White Paper

TRINITY

Spending Wisely in Europe

Successful Commercialization of Biopharmaceuticals in Europe Through Early Investment in Commercial Planning

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INTRODUCTION

By 2022 Europe is forecast to account for 20%[1] of a global US$1.2 trillion pharmaceutical market. For executives from emerging biopharmaceutical companies planning to develop and commercialize their assets in Europe, the views of biopharmaceutical investors are critical, as investors provide the necessary investments. Additionally, investors who have analyzed numerous biopharmaceutical companies will have valuable experience on what drives commercial success.

In this paper, we aim to understand the views of both investors and biopharmaceutical companies, specifically on the investments into, and timings of, pre-commercial activities. We surveyed 42 senior stakeholders in director-level roles or higher from both biopharmaceutical companies and investment firms, including private equity, venture capital, investment banking, and business development and licensing (BD&L).

[1] European Pharma Market Outlook to 2022, Evaluate Pharma, 2017

RESEARCH FINDINGS

EUROPE IS INCREASINGLY IMPORTANT TO BIOPHARMACEUTICAL INVESTORS AND EXECUTIVES

Two-thirds of investors see Europe as an important region for biopharmaceutical companies that should be considered individually as it is the second most important market behind the US for maximizing the uptake of each product. Both investors and biopharmaceutical executives also regard Europe as an even more important market then it was regarded 10 years ago.

When investors are probed, nine out of ten feel that they should not only consider the potential of a therapy in the US when making investment decisions but rather they should also focus on Europe. Biopharmaceutical executives not based in Europe often dismiss Europe as a market in which it is too challenging to achieve reimbursement at the same level as that in the US. Recent launches in rare and orphan diseases, however, have shown that European health technology assessment (HTA) agencies do recognize and acknowledge the benefits of novel therapies.

EUROPEAN COMMERCIAL PLANNING: A PREREQUISITE FOR COMMERCIAL SUCCESS

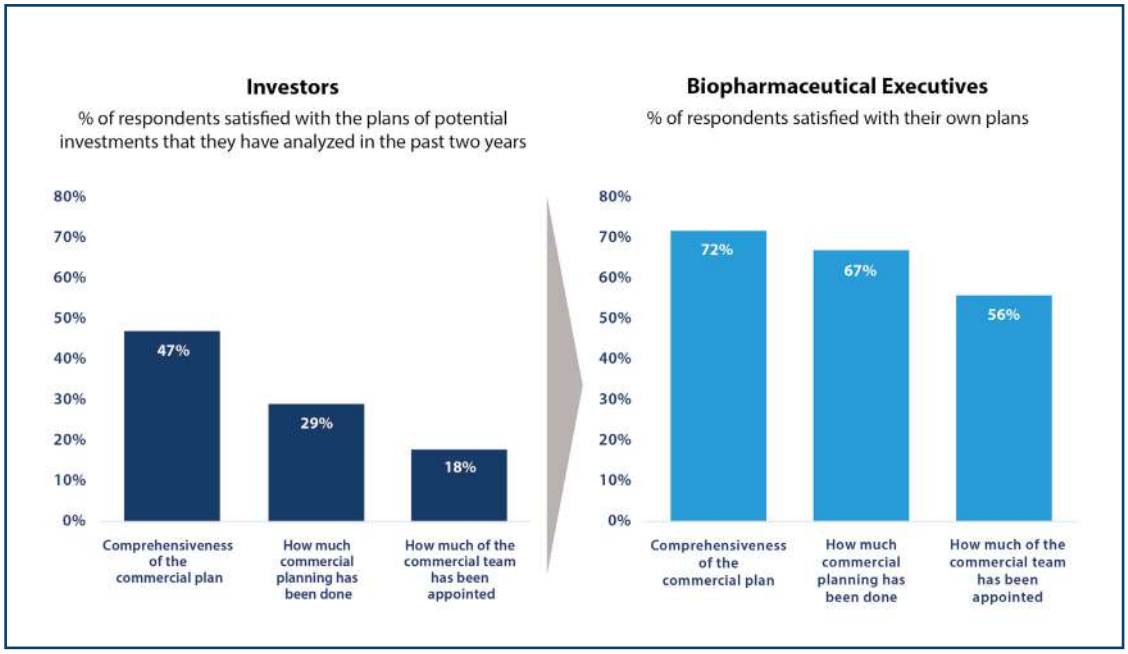
Three-quarters of investors stated that they would not invest in a company that does not demonstrate that they have an adequate understanding of the commercial environment. Over one-third of investors state that lack of commercial planning is one of the main reasons that they do not invest in a biopharmaceutical company. Additionally, a quarter of investors see the lack of commercial planning as one of the top two reasons for a prescription therapy to not meet commercial expectations. These results indicate that for investors, a robust and well-prepared commercial plan is a fundamental prerequisite for securing investment.

