ERIC DESSERTENNE, BIOCORP

Eric Dessertenne holds a pharmaceutical degree from the University of Clermont Ferrand (France), an MBA from ESSEC Business School (Cergy-Pontoise, France) and is a graduate of the Therapeutic Chair of Innovation at ESSEC Business School. He began his pharmaceutical career at Servier in France in the Corporate Strategy department and then moved to the Chinese subsidiary in Beijing, where he handled positions in the marketing and sales force department. Mr Dessertenne then joined LEK Consulting where he worked as a consultant in the Life Sciences and Private Equity practices. In 2014, he joined Biocorp as Head of Business Development & Commercial Operations. He is now Biocorp's Chief Operating Officer.

Here, Mr Dessertenne talks in-depth with *ONdrugDelivery Magazine* about the ways connectivity is developing within the pharmaceutical industry, its likely future course and how Biocorp is positioned. He explores new types of partnership and the emerging ecosystem of associated apps and services within which devices have a crucial place. One of his key themes is how developing connected technologies cannot be merely technology driven but must always meet patient and customer needs.

Q Biocorp is now a world-leading name in the field of drug delivery device connectivity. I wondered if you could begin by describing how it reached this position and detailing its interest in connectivity?

A Biocorp's intention is to meet unmet needs of pharma companies and ultimately of patients, in particular their drug delivery needs. We're answering demand with our technology platforms, some of which are connected and some of which are not connected. We've built a lot of expertise in drug delivery devices over the years in terms of concept generation, device development and right up to and through the filing process in various countries – mainly in the US and Europe. We rely on our expertise in three main segments – mechanical engineering, hardware and embedded software engineering.

What I believe is unique with Biocorp is the way that we don't merely deliver a concept, but how we work design for manufacturing and industrialisation capacity into the process very early. We focus a lot of effort on ensuring that we're generating more than just a simple idea on paper but providing all the tools to our partners in order to make it real, robust and compatible with the different regulations that the technology has to comply with.

Connectivity is a big opportunity and represents a major chunk of our activity. We started working in the area of connectivity quite early on – back in 2013 – and I believe this was before many others. We saw that the rise of connectivity was a solid trend and that it was certainly going to meet unmet needs not only for pharma, but with benefits right through the cost structure to the payers.

We were hearing from others that connectivity was somehow a kind of general option that might or might not be provided on top of an existing strategy. In contrast, our perception was and still is that connectivity needs to be thought about and designed in terms of its specific usage and with a robust business case. It requires more of a holistic approach with connectivity at the centre, not on the periphery as an afterthought or option. This sense of the potential of connectivity which we had five years ago was well founded – you can see today the level of activity and interest from pharma and payers alike.

Q The different types of connectivity technology for drug delivery systems can be categorised in many ways. One way is to divide them into "integrated" and "add-on", and Biocorp has products in both of these categories. Please could you explain the two different approaches and the advantages and disadvantages of each, using Biocorp products as examples?

A It's good way to divide the ways of providing connectivity to devices and, as you say, at Biocorp we have integrated and add-on approaches that answer different needs from our customers.

Broadly speaking, add-ons respond to the requirement for connectivity to be made available "immediately" on an existing drug delivery device. Let's say a pharma company already has a portfolio of products on the market around the world that were filed and approved as drug-device combinations. Gaining those approvals represents a huge investment in a lot of different countries and it is not a process that a pharma company would want to repeat from scratch. But

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at the same time, the company wants to provide the connectivity that its customers – patients and payers – want as soon as possible, with the smallest possible impact on the existing product/existing device. The add-on is clearly the best approach here. It doesn't impact on the industrialisation and manufacturing of the product (usually a drug-device combination) and there is usually just a small impact on the regulatory status of the product.

In terms of development timeline, an add-on can achieve a timeline that is far shorter compared to a product with integrated connectivity. Within a 2–3 year timeframe from the starting point, you can have something available and potentially commercialisable.

We have a major product, Easylog® (Figure 1) which is the add-on for pen injectors that we've been working on for the last few years. This is positioned for a specific category within the pen injector market, where you have a lot of disposable pen injectors, which represent a major portion of the market, mainly in the diabetic market, which is the largest market by volume.

The diabetic field is already very well connected on the side of the blood glucose monitors (BGMs) and continuous glucose monitors, and the missing piece is the pen injector. The Easylog technology completes the circle.

