efpia European Federation of Pharmaceutical Industries and Associations

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An Agenda for Action: Expanding Funding Options for Small and Medium-Sized Pharma companies in Europe

To strengthen the European biopharmaceutical industry, it is essential to bring attention to the network of small and medium-sized enterprises (SMEs), which complement the innovation and growth of large pharmaceutical players and can be supported by their financial and commercial strength. SMEs are vital to driving innovation and filling in the innovation gap in areas where larger companies may not focus. However, when juxtaposed to the US, the European ecosystem faces distinct issues when it comes to funding SMEs, namely: **liquidity challenges** and **challenges in the investment decision-making process**.

The availability of capital in Europe is one of the drivers of the investment challenges, spanning from limited private funding levels such as through venture capital firms (VCs) in earlier stages of development to access to public funding through stock market listing in later stages. Despite signs of expansion in VC activity, the dearth and risk aversity of large institutional investors, such as pension funds, contributes to a liquidity crunch. These institutions are major sources of capital for venture investments and biotech in the US but play a less significant role in Europe due to historical risk aversion, limited sector-specific expertise in analysts and investors, and a perception that venture capital yields lower returns. As a result, for SMEs the capital of large pension funds is inaccessible. Additionally, the Euronext as the principal public market does not offer the same benefits and incentives as the Nasdaq in the US, which means that European SMEs have fewer avenues to access large sums of capital. To address the highlighted challenges, we propose three potential solutions:

Increasing private investor liquidity for higher risk investments - Pension funds reform: To enhance the prominence of institutional investors such as pension funds, pan-EU and country-specific regulatory bodies should revise their frameworks to increase flexibility of pension funds in favour of VC and SME investment. This would increase the total amount of available funds for SMEs, thereby bolstering sector growth, as well as potentially offer higher returns for pension funds as they invest into high-risk high-reward assets.

Understanding intangible factors impacting investments – A cost of raising capital index: The aim would be to construct an index which would track the opportunity cost of securing funding on the Euronext vs the Nasdaq to emphasise the different outcomes in valuations and their drivers. While existing research captures the difference in quantitative costs between the two stock exchanges, the main barriers to securing a higher valuation are intangible factors such as investor and analyst expertise in biopharma, and risk aversion of investors. In the US (and on Nasdaq), such intangible factors can drive the valuation of companies, while within the European ecosystem these factors are lacking.

Increasing private investor funding by pooling resources and sharing risks – Establishing a guarantee fund: To ensure there is a large and sustainable life science investment pool, a €1 billion guarantee fund for limited partners could be set up.[1] It would allow to soften hurdles rates and minimise losses through risk sharing between partners. A lower hurdles rate would grant a larger sharing pool of returns on investments, and therefore would motivate investors to underwrite fund shares for receiving a larger portion of the interest.

[1] EFPIA. EFPIA SMEs' position paper on innovative funding for biopharmaceutical SMEs. Available at: https://www.efpia.eu/media/580572/efpia-smes-position-paper-on-innovative-funding-for-biopharmaceutical-smes.pdf [Accessed 2024]

Unlocking funding potential of institutional investors

Executive summary

Small- and medium- enterprises (SMEs) often face the issue of a lack of funding and have limited access to institutions, public, and private investors which would be able to remedy this challenge. Biopharma SMEs in Europe are significantly impacted as they must thrive in an investment ecosystem in which the key stakeholders are risk-averse and are cautious of investing into biopharma until there are late-stage signs of success. Consequently, the biotech and biopharma companies which often drive innovation in their industry are left without support, which diminishes their potential for success.

Pension funds are a key funding flow for biotech that is not readily available in Europe but is prominent in markets where SMEs have historically thrived. Due to the conservative nature of regulations governing pension providers across Member States, pension funds have limited ability to invest into biopharma while it is classified as private equity. While such restrictions have been put in place to safeguard the beneficiaries from the consequences of risk-favouring investment, they also limit the fund flows going into the economy and to the beneficiaries themselves.

To mitigate the unfavourable investment environment for biopharma SMEs, key industry players, advocacy groups, and trade organisations should collaborate to discuss the potential of pension fund reform across EU Member States. Such dialogue has been successful in European countries such as Switzerland and the UK.