Concerningly, when investors were asked about companies that they have analyzed in the past two years, less than one-fifth said that they were satisfied with how much of the commercial team had been appointed considering the development stage of the company. Additionally, less than one-third were

satisfied with how much of the commercial planning had been done relative to the development stage of the company, and less than half were satisfied with the comprehensiveness of the commercial plans that companies had presented to them. Overall, ***investors are more likely to be dissatisfied than satisfied with the commercial plans of companies seeking investment.***

> Documents prepared by biopharmaceutical companies themselves are generally not directed towards what an investor would want to see.
>
> Europe-based Private Equity Investor

By contrast, we found that most biopharmaceutical executives are satisfied with the commercial plans that they have in place. Seven out of ten executives are satisfied with the comprehensiveness of their commercial plans and how much commercial planning has been done, and over half are satisfied with how much of their commercial team has been appointed. ***Clearly, there is a disconnect between investors' expectations and biopharmaceutical companies' views on the level of planning required.***

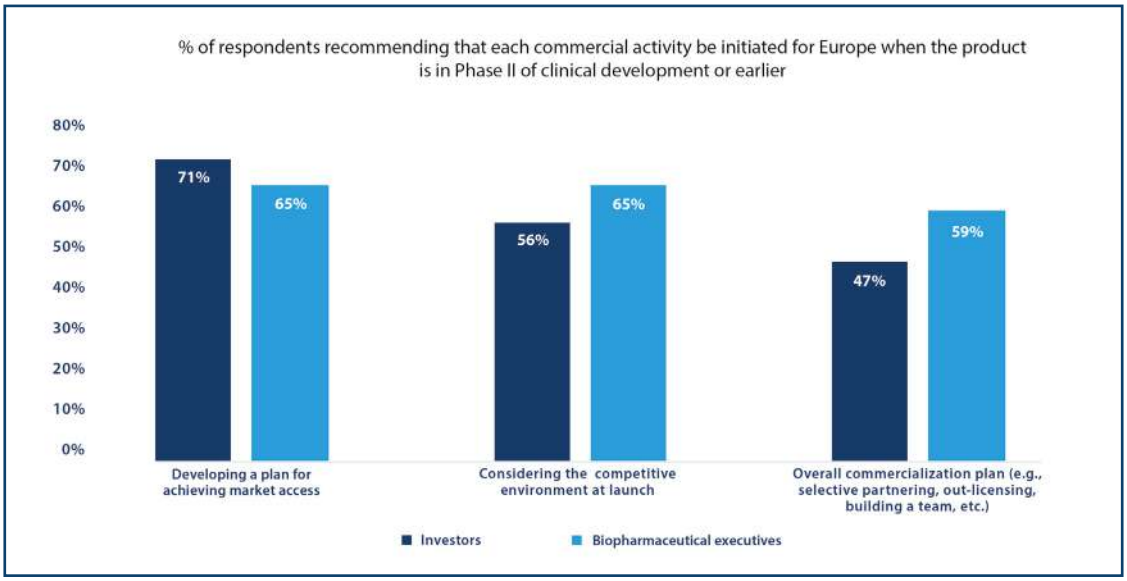


There are potentially many reasons for this disconnect, however, our study found that half of the biopharmaceutical executives actually want investors to provide more clarity on what they wish to see in the commercial plan. Overall, there is an opportunity to close the gap between investors' expectations and what biopharmaceutical companies have planned.