We're also offering Easylog in other chronic disease indications where there's a need to know if the dose was injected, if it was a viable dose, what was the dose injected, and so on. In numerous therapeutic areas Easylog can answer an unmet need in an immediate way.

There are some drawbacks with add-ons as well. For example, you need to ask the patient to remove the add-on from the old device and put it on the new device for reuse. So the add-on concept is necessarily dependent on an additional user step, but Biocorp has spent a lot of time making sure that the process is seamless, so that it's really easy to put the add-on on the new device and that once it's on we're not asking the patient to complete any further steps to prepare or activate it. The patient simply puts the Easylog onto their device and then they use their device as normal.

Then we have the integrated approach, which is exemplified by our DataPen® reusable pen injector (Figure 2) and the recently launched OneJet® disposable autoinjector (Figure 3). In terms of the user experience, integrated connectivity is very easy to use. It enters into a more important process of lifecycle management within pharma companies, to develop a product with a new device with connectivity features embedded. It fits mainly for chronic diseases but also for less price-sensitive therapeutic areas.

Figure 1: The Easylog® add-on brings connectivity immediately to any regular pen injector, whether disposable or reusable.

Figure 2: Datapen® is a reusable, electromechanical connected injection pen that uses standard cartridges.

Figure 3: OneJet®, the first motor-driven, disposable and Bluetooth connected autoinjector.

Having connectivity is an additional cost but the point is to compensate for this by showing that there are demonstrable benefits coming from having connectivity. It's never enough to have connectivity for the sake of having connectivity. It's important to define, specifically, why it is being added. Pharma companies are willing to bear the additional cost of a connectivity-integrated device if they are getting outputs out of it, in particular for expensive drugs where it is clearly beneficial to know that the drug is being injected properly, completely and at the right time, the right dose, that it's being stored correctly under the correct conditions. All this important information can be tracked through embedded connectivity and this is where it makes a lot of sense – both for pharma and for patients.

Cost-savings are clearly important and embedded connectivity can bring cost savings. With regard to adherence, if it can be verified that the patient is getting the prescribed dose, injected properly, this is clearly attractive to the payer, whether it be the insurance company or the state which is paying. Improved disease outcomes and potential reductions in overall cost of care and treatment then follow.

It's important not to think of add-ons versus integrated/embedded connectivity, as a binary "either or" proposition. Add-ons can be used as a way to try connectivity, to bring connected versions of a product to the market for use by patients, and to gather information, including conducting pharmaco-economic studies. Add-ons are relatively cheap in terms of development cost, and very low risk in terms of the original pharma product. Having gathered

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data and proven the benefits of connectivity – including to payers – this then puts the pharma company in a strong, well-prepared position for the second step of integrated connectivity.

However, several pharma companies are already convinced and clear about the direction that they wish to take, and have already initiated integrated connected device programmes. That's the reality. But for sure if companies require additional evidence before committing to integrated connectivity, add-ons can help.

Q Biocorp's technologies span the inhalable and parenteral areas of drug delivery. Does Biocorp have plans to develop connectivity solutions beyond the inhalation and injection routes?

A Biocorp's historical expertise is in parenteral areas, we've been working in the injectable field for more than 20 years. Additionally, thanks to the Inspair® technology, an add-on for inhalation devices (Figure 4), we have moved outside the parenteral space and developed other ways to provide benefits to our customers and to patients. That's our philosophy today regarding connectivity – we will answer unmet needs, whatever the drug delivery route.

We do have plans to work on other areas, however, this would most likely be more based on a specific customer's demands. So, for example, a customer might say to us that Biocorp has demonstrated to the market that it can make connected injectors and apply connectivity in inhalation too, we believe that connectivity could apply in other therapeutic areas or other delivery routes and we believe Biocorp has the skills an expertise to help us in those areas. Biocorp would be open to that – even though as a platform technology provider injectable is really our key area and where we will be most proactive in answering most market needs.

Depending on the type of product we are working on we tackle different issues and address different patient needs. For example with Easylog we're tracking global adherence – whether the dose has been injected and if it was the correct dose. With other devices, Inspair for example, we provide ways to train the patient in how to use the device correctly. The Inspair on a pMDI is able to track whether the patient presses the canister at the same time as they inhale – so it's working on the synchronisation of breath-hand co-ordination, which is very important for pMDIs. In that specific case we could imagine that the Inspair add-on could be prescribed at the initiation of a treatment to help ensure that the device is being used correctly and then after a couple of months if the patient is happy they are trained properly, and there's no requirement for additional data, they could potentially continue without Inspair.