There are limited funding inflows for biopharma SMEs in Europe

One of the most prominent and widely recognized barriers for growth of SMEs in the biopharma sector is access to funding to support research and development (R&D) activities. There are well documented weaknesses in the supply of capital by Venture Capital firms (VCs) in Europe and many policy proposals on how to improve this situation. Less attention has been given the unlocking the potential of pension funds.[1]

As of 2022, the total assets of **European pension funds amounted to €3.136 trillion**.[2] However, only a small percentage of the total assets is invested into growing companies or VC by EU member state pension providers. In 2022, o**nly 0.01% of total assets under management (AUM) of European pension funds was invested into VC**. This percentage is even smaller for direct investment into SMEs.[3]

The underlying issue stems from diversification rules limiting the ability of a pension fund to invest into certain assets. Pension funds in the EU are subject to regulatory frameworks that vary across member states. Simultaneously, the EU has guidelines, such as the Institutions for Occupational Retirement Provision (IORP) Directive, which set out principles for the regulation of occupational pension funds.[4] One of the listed guidelines of the IORP Directive is that investments in all alternative asset classes may not exceed 30% of the total assets of the IORP. This means that pension providers across member states are encouraged to not invest a high percentage of their funds into VC, which in turn limits the funds that VC firms are able to output into SMEs. In addition to this, the IORP Directive encourages providers to limit their investments into high-risk companies, which directly affects the funding SMEs could potentially receive from pension funds.[5]

Across the EU, there are different rules regarding the total percentage of assets which can be invested into from each class. A direct investment into an SME would likely qualify as an investment into a specific type of private equity while an indirect investment into SMEs through VC firms would likely be considered as an alternative investment. Member States have restrictions on the amount which can be invested into private equity. For instance, Germany has several directives and guidelines governing the activities of local pension funds, which limit the amount they are able to invest into private equity, alternative assets, and high-risk companies. Pensionskassen (occupational pension providers) are able to invest under 15% into private equity, i.e., directly into SMEs, and only 7.5% into alternative assets, i.e., indirectly into SMEs through VC firms.[6] As a result, German pension funds are considered some of the most conservative funds across EU member states. Consequently, most EU pension funds' investments are directed towards debt securities and investment funds i.e., high-yielding yet safe options.[7,8,9]

Pension funds: How they are mobilised in the US

US pension funds, since their reform in 1979, have been investing directly, or indirectly through VC firms, into local growing startups including those involved in biopharma. Essentially, allowing their capital to be invested into riskier but more ambitious assets. Prior to this reform, the US was on par with other developed countries in terms of emergence of public companies, however, after its launch, the numbers began to quickly increase.

According to recent research, pension funds in the US occupy over 25% of firm types investing in early-stage funds in North America. By investing into VCs, pension funds create a larger pool of capital for biotechs to access.

The support of such large institutional investors has allowed US SMEs, particularly in the biotech and biopharma sectors, to flourish and grow, without having to be acquired by large pharma companies.

The lack of support from institutional and individual private investors has significant implications on innovation progress and growth, creating what is often referred to as a 'Death Valley' for biopharma SMEs in Europe. Recent data suggests only a quarter of new biotechs instated between 2018 and 2022 originated in Europe; this is rather low when compared to the 65% of US biotechs. [10] Alternatively, a significant number of emerging biotechs that continue development, are acquired or partner with more mature companies before they reach the stage of commercialisation. However, the latter option is becoming less favourable for mature companies, due to geopolitical pressures, inflation, and the cost of capital.[11]

At the same time, these policies and guidelines are negatively impacting the EU general population, as according to recent studies, member states are facing an ageing population. An average person will live longer and therefore will be required to rely on their pension for more years. This poses a concern for pension funds as they will need to increase the returns of their assets to support their beneficiaries.

To develop solutions, it is useful to look in more detail at the specific and strict rules EU Member States impose on pension funds, specifically, restrictions on the nature and volume of investments pension funds can make into different asset types.

Policy change is possible and Europe needs to catch-up

SMEs in Europe are lagging behind their respective US and China counterparts, and those which were able to succeed in clinical trials were often acquired by more mature pharmaceutical companies. To support the biopharma sector in the EU and ensure its future growth, pension funds should adopt more flexible requirements and allow for the diversification of their portfolios. This would offer multifaceted benefits for a range of involved stakeholders. Beneficiaries will be able to benefit from higher returns while SMEs and the EU biopharma landscape will enjoy greater support from institutions and opportunities for growth without overreliance on support from larger pharmaceutical companies. Therefore, pension fund reform which would allow to invest into riskier but potentially more profitable assets would help member states to meet the changing demands of their populations.