MARKET ACCESS, COMPETITION, AND COMMERCIALIZATION STRATEGY ARE KEY FOR COMMERCIAL SUCCESS

When probed on what aspects of commercial planning should be undertaken earliest in the development cycle, three activities were highlighted by investors and biopharmaceutical executives alike as needing to occur early. ***Over half of the respondents felt that there are three activities that should be initiated for Europe when the new product is in Phase II or earlier:***

1. Developing a plan for achieving market access
2. Considering the competitive environment at launch
3. Planning for commercializing the therapy (e.g., selective partnering, out-licensing or building a team, etc.)



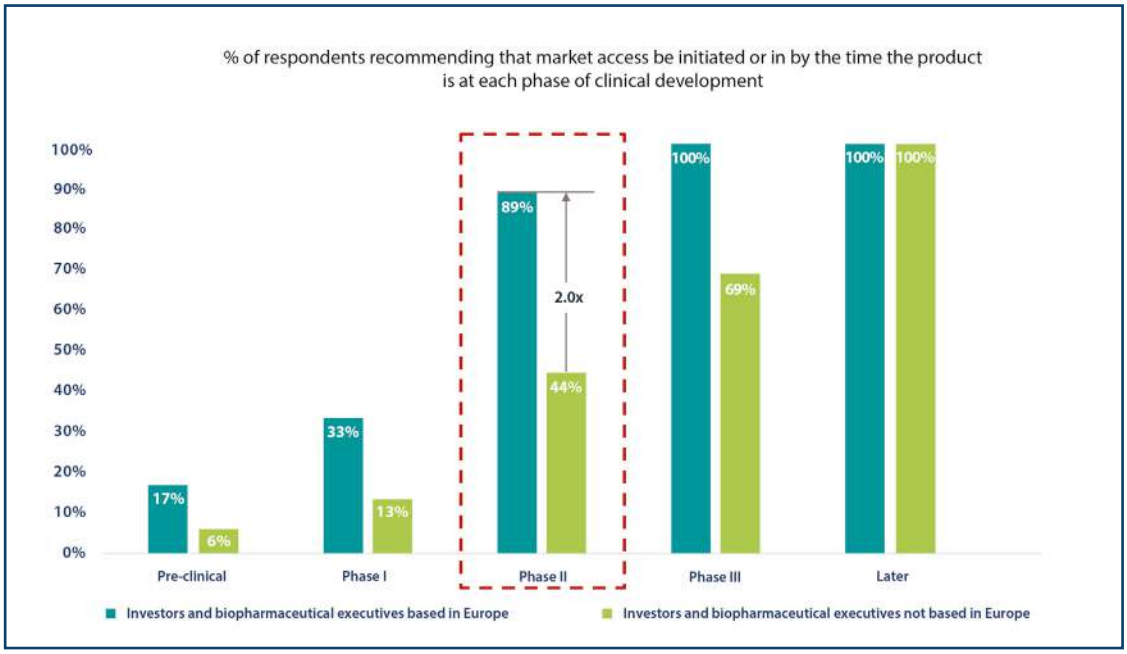
There is consensus that these three activities are the most critical and there is no other activity (e.g., brand planning, launch planning, hiring) that the majority of respondents recommended be initiated when the product is in Phase II or earlier. Certainly, the decision on the overall commercialization plan will impact all subsequent decisions at a later stage. Due care should be given specifically to partnering and out-licensing decisions that impact later decisions and have the potential to limit future options.

EUROPEAN MARKET ACCESS IS THE TOP PRIORITY

Planning to ensure that financial and other barriers to access are cleared for a new product is seen as the most important commercial area for a biopharmaceutical company launching a product. ***When asked about the critical commercial areas for bringing a product to market in Europe, four out of five respondents rated achieving access for patients as one of their top two areas.***

Two-thirds of respondents believe planning to achieve market access should be initiated when a product is in Phase II of clinical development or earlier. Interestingly, biopharmaceutical executives and

investors who are based in Europe generally believe that planning for market access should commence earlier than respondents based outside of Europe. Specifically, almost all biopharmaceutical executives and investors based in Europe think companies should start developing a plan for market access when the product is in Phase II or earlier. By comparison, only half as many biopharmaceutical executives and investors based outside of Europe feel that planning for market access needs to occur this early.