Another area in which connectivity has a crucial role to play is, of course, in clinical trials – specifically, validating the data gathered during clinical trials. In the future, using connected devices during clinical trials will be key to helping ensure that the data submitted to the regulators is robust and that it is accepted without its validity being questioned.

Q With the high-profile Facebook personal data controversy in the US earlier this year, and the recent implementation of the EU's GDPR legislation, data privacy and security is now a topic everyone is thinking about. However, the collection, transmission, storage and use of personal data is central to the entire concept of connecting drug delivery systems so the drug delivery industry has had these topics front and centre for some time. How does Biocorp approach the specific challenges arising from data privacy and security considerations?

Figure 4: Inspair® is a smart sensor for inhalers that records each dose delivery, monitors hand-breath co-ordination and provides feedback to patients on technique.

A It's really important to talk about this and I believe addressing data privacy and security issues properly is key to allowing the broadest possible adoption of connected drug delivery devices. It's essential for us to gain the patient's confidence by demonstrating that we are taking their data privacy and security very seriously.

We're not talking about "normal" data here – this is highly sensitive data relating not only to health and medication but also other personal aspects of patients' lives. If these data are shared with a patient's insurance company, their bank or their employers, this could have an impact. I hear a lot that there are fears amongst patients about how their data could be used by third parties if there was a security breach or leak.

There are clear guidelines and all device manufacturers and pharma companies that might commercialise a connected product must abide by them. This has been absolutely crucial for us since the very beginning and so, for example, when first we embarked on the development of smart devices we acquired encryption technology to ensure that any data we are pushing away from Easylog are encrypted at their origin.

What we've seen over the past couple of years is that there's been a lot of movement in this area from big players. Amazon, Flex, Qualcomm – they all have an ambition to provide solutions for transmitting and storing health data, and also analytics, to pharma, payers and/or patients. These big companies have the global presence to ensure that the solutions are scalable and updated country by country according to the different regulations as they come into force and change.

We see the recent European GDPR regulation as good news not least because it harmonises all the different national regulations that we had until now.

So in terms of our approach, Biocorp has taken a decision to focus on the aspects of data privacy and security that relate to the device itself. So we want to be sure that from the moment the device begins gathering information, and then potentially storing it and sharing it to a third-party device, most often a smartphone application, that this flow of information will be highly secure. We have put a lot of effort into this – I mean, really a lot.

"With Easylog in combination with a connected BGM and other elements, the app coaches the patient, and makes sure they take their medication properly, and that they don't have other issues in their life that could impact their disease. The final customer is the payer, insurance companies in the US. This is a very important new aspect of our business."

We also need to be as open as possible to pharma's requests and requirements. This is where we see the big players I mentioned just now having an influential voice. Our pharma partners are telling us that they are working with, say, Amazon and they therefore ask us to make sure that when we develop a device for them, it can transmit its data to a particular Amazon system.

Q You have been at Biocorp for four years now, things are moving fast and a lot has happened in the industry over this period. What are some of the most noticeable trends that you have seen unfolding?

A When I first arrived at Biocorp, if we were presenting our connected devices to industry, there were a lot of people saying that this would potentially be the solution of the future, it definitely could help patients – they could see the potential, there was strong interest, but the conditional "could" and "might", was used. In these large organisations it was still very much perceived as a technology driven trend and often lacked strong support from the senior management and the digital strategy that would explore where a connected device would fit in.

Now almost all of these big organisations not only have a digital strategy but it is a top priority. Digital is a broad field and can be applied in a lot of ways but for sure connected drug delivery devices form a significant part of it in some of these organisations. They have brought teams together, so you have connected device teams. Most of the big pharma companies and some insurance companies now have a clear view of what they are expecting to achieve. This was not the case four years ago.

Another thing I heard a lot four years ago was that connectivity looked interesting but who will pay for it? Today pharma knows firstly that they can pay. Secondly that they can go to payers and say thanks to this connected device we've reduced the overall cost of disease by a certain percentage so please pay us a premium or please don't break our price by 20–30% as would normally happen if we hadn't invested in connectivity.

Connected devices are now, in fact, a reality. Products have been launched, and there are some positive outputs. For pharma especially, this really is a remarkable transformation in only four years.

Q Please would you describe the most recent news and progress at Biocorp?

A We've been very active in terms of development. At Pharmapack Europe in Paris earlier this year, we unveiled our latest device, the Onejet. It is the first motor-driven, disposable, natively connected autoinjector, and we received the Innovation Award at Pharmapack for that. Onejet is very important for us and it is not merely a technology for its own sake – it answers a need in the autoinjector space.