For pension funds to support SMEs either through direct or indirect investment discussions would need to be held both on the wider EU level and on a Member State level. For pan-EU guidance, the Members of the Parliament (MEPs), the Economic Policy Committee, and the European Insurance and Occupational Pensions Authority could incentivise country-specific occupational pension providers to invest into biopharma SMEs to bolster the sector's growth. However, this should be framed as guidance as the EU Committee has limited ability to impact the national frameworks of Member States.[12]

As most regulatory restrictions are implemented on a country level, the mechanism to increase flexibility in favour of VC and SME investment would be more direct. Each Member State has specific regulations enforced which may differ by pension provider, therefore, to direct investment into growing companies there should be a push from EU member state governments to support this. There are several examples of pension funds more actively participating in SME funding. They showcase that pension fund reform is possible and can help support growing SMEs either through direct investment channels or through secondary ones such as specialised VC firms.

Country	**Developments**
UK	In 2023, in the UK, "The Mansion House Compact" was launched, aiming to boost pensions and increase investment into growing British businesses.[13] Nine pension providers agreed to allocate a minimum 5% to unlisted equities through defined contribution pension funds, and other sources of long-term savings, by 2030. This may unlock an additional £75 billion for high growth businesses such as life sciences and biotech. However, this change was met with significant pushback from UK pension funds as they expressed concerns over taking on the potential risk of investing into private equity. "The Mansion House Compact" was the result of significant efforts by the UK Bioindustry Association which began in 2017. This included direct conversations with pension providers as well as with the UK government to illuminate the challenges faced by the British biopharma sector. Consequently, through joint industry advocacy a new funding flow will open for British SMEs.
	In 2014, Henri Meier, the CFO of the Roche Group, began advocating for pension funds to collectively invest into high growth businesses.[14] He was dissatisfied with the fact that Swiss pension providers allocated less than 6% of their assets to alternative investments, such as VC. To address this, he created a fund of funds which pools investments into specialised VC firms, from

Switzerland	institutions such as pension funds.[15] This is a vehicle for pension funds to support growing companies, such as biopharma SMEs while reducing their investment risk. The Fund's success was driven by Henri Meier's dedicated advocacy and commitment to mobilizing collective savings for the greater good of the economy and growing companies.
Sweden	Similarly, Sweden has formed a relationship between pension funds and VCs through pension fund reform. Specifically, they have eased restrictions, increasing the allowance for alternative investments (such as into VCs) from 5% to 40% in 2018. To aid SMEs directly, Sweden has permitted a state-owned pension fund AP6 to invest into unlisted companies. This has helped bolster Sweden's VC ecosystem and brought about significant returns for AP6 – 21% from 2013 to 2022.[16]
France	Additionally, there is evidence of other stakeholders initiating the dialogue on pension reform. France Digitale – an organisation supporting innovative companies in France – has launched an analysis that advocates for an overhaul of the European innovation funding policy, particularly by generating incentives for pension funds to invest in European VCs and SMEs.[17]

The need for coordinated action at European level

Addressing the funding gap for biotech innovation in Europe has been in increasing focus by policymakers. A number of **recent policy initiatives and proposals are welcome developments,** including: the Commission targeted actions to boost biotechnology and biomanufacturing in the EU[18], the ECB statement advocating for Capital Markets Union[19], the open letter by Enrico Letta, emphasizing the importance of strategically leveraging both private and public resources effectively[20], and the Draghi report for a sustainable prosperity and competitiveness[21]. Additionally, this remains a priority for the Council new European competitiveness deal, which underlined that access to capital, including venture and growth capital, should also be facilitated and simplified, especially for SMEs and start-ups.[22]

To support these stated objectives and policy developments, the **EU SME sector in biopharma has proposed a set of concrete solutions** including: 1) Pension fund reform to increase liquidity of private investors for higher risk investments, 2) Decreasing the cost of raising capital in stock markets by addressing underlying factors that impact investment valuations and 3) Establishing a guarantee fund for investors to pool resources and share risks.

Building on the recognition of the issue and momentum in policy agendas, a shift is required in the magnitude, focus and commitment to implement required reforms and **carry these out during the next mandate of the European Commission.** This relies on effective multi-stakeholder collaboration including the EU SME sector in biopharma.

