Expert View

FRACTIONAL INVESTMENT IN DEVICE PLATFORMS – A NEW FUNDING PARADIGM

Drawing on his extensive experience in the drug delivery device industry, **Paul Jansen** considers how funding for delivery device development has shifted over the years, from the pre-platform model to currently accepted practice and looks forward to how it may further evolve to support the development of novel devices in the biologics space and beyond.

"MOST DEVICES WERE CONSIDERED AS SECONDARY PACKAGING. EACH DRUG HAD A BESPOKE DEVICE DEVELOPED FOR IT AND, FOR THE MOST PART, COST WAS NOT CONSIDERED – ALL THAT MATTERED WAS SPEED TO MARKET."

Drug delivery and device development used to be a very different world. In particular, project funding was very different to today. While, funding has evolved over the years, another new opportunity remains to be considered.

THE RISE OF PLATFORMS

In the early days of what is now known as combination product development, each device was bespoke. When the pharma R&D department had a new drug, they would work with the marketing department to decide how best to sell the product. For parenteral products developed in the 1980s, this usually meant subcutaneous or intramuscular delivery. The marketing department would then come to the manufacturing packaging team, which, in some companies, had expertise in designing drug delivery devices, and request a device to deliver the drug. Most devices were considered as secondary packaging. Each drug had a bespoke device developed for it and, for the most part, cost was not considered – all that mattered was speed to market.

Eventually, however, cost became more important and pharma companies began developing and creating technology platforms. Perhaps one of the first was the SoloStar® (Sanofi) pen platform launched in 2007. While the original design was specifically for Lantus (insulin glargine), the technology used in SoloStar has since been repurposed for more than a dozen different drugs. Other platforms followed – Ypsomed's (Burgdorf, Switzerland) YpsoMate autoinjector platform and SHL's (Zug, Switzerland) Molly autoinjector platform both have multiple devices launched with more planned. And there are others. The platform model is now a standard way of developing drug delivery devices.

The platform concept offers many benefits for pharmaceutical companies. As the base technology is already developed, the risk of using the technology with another drug is significantly reduced. There is much less concern about the reliability of the device, especially if it is already on the market and well-understood. Also, compared with designing a new device from scratch, less time is required to iterate a platform device for a new use case and the development costs are lower. In practice, the regulatory agencies that had already approved the SoloStar Lantus combination product were comfortable using an already approved device for another drug. Finally, there is much less risk for patent infringement litigation. All in all, having a platform was a great step forward for the pharmaceutical companies.

As the same time CMOs that had been satisfied making pharma-funded and, in many cases, pharma-designed devices realised that they could develop their own technology platforms, which would allow the CMO a better chance to secure manufacturing contracts. If the CMO developed the product, they would naturally have a good technical understanding of the device. The subsequent technical transfer from development to manufacturing and manufacturing scale up would be easier, faster and involve less risk.

FUNDING PLATFORM DEVICES

The first attempts at CMO-developed platform devices were funded in a variety of ways. Both the CMOs and pharma wanted to manage risk. In the perfect (for

"WHAT THEREFORE EXISTED WAS THIS ODD, DIFFICULT DANCE BETWEEN TWO PARTNERS BOTH TRYING TO MINIMISE THEIR FINANCIAL EXPOSURE WHILE SIMULTANEOUSLY DESPERATELY WANTING TO MINIMISE THEIR PROJECT RISK EXPOSURE."

the CMO) scenario, the CMO provided a proof-of-concept model (although many of the early designs were nothing more than a fancy PowerPoint slide presentation) that the pharma company then agreed to develop and fund fully. The CMOs, not being entirely sure that their technology would work or that anyone would buy it if they made it, wanted to carefully manage their financial exposure; thus, the funding provided by the CMO was the minimum required to convince the pharma company to buy the design and fund the remainder, which was, in fact, the majority of the development and scale-up. Moulds and automation were generally funded by the pharma company.

While, on the one hand, pharma required CMOs to make their devices, they were wary of the risk associated with the failure of the CMO and thus retained ownership of key manufacturing equipment, such as moulds, automation and packaging. What therefore existed was this odd, difficult dance between two partners both trying to minimise their financial exposure while simultaneously desperately wanting to minimise their project risk exposure.

As with any new ideas, after some trial and error, both parties started to get comfortable with letting go. Pharma understood the value of letting a competent CMO develop, validate and scale the required device. The CMOs gained experience and competence in their designs, processes and capabilities. With this experience, the CMOs gained traction and started developing and promoting their platforms, which were now developed all the way through validation and with fully validated and automated assembly in place. All pharma had to do was determine their specific use case product specifications and the CMO would iterate their platform product to meet those requirements.

At this point, it became possible for many pharma companies to have devices based on the same platform but with their own specific variations, such as colour and shape. This model has now been in place for pen injectors, autoinjectors and wearable injectors for years. Over the past five to seven years, this concept has become firmly entrenched, now even with some companies that never previously outsourced device development starting to do so.

THE CHALLENGE OF FUNDING INNOVATION

However, as is often the case, market dynamics have changed again. Money is tighter than ever, so funding has become noticeably harder to come by. There is downward pressure on pricing and increased pressure on sustainability. This has had a particularly acute effect on smaller device technology companies.

While the existing funding model works well for established device formats, such as pens, autoinjectors and wearable injectors, it is less so for the new technologies being developed to satisfy the needs of novel biotech therapies with larger delivery volumes and higher viscosities. There are many new smaller device start-ups with great technology that require funding to take their product from proof of concept to commercialisation, yet their novelty has made financing device development challenging. These small companies typically need a first customer to make their product credible and, very often, no one wants to be the first customer – everyone wants to be a fast follower for the technology. This leaves development funding in question.