Just to explain how we are developing technology to meet specific needs and not for its own sake; we have worked a lot on add-ons and we saw that this worked for pen injectors. However, the use case for autoinjectors was not so good because we are looking at one shot, and it is asking patients a lot to take off the add-on and put it on another autoinjector out of the box every time. It isn't in step with a chronic treatment. So we decided that the autoinjector would be natively connected.

Onejet meets both the technical challenge of developing such a product and the user needs of getting immediate feedback on usage. It's a major accomplishment for us and we're proud of this product.

Regarding partnerships, we are working very closely with a lot of pharma companies and recently we've extended the scope of our partnerships by signing a deal with a service provider in the diabetes sector called Chronicare (Newtown, PA, US) that offers an intelligent app with embedded algorithms for diabetic patients. With Easylog, in combination with a connected BGM and other elements, the app coaches the patient, and makes sure they take their medication properly, and that they don't have other issues in their life that could impact their disease. The final customer is the payer, insurance companies in the US. This is a very important new aspect of our business and it is a very important milestone for Biocorp. It will continue to be important. We are entering into a more holistic approach where there is the drug, the device and all of the surrounding services, and this potentially extends the scope of our partnerships and broadens the type of partners we can search for.

In terms of therapeutic area, this partnership is focused on diabetes and Easylog really completes the circle with the BGM and the app. The huge benefit in diabetes is obvious but this applies across a range of indications. In Parkinson's disease for example, where you have a need for dose titration when initiating treatment. How are you sure that the regimen is respected? With a connected pen you can be sure that you get the correct titration.

Also we are taking a great interest in the types of deals that big pharma companies are signing for companion apps. For example, the French company Voluntis partnered with Roche to develop an app for use in breast cancer. Companion applications that have a true medical effect and are considered a medical device are of real interest to pharma companies and this fits very well with a connected medical device.

Q And finally please tell us about some of the broader aims and objectives of Biocorp looking on into the longer-term future?

A At its core, Biocorp is a technology innovator and we will continue down that path – providing what we consider to be the best solutions for our partners. But I strongly believe that simply providing the technology is not enough. The technology is crucial for certain, but it has to fit properly in an ecosystem that is changing very rapidly. For example, in the future our systems might not simply track information but might guide and advise patients, going a step further.

Biocorp is very alert to these possibilities and this is where I believe we could see considerable additional value in the future. I think what we will have to do as a technology provider in the device field is perhaps comparable to what the big tech companies, such as Apple, have done in their industry – first to develop the device for patients, and then provide additional services as well. You have to be open to that ecosystem. We were saying that in four years things have changed a lot and I believe there will be even greater change in the next four years. This is where Biocorp wants to go, moving together with its partners.

ABOUT THE COMPANY

For 20 years, Biocorp has been designing, developing and manufacturing medical devices for the pharmaceutical industry, enhancing drug reconstitution, safety, packaging and delivery. Today, Biocorp continues to innovate in medical plastics, bringing new solutions to the market such as the Newguard™, an integrated passive safety system for PFS compatible with nest, and Biopass, a reconstitution system with an integrated needle ready to inject.

Recognised for its expertise in device R&D, Biocorp has incorporated software development capacities to develop connected drug delivery systems, including the DataPen®, a reusable smart pen injector that automatically transmits data to a treatment mobile app, helping patients to manage their treatment, and a range of add-ons, smart sensors for existing drug delivery devices (pen injectors, MDIs).

In addition to its R&D activities, Biocorp also provides manufacturing services for plastic injection, process assembly and blister packaging.

BIOCORP

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ON drugDELIVERY

2018/19 EDITORIAL CALENDAR

Publication Month	Issue Topic	Materials Deadline
July 2018	Novel Oral Delivery Systems	DEADLINE PASSED
August 2018	Industrialising Drug Delivery Systems	Jul 5th 2018
September 2018	Wearable Injectors	Aug 2nd 2018
October 2018	Prefilled Syringes & Injection Devices	Sep 6th 2018
November 2018	Pulmonary & Nasal Drug Delivery	Oct 4th 2018
December 2018	Connecting Drug Delivery	Nov 1st 2018
January 2019	Ophthalmic Drug Delivery	Dec 6th 2018
February 2019	Prefilled Syringes & Injection Devices	Jan 3rd 2019
March 2019	Skin Drug Delivery: Dermal, Transdermal & Microneedles	Feb 7th 2019
April 2019	Pulmonary & Nasal Drug Delivery	Mar 7th 2019
May 2019	Injectable Drug Delivery: Devices Focus	Apr 4th 2019
June 2019	Connecting Drug Delivery	May 2nd 2019