What is clear is that ***biopharmaceutical executives and investors based in Europe think that planning for market access to ensure that financial and other barriers are cleared is a critical activity and should be initiated early, often when a product is in Phase II or earlier.***

> **Reimbursement is decentralized in Europe. There is a very complex framework of which countries look to which other countries for prices – so which countries you launch in first is very important. It takes different lengths time for each country and there are different processes. It ends up getting quite convoluted!**
>
> **Europe-based Private Equity Investor**

Based on our experience, we agree that considering market access early in a product's development is an important step to ensuring commercial success in Europe. Those experienced in Europe know the complexity of ensuring that patients can access the market in regions with different languages, different criteria for reimbursement and different willingness to pay for different therapies. European countries reference the price of medicines from one another, which makes launch sequencing critical. The launch sequence should provide input to the company's strategy for Europe, including what commercial organization structure is needed at country level, and how to set up the supply chain across Europe. Given that payers and HTA agencies in different European countries differ in their preference for comparators and endpoints when evaluating a product, the launch sequence also serves to guide which comparators to include in clinical trials.

In most European countries, healthcare is socialized nationally, meaning that patients are not accustomed to paying out of pocket for prescription therapies and failure to achieve nation-wide reimbursement often means virtually no sales in that country.

CONSIDER THE COMPETITIVE ENVIRONMENT IN PHASE I

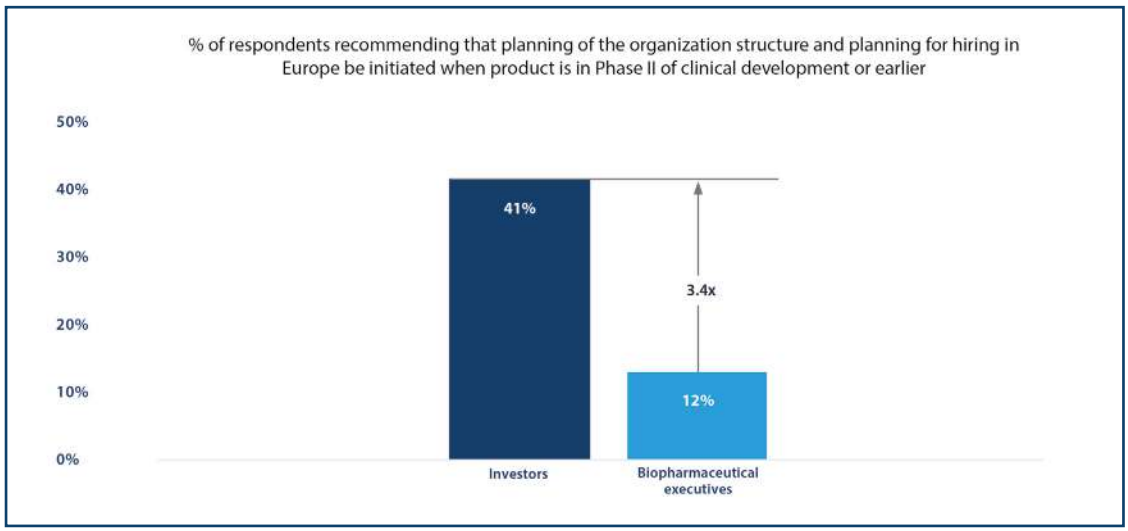
Notably, four out of ten investors feel that it is necessary to consider the competitive environment at launch when a product is in Phase I or earlier. In comparison, less than one-third of biopharmaceutical executives felt that considering the commercial environment needs to occur this early.

