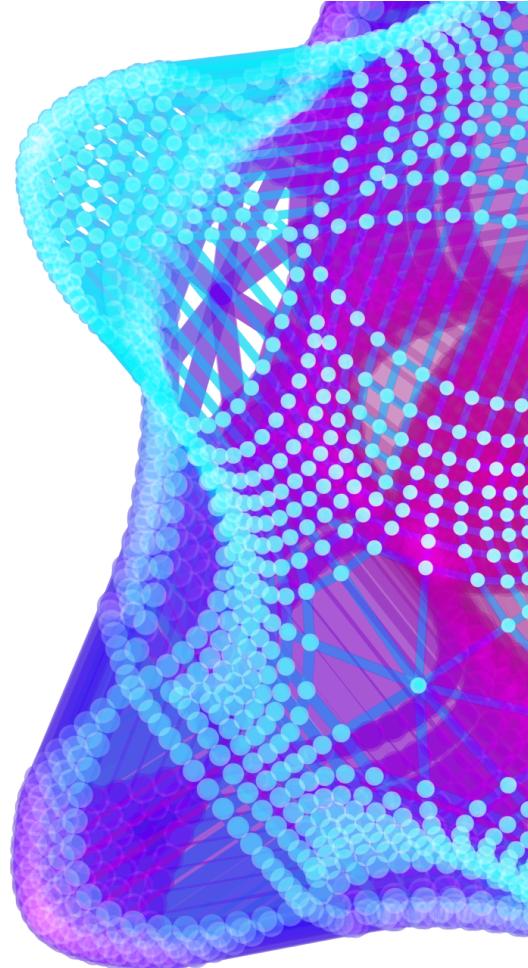
Jurisdiction: North America/EMEA

Baker McKenzie advised the syndicate of 14 initial purchasers on the USD 2.1 billion dual-tranche high-yield bond offering by certain subsidiaries of Teva Pharmaceuticals Industries Limited.

Teva Pharmaceuticals is a global leader in the pharma industry — developing, producing and marketing both generic drugs and specialized pharmaceuticals. Around 200 million people a day use a Teva-produced medicine.

Deal Highlights:

- The offering comprised of a USD 1 billion 7.1% five-year tranche and a EUR 1 billion 6% five-year tranche.
- Concurrently with the bond offering, Teva ran a successful three-tiered priority-acceptance tender offer to purchase up to USD 1.5 billion of certain of its other outstanding bonds.
- Also in 2019, Baker McKenzie advised Teva's 14 member bank syndicate in connection with a new USD 2.3 billion credit facility for Teva and certain of its subsidiaries.



Canntrust

Deal Value: USD 200 million
Jurisdiction: North America

Baker McKenzie acted as Canadian counsel to a syndicate of US and Canadian underwriters on the cross-border public offering of CannTrust. CannTrust is a publicly listed company floating on both Toronto Stock Exchange (TSX) and the NYSE, and develops, produces, and is a fully licensed and regulated provider of medicinal cannabis.

Deal Highlights:

- The offering was made in accordance with the Multijurisdictional Disclosure System established between Canada and the US.
- Canntrust intends to use the net proceeds for general corporate purposes, including cultivation and facility expansion, expanded outdoor growing, international expansion, enhanced extraction capacity, upgrades for GMP Certification and biosynthesis development.
- This syndicate was led by Bank of America Merrill Lynch, Credit Suisse and RBC Capital Markets.

3SBio Inc.

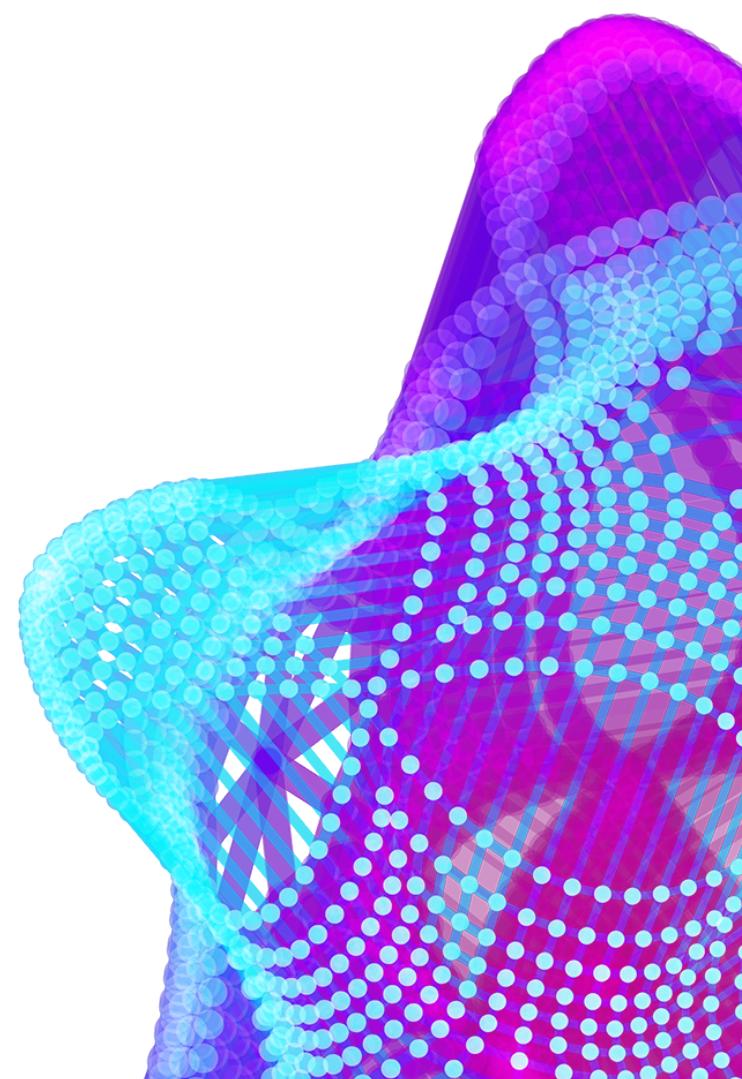
Deal Value: EUR 300 million
Jurisdiction: Asia Pacific

