AARON MANN, CHIEF EXECUTIVE OFFICER, KINDEVA

Aaron Mann is the Chief Executive Officer of Kindeva Drug Delivery and was previously President and General Manager of 3M Drug Delivery Systems. He holds a BA in Economics from Carleton College and an MBA from the Harvard Business School.

In this exclusive interview with ONdrugDelivery, Aaron Mann discusses how Kindeva is positioned to move forward as a major CDMO specialising in inhalation and transdermal (passive and microneedle-based) dosage forms, having been formed in May 2020 when Altaris Capital Partners acquired 3M's drug delivery business for US$650 million (£496 million). We discuss the divestment and Kindeva's formation, and how the new company represents a valuable opportunity to meet today's challenges, building on the organisation's legacy experience, track-record and capabilities, whilst also innovating in new directions and developing new interesting ways of doing business and working with partners. We also cover the impact of Covid-19, environmental sustainability, and current challenges faced by the pharmaceutical industry.

Q Congratulations on your appointment as Chief Executive Officer of Kindeva Drug Delivery at its formation. Can you describe Kindeva in terms of how it is positioned, broad mission and strategy, key elements of the business offering?

A Well, thank you – it's really a privilege. We have such a remarkable team and Kindeva represents an amazing opportunity to help drive our customers' success.

So, Kindeva is one of the larger leading CDMOs globally, with a particular focus on complex drug and combination products. Our passion is helping our customers realise the whole potential of their programmes.

Our capabilities today reflect our depth of expertise in formulation, in development and through to manufacturing. Customers engage us at all stages along the development continuum. We take in an API from our customers and when they return they are collecting commercial batches from us, for marketing and distribution. We offer a global turnkey capability.

Historically, we've been focused in the inhalation space and we are well known for a lot of pioneering work around metered-dose inhalation. We also have considerable experience across different delivery technologies including in the transdermal space with patches and drug-in-adhesive systems. And increasingly we work with active transdermal systems and microneedle-based platforms.

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We draw on our deep experience and integrated capability set from early development through to manufacturing, so from a project's outset we're able to think through all the factors at play, the trade-offs, and the implications of different choices, which are different in each of the delivery routes.

Figure 1: Kindeva is developing smart, connected drug delivery solutions.

Kindeva is a new name, a new entity, but the reality is that we have extensive, deep and unique experience having helped our customers develop a large number of products through to market. We have a track-record with regulatory authorities throughout the world. The fact that it's integrated right within the business, sitting side-by-side with the labs and manufacturing as opposed to residing in a third-party consultant, brings a further level of benefit. This minimises risk for our customers – their programmes' chances of success are increased.

Innovation is a core part of our DNA and as Kindeva we're accelerating our innovative capabilities, continuing to engage with customers around inhalation, transdermal and microneedle technologies, and delivering solutions around smart and connected devices (Figure 1).

Ultimately, we're focused on helping our customers help their patients. Fundamentally that is the need. Kindeva can help people receive the therapy that's important to them.

Q Could you outline the role of Kindeva's products and services during the coronavirus pandemic? And how is the company navigating this period affected by the outbreak in terms of operations?

A The focus that my management team and I have every day is on our people. We can only make the best contribution if we are really taking care of our people. You saw that reflected in our culture before the transaction as well, so we're certainly benefiting from bringing that culture with us – helping our people take care of themselves and take care of each other. Many of our folks have needed to be in the labs and factories to keep these essential projects going throughout the pandemic, as our business is defined as an essential industry. And our teams in our manufacturing facilities, in our supply chain, in our labs, they've done a terrific job.

In terms of the role of Kindeva's products during the coronavirus outbreak, a number of our products and of our customers' products, are playing really important roles. First, with the inhalation space being one of our core areas and Covid-19 being a disease that affects the respiratory system, the applicability is self-evident. Inhalers are always important when you're dealing with a respiratory disease. We're hearing from our customers that the need for inhalers is growing.