When we dive deeper, we see that ***understanding the competitive environment early helps guide the design of subsequent larger, potentially pivotal, clinical trials.*** A clinical trial that is supporting an asset's regulatory approval in a non-European country may not generate the correct data for European authorities. Similarly, payers will often be influenced by a different set of secondary endpoints or even patient-reported outcomes. In fact, standard of care options, competing products and what payers and HTA agencies would accept as a suitable comparator, differ across European countries. Having the right comparator in clinical trials, informed by competition, is critical to obtaining the best outcomes for achieving market access.

PLANNING FOR ORGANIZATION STRUCTURE AND HIRING IN EUROPE EARLY

Investors generally believe that developing the organization structure and the commercial hiring plan for Europe should start earlier than when most pharmaceutical executives feel they should initiate planning.

When asked when a biopharmaceutical company should initiate planning of the organization structure and developing the commercial hiring plan in Europe, four in ten investors feel it should be initiated when the asset is in Phase II or earlier. By the time the asset is in Phase III of clinical trials, over seven in ten investors would expect a company to initiate planning.



However, biopharmaceutical executives typically start thinking about the organization structure and hiring in the later stages of a product's development. Specifically, only one in ten pharmaceutical executives feel it is necessary to initiate planning in Phase II or earlier, and under half feel planning should commence in Phase III or earlier.

Executives that are not based in Europe feel planning should start even later. ***Less than one-third of executives based outside of Europe feel planning should begin when the asset is in Phase III or earlier, and a third will not have developed an organization structure and hiring plan until after filing.***

Based on our experience, we recommend that companies, particularly those with less experience of the European market, consider initiating planning their commercial organization when their asset is in Phase II.

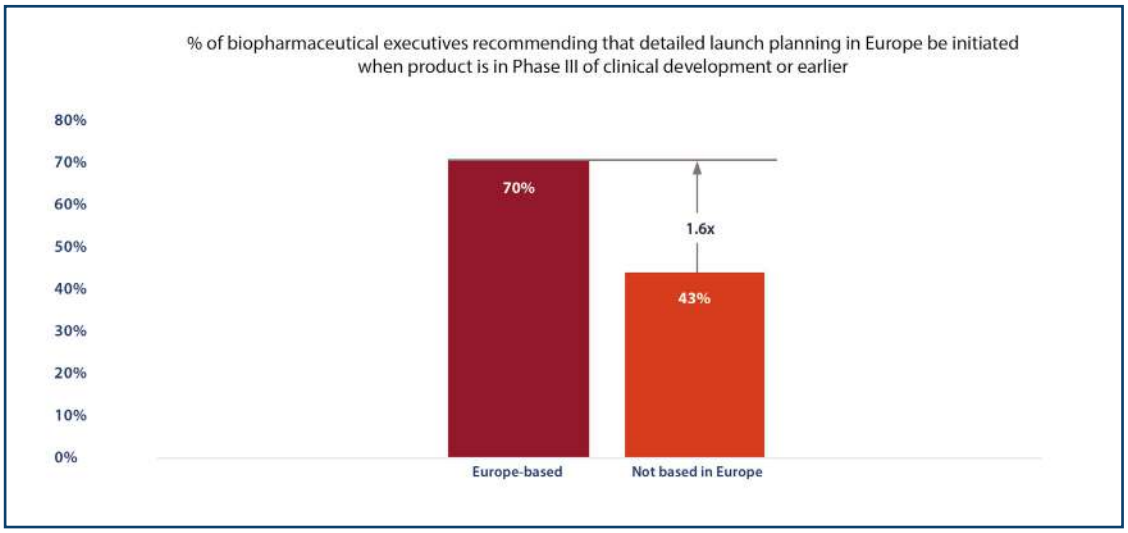
Companies should consider acquiring talent with experience of commercializing assets in Europe. This includes the hiring of senior commercial leadership (e.g., chief commercial officer, commercial head of Europe). Knowledge of local markets helps executives to design more effective and commercially successful European strategies, including how to achieve access for patients, how to design clinical trials and how to develop a brand to differentiate from competitors. Also, a clearer understanding of the local market enables development of stronger financial estimates, particularly on future commercial hiring requirements, and hence supports discussions with investors.