Tracking the Cost of Raising Capital for Small and Medium Size Pharmaceutical Companies in Europe

Executive summary

Small and medium enterprises (SMEs) have been at the forefront of innovation in the biopharma industry, delivering new solutions with impact on patients, their families, and more broadly healthcare systems. Such innovation requires considerable investment and support, which is to a significant extent sourced from private funding to support clinical development. There are many different ways of raising private capital for drug development including attracting venture capital or private equity investment, out-licensing drug candidates, bank loans or listing on the stock markets through an Initial Public Offering (IPO). European SMEs face a challenging decision of which stock exchange to float on as the US has historically had a greater level of IPO activity and created more success stories building investor confidence as compared to Europe which has a fragmented market and underperforms in terms of valuations and degree of activity. Indeed, in the period 2015-2020, Euronext hosted 20 flotations as compared to Nasdaq's 261 flotations of research stage biotech companies.[23] This difference in activity is affected by quantitative factors such as cost of listing and other associated fees, and intangible factors such as investor behaviour and analyst expertise. The European Euronext is much smaller than its American counterpart and the investors, historically, have been more risk averse, resulting in SMEs receiving lower than expected valuations and therefore have limited ability to secure capital.[24] Nasdaq on the other hand offers unrivalled access to investment capital, but there is evidence that US investors tend to favour US-based biopharma firms over European competitors, which similarly leads to underwhelming valuations.

To better understand the factors influencing the ability of European SMEs to secure investments, both intangible and quantitative costs should be tracked and evaluated. This analysis will inform relevant stakeholders and may help European SMEs choose the stock exchange that leads to a higher valuation and better growth opportunities.

SMEs face challenges when trying to secure capital on stock exchanges such as the Euronext and the Nasdaq

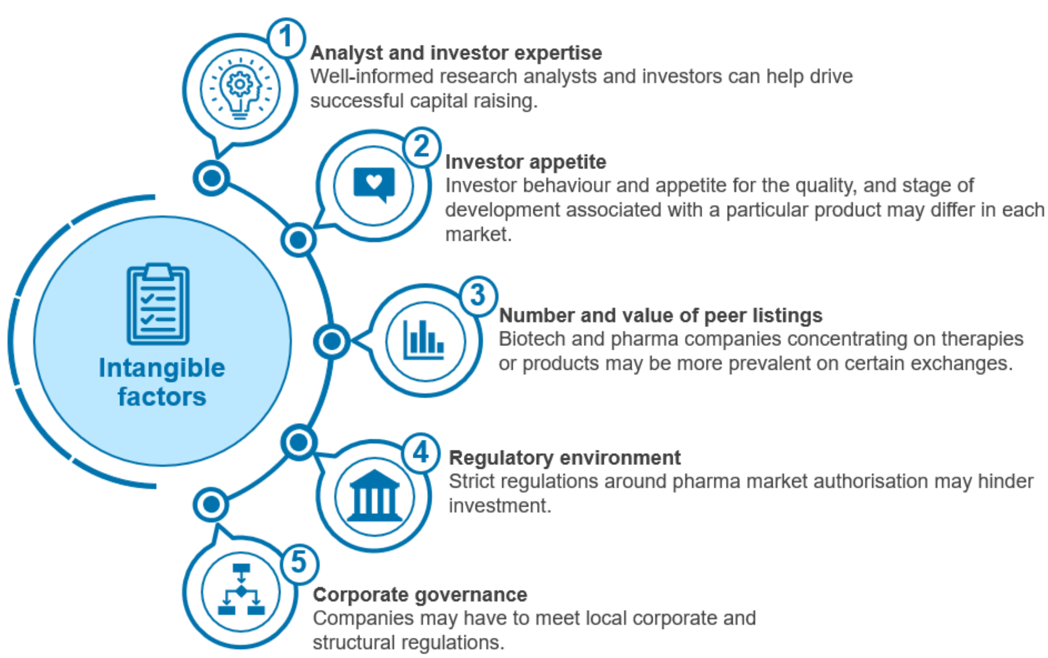
Medicine development requires significant funding and recent cost estimates for developing a new drug range from $314 million to $2.8 billion (but these can go up to $6billion for certain therapeutic classes such as Alzheimer's disease).[25] Therefore, raising capital through private and public funding is a critical enabler of the innovation process.

European SMEs are faced with a unique issue of incurring a high cost of raising capital both on the Euronext and the Nasdaq. While Euronext was established as an attempt to form a pan-EU centralised trading platform, there are still barriers in place which slow down cross-Member State investments. According to interviews conducted with financial experts, certain Member States prioritise investment into domestic SMEs rather looking outward into other EU countries.[26] Therefore, the limited popularity of the Euronext, is acting as a barrier for SMEs looking to secure capital. This significantly limits their potential and diminishes their likelihood of becoming strong players on the international market.