There have been some concerns about nebulisers potentially generating droplets capable of spreading viral matter so there's been a move away from nebulisers in some hospital settings and alternative devices such as MDIs are used. This increases underlying demand for us. Also, some of the inhaled products that we make have been investigated for potential efficacy against Covid-19 symptoms.

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Figure 2: Kindeva's hollow Microstructured Transdermal Systems (hMTS) are designed for intradermal delivery of vaccines and biologics.

We've played a role in helping pioneer microneedle platforms for intradermal delivery (Figure 2), and this delivery route can trigger a very strong immune response. Our customers have been working on cancer vaccines and immuno-oncology for some time and so the question becomes, does this delivery approach have potential for a SARS-COV-2 vaccine?

One of the further benefits of microneedles is of course that they allow self-administration which would have significant advantages for the kind of mass vaccination programme required for coronavirus compared with requiring a healthcare practitioner, for each and every person being vaccinated, to go to a refrigerator, take a refrigerated dose and inject it. If we're able to come up with something that's self administered, the ability to get it out across the globe and achieve the immunity across populations that is required, could be heightened.

Q The coronavirus outbreak struck just as the divestment of Kindeva from 3M was taking place. How did it affect the process?

A I think it's a testament to everyone who was engaged in it that we were able to complete the process despite the coronavirus outbreak.

The team at Altaris have been terrific partners. Their conviction around the drug delivery space, and their experience with these kinds of transactions have been invaluable as has their support for the team that leads the drug delivery business. That team did not miss a beat running the business while simultaneously working to-plan on the divestment, all with a virus outbreak happening at the same time.

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Q Staying with the transaction, can you describe what is included in the transaction and how Kindeva will be able to stand-up on its own?

A There is immense opportunity with the drug delivery business, but

the best way to realise that was with someone else investing behind it. Notice that 3M is retaining a 17% stake in the company. As opposed to having any lack of conviction about the industry, they do see the opportunity.

In terms of what comes with the divestment, it is the core of the business; the vital parts of what we do. First and foremost, this means all of the people. If you look at the business from the top down, the Kindeva leadership is the same leadership team that was running the drug delivery business at 3M. Even more importantly, our technical whizzes, our regulatory experts, our R&D teams, both in the US and in the UK where we have a large footprint. Those people and those labs are part of the transaction as is our terrific manufacturing infrastructure, again both in the US and the UK. Also included is the technology, the IP that underpins what we do.

From the point of view of our customers, in some respects it is just a change in name. They're interacting with the same people, at the same plants, the same products, the same capabilities at Kindeva as they were when the business was part of 3M.

We've had tremendous support with regard to the transition to enable fast and responsible decision making to achieve a very thoughtfully planned separation ensuring that Kindeva stands on its own two feet.

Q How do deals like this affect employees? Do patients benefit ultimately?

A I've been impressed by the amount of energy generated with our people by this opportunity to really take ownership of our culture of the direction of driving the business. It is different when you're part of a much larger multinational. As Kindeva we have the ability to, for example, make faster decisions around how we're going to invest in growth, what we're going to put our efforts and energy behind, where we're going to choose to innovate. That gets our people more involved and energised, and we can envisage achieving beyond our already very high level of achievements within 3M. Accelerating the innovations that go into development and getting better products out faster – clearly this ultimately leads to patient benefits.

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Q Could you describe Kindeva's customers? What are the challenges they are facing and how can Kindeva help them overcome current challenges?

A Our customers include large global biopharma players, particularly those who have historically focused on inhalation in asthma and COPD, and have more recently been tackling other disease states via the inhalation route. And at the other end of the size spectrum we have quite a number of smaller / start-up companies, for example in the immuno-oncology space and other complex vaccines. Here there is a lot of translational research, developments out of universities and so on. So we work globally and with companies of all sizes.

In terms of the challenges our customers are currently facing, clearly in the near term they are all considering the coronavirus outbreak and its aftermath. That's going to impact each of them differently dependent on their portfolios and their footprints. As a CDMO, Kindeva is there to support them as they navigate these obstacles.