Identifying, hiring, and retaining the right talent often takes considerable time and effort, and could be particularly challenging for emerging biopharmaceutical companies without established brands in the European market.

> **You need to have the commercial structure, the sales reps and all the things you need to commercialize your drug, already in place by the time you complete Phase III. Otherwise if you wait until approval, you won't have enough time to build the organization structure and you will miss out on the market.**
>
> **Europe-based Venture Capital Investor**

BIOPHARMACEUTICAL EXECUTIVES BASED IN EUROPE PRIORITIZE LAUNCH PLANNING

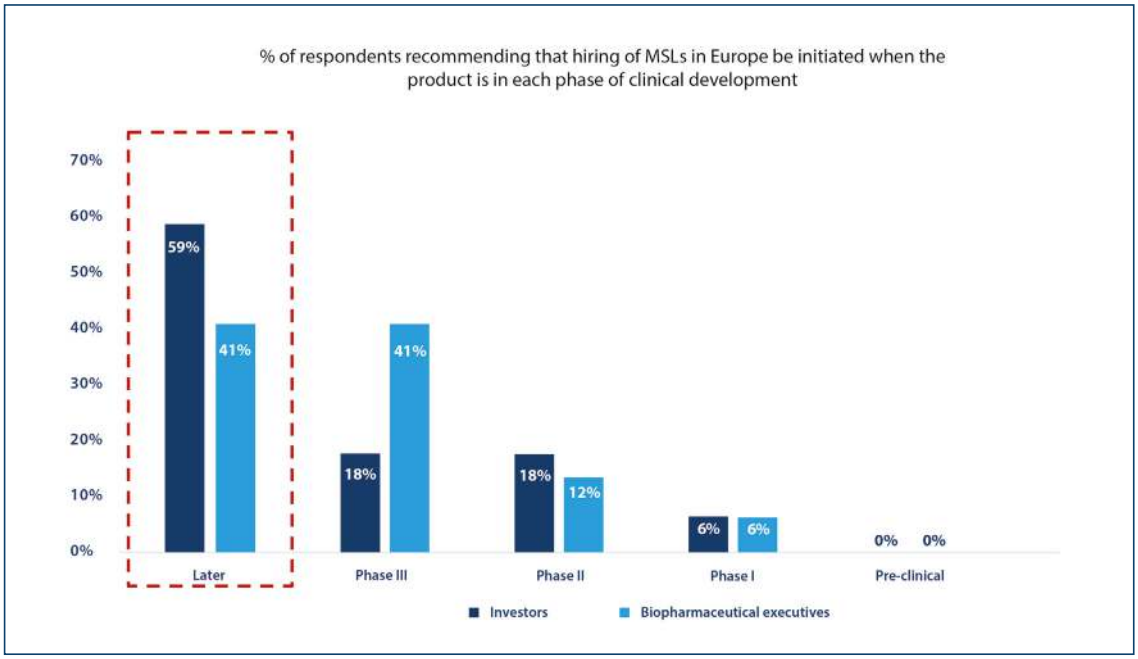
Biopharmaceutical executives who are based in Europe generally believe that detailed launch planning should commence earlier than executives based outside of Europe. Specifically, seven in ten biopharmaceutical executives and investors based in Europe think companies should start developing a detailed launch plan when the product is in Phase III or earlier. By comparison only four in ten biopharmaceutical executives based outside of Europe feel that planning for launch in Europe needs to commence so early.



In our experience, detailed launch planning should commence at least two years before the anticipated launch in that region.

HIRING MSLs EARLY SUPPORTS MARKET UNDERSTANDING

When asked when a biopharmaceutical company should initiate hiring the first MSLs in Europe, about half of the respondents feel that activity should be initiated when the product is in Phase III or earlier. Interestingly, ***about half think that hiring MSLs could start later and would wait until after the regulatory documents are filed before doing so.***



From our experience MSLs are critical to the commercial success of a product. They help prepare the market to support the launch of a product, including helping raise disease awareness, and pre-empting any prescriber barriers. MSLs are also crucial for collecting physician and key opinion leader (KOL) insights to underpin the development of strategies that encourage success in launch. This is particularly important given the differences across European countries.