Baker McKenzie advised 3SBio Inc. as to Hong Kong and US law regarding its issuance of EUR 300 million convertible bonds.

3SBio Inc. is a leading company in China's rapidly growing biopharma industry, focused on mammalian cell-based biopharmaceuticals in the biotechnology industry. 3SBio Inc. also develops, manufactures and markets biopharmaceutical products globally.

Deal Highlights:

- EUR 300 million zero coupon convertible bonds.
- Listed on the Hong Kong Stock Exchange.
- 3SBio Inc. used the funds raised from the offshore Euro-denominated bonds to optimize their liquidity, fund their business expansion plans, reduce financial costings and raise further working capital.



Novaliq GmbH

Deal value: USD 165 million

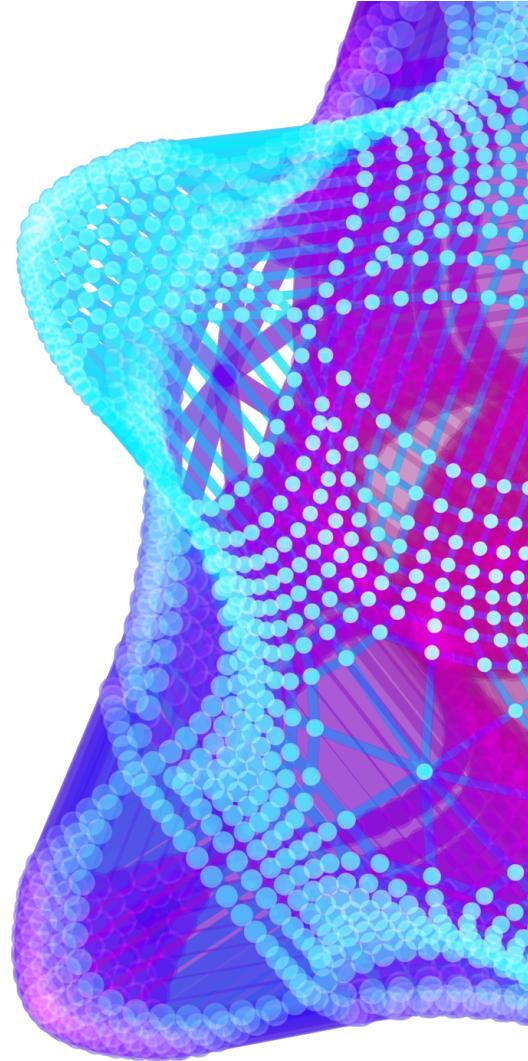
Jurisdiction: EMEA/Asia Pacific

Baker McKenzie acted as lead counsel to Novaliq on all aspects of the licensing agreement between Novaliq and Jiangsu Hengrui Medicine Co., Ltd. Novaliq and Jiangsu closed an exclusive license agreement to develop, manufacture and commercialize the innovative, water-free drugs NOV03 and CyclASol® for the treatment of dry eye disease in China.

Novaliq is a German pharmaceutical company focusing on ocular therapeutics. Jiangsu is a leading biopharmaceutical company based in China and currently has more than 140 clinical trials ongoing worldwide, with an in-house sales force covering more than 18,000 hospitals in China.

Deal Highlights

- Under the terms of the agreement, Novaliq is eligible to receive an upfront payment of up to USD 9 million and up to USD 156 million in milestone payments linked to pre-defined development, regulatory and commercialization objectives.
- In addition, Jiangsu Hengrui Medicine will be obligated to pay Novaliq tiered percentage royalties on net sales of NOV03 and CyclASol® in China. Thus, Jiangsu Hengrui Medicine secures exclusive rights to develop, manufacture, and commercialize both drugs in China.
- Jiangsu Hengrui Medicine will be responsible for all development, regulatory and commercialization activities and related expenses in the territory.



Key Contacts and Methodology



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Methodology

- All data in this report is taken from Refinitiv or Pitchbook, correct as of 23 December 2019, unless otherwise specified.
- All values are rounded to the nearest USD billion or percentage point.
- Commentary for this report was gathered from Baker McKenzie partners and expert insights from external specialists and professionals.

Leading and closing three deals a day

Transactional Powerhouse

We provide commercially-focused, end to end legal advice to maximize deal certainty and secure the intended value of transactions. Our 2,500 lawyers combine money market sophistication with local market excellence. We lead on major transactions with expertise spanning banking and finance, capital markets, corporate finance, funds, M&A, private equity and projects. The combination of deep sector expertise, and our ability to work seamlessly across each of the countries where we operate, means we add unique value in shaping, negotiating and closing the deal.