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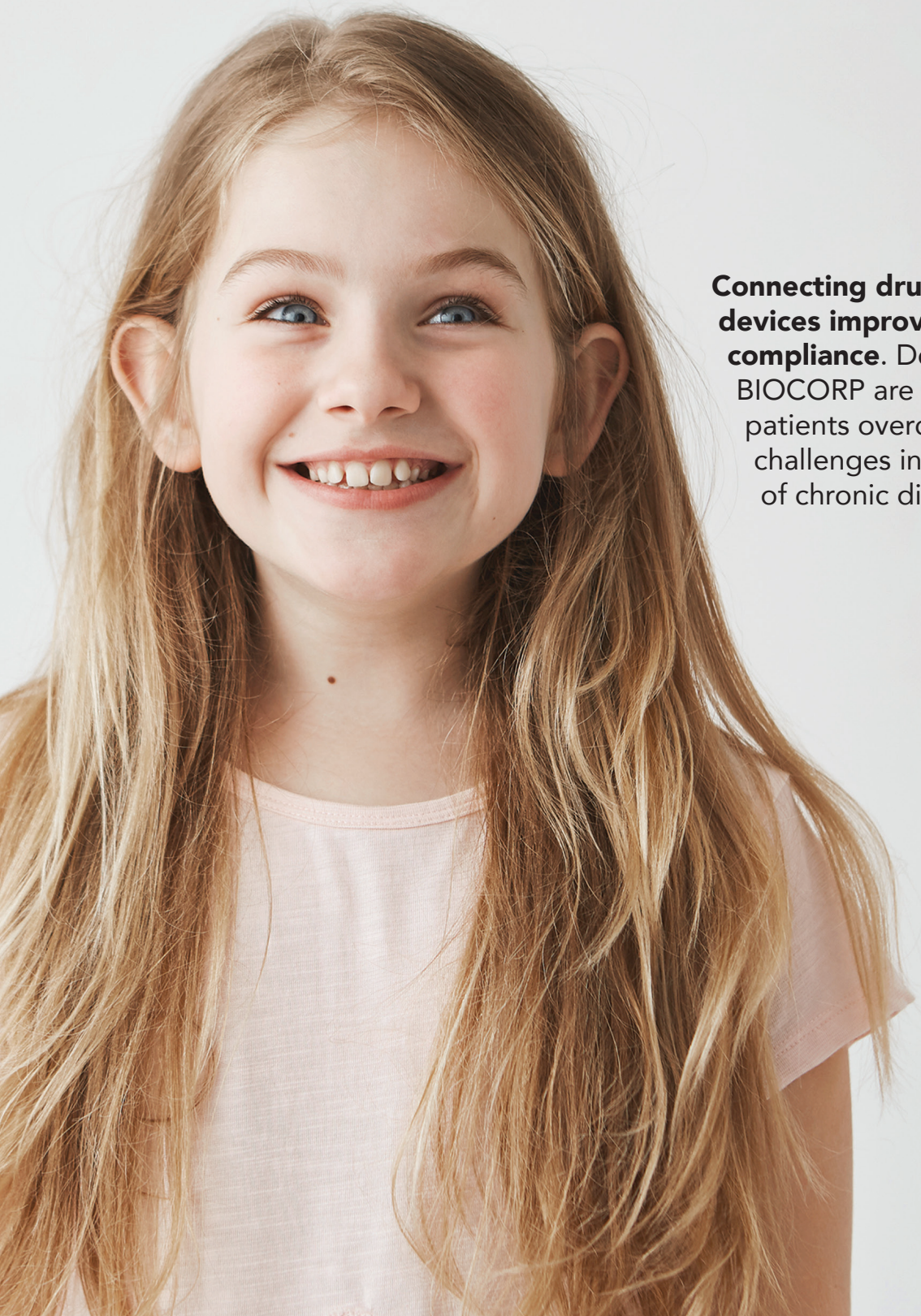
TO OFFER THEM THE CHANCE OF MAKING
THEIR DREAMS COME TRUE



Connecting drug delivery devices improves patient compliance. Devices from BIOCORP are there to help patients overcome the various challenges in the management of chronic diseases.

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