Overall, we recommend that biopharmaceutical companies consider whether earlier hiring of MSLs could benefit long term and outweigh the costs.

A EUROPEAN BRAND PLAN IS CRITICAL

Four in ten respondents not based in Europe expressed the view that a European brand plan should not be initiated until after Phase III is complete. In our experience, developing the European brand plan involves understanding the patient journey in local markets in detail, allowing companies to identify specific interventions to support the highest possible uptake of the product. A European brand plan is an important activity that should be started well before the completion of Phase III.

> **In my experience, the company board in the US is often surprised that the strategy in Europe needs to be different from that of the US. It is very difficult for people without experience in Europe to appreciate that.**
>
> **Europe-based Biopharmaceutical Executive**

Our recommendation to biopharmaceutical firms is to start the European brand planning process at least two years prior to anticipated launch in Europe, to allow time to build an in-depth understanding of the country-level nuances and develop commercial strategies to achieve the best possible uptake.

SUMMARY

Our analysis of investors' views shows that investors are averse to investing in any company that does not demonstrate that they have an adequate understanding of the commercial environment at launch and has not done sufficient commercial planning.

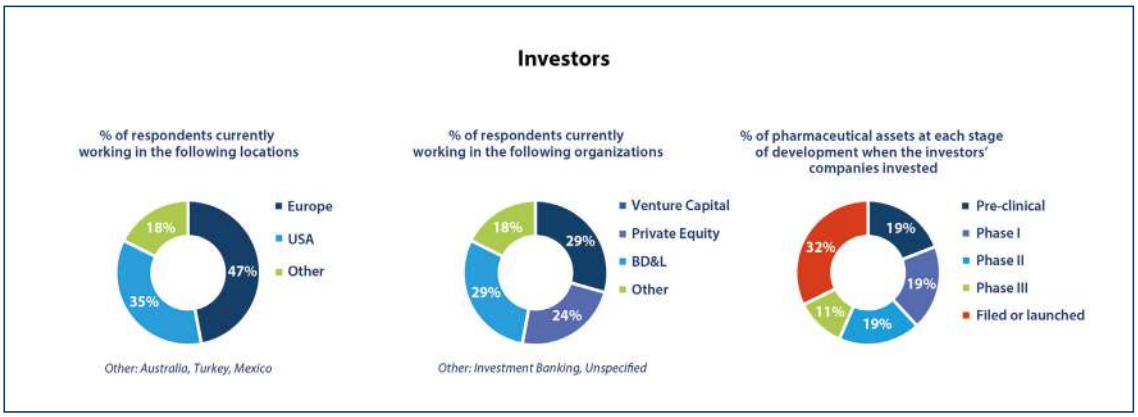
Our analysis shows that:

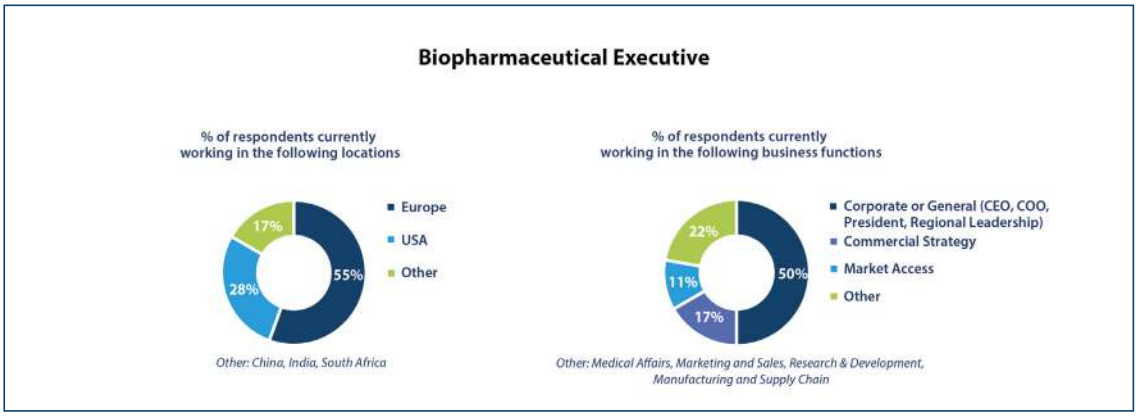
- Europe is increasingly important to investors and biopharmaceutical executives
- Early commercial planning in Europe is a prerequisite for commercial success
- Enabling market access in Europe is the top priority
- Companies should consider the competitive environment as early as Phase I
- Companies should consider initiating planning of the organization structure and hiring in Europe when their asset is in Phase II or earlier
- Launch planning should commence at least two years before the anticipated launch
- Companies should consider hiring MSLs before completion of Phase III to prepare the market
- Companies should consider starting the European brand planning process at least two years prior to launch