More broadly, pharma is of course being challenged by the increasing costs and risks involved with successfully developing and commercialising a product. We all read in the press what the cost of a success is, how it's rising, how the timeline is stretching out and how big pharma companies are facing challenges around capital and resources allocation.

In some ways that makes it just the right time for us to be establishing Kindeva as an independent company, as an even stronger partner to those customers. What we're capable of doing in terms of services at the complex end of the industry is in many instances exactly what they are looking for – partners with the expertise, the experience and the track-record to take on these difficult challenges and deliver successful products.

With more biologics coming through, and the increase in emphasis on the patient, looking into adherence and compliance, a company that's focused on drug delivery and development really can add value, for example by solving usability challenges, identifying failure modes, and the challenges of ensuring patients use their devices properly so that their therapy is effective. These things can sometimes seem quite simple to us, but not getting it exactly right and not providing the right technology and associated support to help a patient self-administer, can create a gap between what you expect to be the therapeutic outcome and the actual outcome.

Across the industry today, and especially in the inhalation field, environmental sustainability is a major consideration. Obviously as a major MDI manufacturer, sustainability is something that Kindeva is thinking deeply about and has policies on.

Our team has been addressing environmental issues for many years, all the way back to the transition from CFCs to HFAs and the Montreal Protocol. We played a significant role in helping customers migrate to HFAs then and, although we're not quite ready to share details yet, our team has been working on what the next generation looks like when it comes to reducing the environmental footprints of devices. We're also looking to develop the conversation beyond the environmental impact of a single device, to look at therapies that are more effective or easier for patients to use, including at home, and therefore patients get healthier faster and reduce their environmental footprint in other ways. It's a complex conversation but an important one. As Kindeva, we intend to play our part. Our teams have a deep understanding of all of this, and this is a terrific asset for our customers.

Q What Kindeva product/technology/service offerings will facilitate its growth?

A Our core activity will remain working to help our customers tackle challenges in inhalation and both active and passive transdermal delivery, including microneedles. Our conversations with customers are as much about the capabilities that we have and how we can use those capabilities to help them, as

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about the technology platforms with which we are most experienced.

As you can imagine, the formation of a new company marks a time for renewal, taking stock and thinking about new, different, better ways of doing things. It leads to us and our customers thinking about the possibilities of partnering and working in ways that perhaps we were not accustomed to whilst part of 3M. Those exciting sorts of conversations are already starting with our customers.

From December 2019, when 3M first announced the intention to divest the drug delivery business, support from our customers has been unwavering. Of course, they had questions, in particular about whether the new business would comprise the same people. And when we reply, "Yes, absolutely", they have been delighted. It's exciting to have this rush of inbound interest in Kindeva and dialogue with our customers. They see the same opportunities that we do.

ABOUT THE COMPANY

Kindeva Drug Delivery is a CDMO offering its partners integrated, end-to-end capabilities spanning formulation, product development, scale-up manufacturing and commercial manufacturing. Its full-service innovation offering covers: inhalation (pMDIs, DPIs, connectivity, nasal delivery); transdermal delivery (drug-in-adhesive systems, membrane systems, reservoir systems, gel patches); and intradermal delivery (microneedles based on solid and hollow microstructures). Kindeva Drug Delivery has locations in the US and the UK and employs over 900 people. It was formed in 2020 when 3M's Drug Delivery Systems business was acquired by Altaris Capital Partners for US$650 million, and renamed Kindeva. 3M retains a 17% minority holding and Kindeva benefits from its 3M heritage comprising >60 years' pharmaceutical development, commercialisation and contract manufacturing services experience across inhalation, nasal, transdermal and microneedles.

Kindeva DRUG DELIVERY

Aaron Mann
Chief Executive Officer
E: contactus@kindevadd.com

Kindeva Drug Delivery
42 Water Street
St Paul
MN 55170
United States

www.kindevadd.com