To avoid the limitations and barriers of the European investment ecosystem, many SMEs choose to IPO and list on the US Nasdaq as there is a higher probability to secure capital and move further along the SME development path. The reported **market cap of Nasdaq in August 2023 was $21.7 trillion**, while that of the **Euronext is $7.2 trillion i.e. 3 times lower**.[27] The US investment ecosystem has historically been more amiable towards SMEs and biopharma due to intangible factors such as investors sector expertise and risk appetite.[28] However, SMEs which have chosen to list on the Nasdaq have encountered another set of problems, associated with being non-domestic companies i.e. they possess a different corporate structure and are affected by the European regulatory framework for medicines. Apart from having to restructure the company to fit the US-specific requirements, SMEs are likely to receive lower valuations compared to their US-based counterparts, based on investor confidence.

The key point of performing an IPO is the ability to raise capital by tapping into public investment, in order to support operations, fund research, or pay off any outstanding debt.[29] Regardless of the clinical stage of the SME's product, this liquidity is paramount for their future development. However, the amount of capital raised relies on several factors outside of the SME's influence. There are two main categories of costs affecting the success of an IPO: direct or tangible costs and indirect or intangible costs. Direct tangible costs include listing fees, restructuring costs, and other administrative considerations. Such costs are easy to calculate and track between stock exchanges to demonstrate where listing is costlier. However, according to interviews with SMEs and financial advisers, quantitative costs are not key in highlighting the difference in raising capital on the Euronext vs the Nasdaq.[30] Instead, intangible factors whose absence can be reformulated into costs are the main determinators of successfully securing liquidity. Below are some examples of intangible factors which may differentiate listing costs and success on various stock exchanges.

Figure 1: Intangible costs that impact the success of an IPO



Source: CRA analysis

The direct tangible costs of listing on the Euronext can be comparable or lower to Nasdaq, as actions such as corporate governance restructuring is not required, however, intangible costs are much higher.[31] Firstly, the NASDAQ and the Euronext vastly differ in size. Therefore, by floating on the Euronext SMEs may be foregoing a larger pool of capital, hence limiting their funding opportunities. Secondly, the US is associated with a stronger investor environment: investors are likely to have a stronger risk appetite, looking to secure higher returns. This is reinforced by analyst expertise, large investment banks such as Goldman Sachs, J.P. Morgan and others have a stronger presence in their home market and have in depth knowledge into various industries, such as biopharma and biotech. The combination of analyst expertise and investor appetite leads to a potentially higher valuation of the listed company as the former are able to better understand the value of the SME and its probability of success in the industry. However, it is important to note that while European SMEs would be likely to secure a higher valuation on the Nasdaq than on the Euronext, that valuation can potentially be lower than that of a similarly sized company with a similar

Comparison of IPO of EU-based vs US-based company on Nasdaq

CymaBay is a US-based company developing a drug for primary biliary cholangitis (PBC). It has a small number of employees and focuses on clinical development. A similar company exists in France, which was founded at a similar time and is currently focusing on the same disease. Both companies are now listed on the Nasdaq however, as evidence and interviews show, they have been regarded differently by US investors. In June 2023, Genfit release positive phase III data in PBC for their drug Elafibranor. At the same time, CymaBay release a communication at the European Association for the Study of the Liver conference, based on a previous post hoc analysis highlighting encouraging effects.[1] While no new data was provided by CymaBay, US analysts still saw this communication as an advantage and demonstrated more confidence in CymaBay as opposed to Genfit.

product from the US.

Figure 2: Case study – comparison of IPO of EU-based vs US-based company on Nasdaq[32,33]

CYMABAY THERAPEUTICS vs GENFIT TOWARDS BETTER MEDICINE

	US company	EU company
Listed on	NASDAQ	NASDAQ
Therapeutic area	Primary biliary cholangitis	
Product	Seladelpar	Elafibranor
Market cap	USD 1.13B	USD 192.228M

Source: CRA analysis

The case study above highlights that even if an SME chooses to list on the Nasdaq, it will be faced with additional challenges due to the impacts of intangible costs, specifically analyst and investor confidence. US-based SMEs with similar products and of similar size may be able to secure a higher valuation on the Nasdaq due to their structure and origin, as such factors instil confidence in analysts and investors, who are more certain in the success of US SMEs. This creates a loop: EU SMEs struggle to receive funding on the Euronext due to the limited investment environment, they leave to the Nasdaq, however US investors are uncertain of whether a European SME can be highly successful due to the limited nature of the European investment environment. Moreover, the uncertainty of both US and European investors is reinforced by the restrictive regulatory environment in Europe, where manufacturers face delays in market access, lower pricing of products, and stronger restrictions on the addressable patient populations.