Conclusively, we recommend that companies invest early in commercial planning to ensure the success of their products in Europe.

OUR APPROACH

In our study we surveyed 42 senior stakeholders in director-level roles or higher from biopharmaceutical companies and investment firms, including private equity, venture capital, investment banking, and business development and licensing. The background of the respondents is summarized below.





AUTHORS

Jackson Carroll

Principal | Munich

Jackson has 17 years of consulting experience and a strong business background. He has undertaken strategic analysis, assessment of new opportunities, launch support, forecasting, business planning and organizational redesign for leading pharmaceutical and healthcare companies in Europe. Jackson's consulting experience is in diverse therapeutic areas including diabetes, oncology, and hemophilia and has worked for clients in the UK, US, Turkey, Thailand, and over 15 European countries.

Before joining TRINITY, Jackson worked with McKinsey & Company, ZS Associates, Syneos Health Consulting, and Accenture, as well as working as a freelance strategy consultant for life sciences and pharmaceuticals firms in Europe. Jackson earned an MBA (with Distinction) from London Business School and a Bachelor in Information Technology from The University of Queensland in Australia.

Dr. Tony Xu

Sr Consultant | Munich

Tony has rich experience in a range of commercial strategy topics developed through working with large global pharmaceutical companies as well as emerging biotechnology companies. His consulting projects include developing a 2025 global business model, an EU launch strategy through strategic market segmentation and detailed understanding of the patient journey, a launch plan for Europe, a 2020 global payer strategy, and a portfolio expansion strategy. Tony currently lives in Munich but has previously spent extended periods of time in London and Shanghai.

Before joining TRINITY, Tony worked with Sanofi, A.T. Kearney, and Syneos Health Consulting. Tony combines business with science by earning a full scholarship PhD in Pharmacology from The University of Cambridge and has several scientific publications.

Herman Sanchez

Senior Partner | Princeton

Herman has been working in the life sciences industry for over 20 years in various positions, including designing and running randomized trial research, optimizing of clinical administration of health services, and working as a strategic consultant to the life sciences industry. He joined TRINITY over a decade ago and has worked closely with clients to support strategic decision-making across the product lifecycle. As a leader at TRINITY, he has worked to build TRINITY's European office and helps to run and build the company's centers of excellence in Market Access, Launch, and Health Economics and Outcomes Research (HEOR). Herman earned an MBA from the Tuck School of Business at Dartmouth and an AB from Harvard University.

For more information or if you have any specific questions, please contact:

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About TRINITY

TRINITY is a trusted strategic partner, providing evidence-based solutions for the life sciences. With over 20 years of experience, TRINITY is committed to solving clients' most challenging problems through exceptional levels of service, powerful tools, and data-driven insights. TRINITY's range of products and solutions includes industry-leading benchmarking solutions, powered by TGaS® Advisors. TRINITY, together with its subsidiary TGaS Advisors, has 5 offices throughout the US, including Boston, New York, Princeton, Philadelphia, and San Francisco, as well as Toronto, Canada, Gurgaon, India and Munich, Germany. To learn more about how TRINITY is elevating life sciences and driving from evidence to action, visit trinitylifesciences.com.

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