This dilemma has caused new ideas on funding to emerge. There are some models where a CMO and pharma partner agree to share the cost of development. In so doing, they share the risk and reward. Some companies have gone as far as to share savings generated by continuous improvement programmes equally between the CMO and the pharma company.

THE SHARED INVESTMENT APPROACH

Recently, a few companies have taken the risk-cost sharing concept one step further. In debating this model with them, it has become clear that this is a positive approach that smaller companies with new technology platforms should consider using to fund their developments.

The concept is a development model based on shared investment. One way to think of the concept is as "fractional development financing". Similar to fractional housing, where a fixed number of people own a single home, multiple pharma companies contribute money to develop a single platform that is then accessible to all of them for specific customisation. While, in principle, the approach is quite straightforward, the devil is in the details.

There are three options that have been discussed. There are certainly more variants possible, but these three help to illustrate the concept:

1. Fund the company that is developing the technology with an up-front understanding of what rights the investment gives each company.
2. Draft a single master development agreement that serves as a governing document for all participants, defining intellectual property (IP) ownership, milestones for device development, funding and governance.

"THESE SMALL COMPANIES TYPICALLY NEED A FIRST CUSTOMER TO MAKE THEIR PRODUCT CREDIBLE AND, VERY OFTEN, NO ONE WANTS TO BE THE FIRST CUSTOMER – EVERYONE WANTS TO BE A FAST FOLLOWER FOR THE TECHNOLOGY."

3. Parallel statements of work where each participating company would have a separate development contract and all deliverables and timelines are aligned by the technology company.

In each of these scenarios there are multiple other considerations. A steering committee needs to be established with representation from each of the participating pharma companies that can make key decisions. There should be a mechanism in place to manage a company wanting out of their fractional investment due to changing needs, strategy or circumstances. Data management is another key concern – specifically pharma company data on molecules must be kept strictly confidential.

Since the pharma companies will be making investments in new technology IP, data rights must be defined and understood. The core platform technology IP should remain with the technology company. It may be developed further with the fractional investments from pharma, but the rights should be retained by the technology company. The pharma companies' molecule-specific IP, data and device-platform-specific customisations should remain private and the property of their respective pharma company. Jointly developed improvements would be available to all the fractional investors but would be assigned to the technology company, although there could be optional exclusive rights granted to investors on specific configurations for an additional investment.

Walking Through a Hypothetical Example

As an example, consider a hypothetical fractional investment concept for Technology Company A, with Pharma Company B, C and D investors. Pharma Company B, C and D will work with Technology Company A to define what development activities they will fund; for example, up to design validation testing, providing clinical samples and manufacturing capabilities. Together, they will define milestones for the development activities; for example, being validated platform configuration complete, clinical use assemblies becoming available, draft documentation for regulatory use becoming available and completing test method validation.

Based on the development activities and milestones that have been defined, the funding model is then agreed upon. The model could be an equal cost share model. The total cost for the agreed-to activities is US$21 million (£15.6 million). Each company would then contribute $7 million. Each of Pharma Company B, C and D share equally in the non-custom deliverables that they have agreed to fund.

Alternatively, the funding model could be a tiered participation model. Tier One could be defined at $14 million. Tier Two would then be set at $7 million. The Tier One participant would have priority input, early access to prototypes and clinical samples and other agreed upon benefits. There are many variations that one could think of, so the details would be dependent upon the fractional investment partner companies. However, the core concept is that greater fractional investment brings extra rights with it.

Regardless of the model agreed upon, there still remain a number of considerations that the fractional investors and the technology company need to think through and decide on. How are costs controlled and reported? Is it possible for one fractional investor company to purchase further priority or exclusivity over other investors?

FUTURE OUTLOOK

While the idea is yet to be tested in real life with a real product platform and real fractional investors, the concept is viable. The key messages to take away from this idea are:

1. Pharma and technology companies need not go it alone when developing a new device platform – be creative and think out of the box
2. Shared risk equals shared speed, shared leverage and reduced financial burden
3. Fractional investment de-risks the development of a validated device platform from a time and cost perspective
4. The concept supports the generally accepted best practices – one platform device for many drugs.

It is my hope that the reader will be provoked to think more about this, develop the concept further and perhaps lead the charge to try it.

Paul Jansen

Paul Jansen currently works as a drug device development consultant. He is a member of the Kymanox Executive Advisory Board, as well as serving on the Advisory Boards of Evoleen & Windgap Medical. He was formerly Associate Vice-President, Medical Device Development, at Sanofi until his retirement in January 2017. Mr Jansen is a Professional Engineer with more than 30 years of experience in medical devices. He completed his degree in mechanical engineering and has completed graduate work in biomedical engineering at the University of Toronto (Canada).

Mr Jansen has extensive experience in the design, development, manufacturing and lifecycle management of medical devices, including multiple patents to his name and deep experience in the creation and management of IP portfolios. He has successfully led teams that have developed and launched several award-winning devices, including Lantus SoloStar. Additionally, he has expertise in the design and development of injection-moulding systems and electronic components. Mr Jansen was a long-time member of the ISO, serving as Working Group Convenor and Expert on many work groups responsible for standards related to injection devices. Until January 2022, he was the Chair of Technical Committee 84, Devices for the administration of Medicinal Products and Catheters.

T: +1 857 203 1470
E: paulejansen@gmail.com