All of these factors affect the choice of stock market for SMEs, often driving the latter to list on the Nasdaq. According to data from the period 2015-2020, **Euronext has hosted 20 flotations of research-stage drug developers**, compared to **Nasdaq's 261**. Of these 261, **17 were Europe-based companies** that chose to list in the US instead.[23] The **number of domestic companies listing on the Euronext has decreased by 15%** since 2009, with **no biopharma IPOs recorded between February 2022 and July 2023**.[34] But as mentioned above, when choosing to list on the Nasdaq, European SMEs are still failing to secure as large of a valuation as US domestic companies. Moreover, they exit their domestic market, limiting their proximity and commercialisation success in the EU, which leads to further restrictions.

There is a need to improve the awareness and tracking of the real cost of raising capital for European biopharma SMEs

In order to support European SMEs on their growth path towards product development and commercialisation, the European investment environment must be adapted to be more amiable towards high-risk innovative companies. Centralised trading platforms such as the Euronext need to be enhanced and used more widely to attract more domestic and international investors. However, the investment environment is governed by exogenous factors as well as various EU-wide policies. Although the barriers to private funding for biotechs in Europe is well documented, there is limited analysis and data of the real cost of raising capital on the Euronext compared to Nasdaq, which should be informed by both tangible and intangible costs. Therefore, to facilitate the transformation of the European investment environment, more attention needs to be brought to how these costs can be measured, tracked over time and addressed.

One way to showcase the difficulties SMEs face is to collect and analyse evidence of companies encountering various costs when listing on the Euronext and the Nasdaq. As mentioned previously, direct and tangible costs are easy to track and express as they are readily available. These costs are well known; however, they are not the main determinant of the cost of raising capital or probability of success. Nevertheless, it is valuable to provide the evidence and comparison of the costs to support the argument that they are not the main driver of cost of raising capital. According to SME interviews, the associated monetary costs of flotation on either of the two exchanges is largely the same with some small differences.

Intangible costs, on the other hand, will be more difficult to calculate, however they are paramount to explain the challenges of SMEs. In addition to quantitative estimations, intangible costs could be demonstrated through qualitative case studies, as outlined in the mentioned case study, broader statistics of SMEs successfully launching on the two stock exchanges and their evolution over the years. Qualitative case studies which compare similar companies from the US vs those from Europe, could explicitly control for the size of the company (ensuring it fits within the definition of an SME), the therapy area to which the company's product belongs to (to minimise any discrepancies between therapy areas), and the clinical development stage. This would allow to highlight the effects of intangible factors of the investment ecosystem.

A real cost of raising capital index can be constructed to fulfil two goals: inform decision-makers of the challenges SMEs face, and monitor any changes to the environment, both endogenous and exogenous. The index could track both tangible and intangible costs, demonstrating the significant impact of the latter on the success of SMEs. In addition to tracking the costs, the index of intangible costs could help stakeholders better understand the drivers behind them, and the potential ways of addressing or preventing their impact. Understanding exogenous factors driving market forces is increasingly important, especially as biotech IPO and investment activity is once again picking up, receiving share gains of up to 36%.[35]

Moreover, discussions can be held with key involved stakeholders such as SMEs with recent experience of flotation, Euronext representatives, and financial experts with biopharma expertise. These conversations can help bring attention to the problem and initiate dialogue between those involved.

Developing a real cost of raising capital index required a multi-stakeholder approach

Addressing the funding gap for biotech innovation in Europe has been in increasing focus by policymakers. A number of **recent policy initiatives and proposals are welcome developments,** including: the Commission targeted actions to boost biotechnology and biomanufacturing in the EU[36], the ECB statement advocating for Capital Markets Union[37], the open letter by Enrico Letta, emphasizing the importance of strategically leveraging both private and public resources effectively[38], and the Draghi report for a sustainable prosperity and competitiveness[39]. Additionally, this remains a priority for the Council new European competitiveness deal, which underlined that access to capital, including venture and growth capital, should also be facilitated and simplified, especially for SMEs and start-ups.[40]

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