In this interview, following the award of a significant pharmaceutical product development grant, the completion of a major funding round and the appointment of a new chief executive officer, Charles Potter, PhD, Founder & Chief Business Officer of Glide Pharma, speaks exclusively with ONdrugDelivery Magazine about the next chapter in the development of a truly novel dosage form and delivery device.

Q1. Firstly, please could you tell us what is the Glide SDI® (Solid Dose Injector)? Why is it different?

When you think of an injection, typically you think of a needle and syringe and therefore the drug is in a liquid form. Glide Pharma has developed a very different technology where we are formulating and injecting the drug in a solid dosage form. So the technology is very different from any other system that is out there.

The only company that has ever developed anything for automatically injecting a solid before was PowderJect, whose technology injected powders. There are some products that have been on the market for a while that are delivered in a depot/implant form. The best known of these is Zoladex (AstraZeneca’s anticancer drug goserelin acetate) which is delivered through a needle and pushed out with a trocar under the skin. However, this is a clinical procedure that can only be carried out by trained healthcare professionals.

Glide, in contrast, has a very simple technology for delivering a solid dosage form, which can be used for self-administration of injectable drugs by patients in the home environment.

Q2. So how does the Glide SDI achieve solid dose delivery? How does it work?

The formulated drug is effectively the needle. We have a tiny dosage form, much smaller than even a grain of rice, and it has a point at one end (see Figure 1). The drug is formulated with excipients to ensure that the formulation is solid enough to penetrate the skin, and when the dosage has been pushed into the skin it dissolves and releases the drug or vaccine. The technology is applicable to drugs and vaccines of any molecular weight, although there is a limitation on the maximum dose that can be incorporated in a formulation. The excipients are chosen to give the drug stability as well as the physical strength to penetrate the skin.

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The cassette is a single-use, disposable component, prefilled with the drug in a sterile dosage form. The cassette is removed from its packaging and placed into the end of the actua-
tor, and the whole device is pushed against the skin. At a preset spring force, an audible click is heard signifying that the drug has been delivered. The cassette is removed from the actuator and thrown away and the actuator automatically resets ready for reuse.

Q3. Thinking about storage, this cassette is significantly smaller than, for example, a vial or prefilled syringe isn’t it?

Yes, this system would be smaller in terms of shelf space. The other crucial advantage in terms of storage is that because it is a solid dosage form it is potentially more stable than a liquid, and may not require cold storage. This means that storage in the home is significantly simpler of course, but there are also savings all the way down the supply chain from warehouses to transport and storage in the pharmacy. There are not only cost savings; a stable solid dosage form avoids a lot of issues too. There is evidence in the literature that up to 50% of vaccines end up getting thrown away because of breakages in the cold chain. If you don’t even have to have that cold chain, the advantages are clear.

Q4. In terms of its applications, how is the Glide SDI differentiated from other injection approaches such as traditional needle-based systems and NFI s such as liquid jet injectors?

Importantly, we push the drug into the skin. We do not fire the drug. Liquid jet injectors fire the drug at the skin and, depending on the velocity with which they fire it and depending on whether the skin is that of a male or female, older or younger, and depending on where it is administered – on the arm, or the leg, for example – it will go to different depths. Everybody’s skin is different.

The Glide SDI pushes the drug. It pushes it hard enough to get through the tougher skin of a ‘hairy male adult’ and then when it stops pushing the dosage stops moving. It is not moving fast, it is not a bullet. Therefore, we believe we are implanting to the same depth in the skin with every injection, independent of skin type, and anticipate a more accurate, reliable and repeatable delivery than perhaps even with a needle and syringe where the injection depth varies depending on injection technique.

We are also in control of the release profile. This is dependent on the formulation and we can formulate with sugar-based formulations which dissolve very quickly (within seconds) in the tissue and can release the drug with the same profile as with a needle and syringe. We can achieve bioequivalence with subcutaneous injection meaning our first products can be brought to market relatively quickly as differentiated generics. Or we can put polymers into the formulation causing the drug to be released over days, weeks or even months, depending on the polymers used. We can tailor the release profile and that is one of the key benefits of the technology. Additionally, in vaccine delivery, in a number of preclinical studies, we’ve demonstrated increased efficacy compared with needle and syringe. We have several sets of data already and are building on this. Vaccines are likely to become a big part of our business.

The device is a simple mechanical system.

Q5. How does the SDI benefit the patient, compared with other delivery systems? What sets Glide SDI apart?

We believe the Glide SDI will benefit people in three broad categories: patients, healthcare professionals and pharmaceutical companies. We offer significant benefits across all three of these key categories. The really major benefit for the patient is actually a benefit that feeds back to healthcare providers and pharmaceutical companies also. That benefit is compliance.
For any pharmaceutical treatment, patients not taking their medication is a major problem, and this is especially true of injections. A really simple technology is needed, which provides medication that patients are happy to take, and that is convenient for them to take in order to ensure that they will take it. When patients do take the medication, their disease is treated more effectively, healthcare costs are reduced, doctors are happy, and pharma companies are happy because their products are being used rather than wasted, and so there is a benefit across the whole system. Getting a product out there that patients are happy to use is really key for Glide Pharma. Indeed it’s crucial for the whole of drug delivery and it’s crucial for all of the pharma industry too.

Q7. A novel dosage form is transformative for the industry, but doesn’t the prospect of scaling-up the manufacturing of such a novel dosage form for market bring with it particular difficulties?

As well as being the most exciting thing about the Glide SDI, the fact that we have an entirely novel dosage form is at the same time the biggest challenge for us. We can’t just go and buy a tableting machine or ampoule filler off the shelf. We have to develop our equipment ourselves. Now whilst this is the biggest hurdle for us, it will also in time become one of our major strengths because once we have that in place, and we have the IP protecting it, we will have the patented process for manufacturing scale it. If we can emulate even just a fraction of the success that inhalers and patches have had, but we maintain the intellectual property for it, then we’re in a very strong position.

The key thing we are now doing but hadn’t done up to now is process development scale-up. But you need sufficient funds to put a pilot manufacturing scale process in place. This is why we’ve recently raised a larger amount in each funding round. That has allowed us to demonstrate that the technology works, that we can achieve good stability and that we can get very good vaccine responses. In particular, we have shown that the technology works in humans and that they like it.

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Q8. You invented the SDI technology back in 2001, creating the very first sharp, strong solid dosage forms at home in your kitchen. Glide now has a clinical-stage technology, which has attracted significant funding, and a growing team. What has been the biggest challenge along the way?

I guess the challenges are two-fold. Funding is always a challenge and we’ve had a slightly unusual funding history in that all of our funding up until recently has come from business angels and small venture capital trusts in the UK. Most companies of our sort would have gone out and got the venture capital groups on board early on. We hadn’t, so we were taking on relatively small amounts of funding every year or two. That was great, it meant that we had some very supportive shareholders, and we could raise money fairly quickly, but we could only do a limited amount of work with each funding round. That has allowed us to demonstrate that the technology works, that we can do controlled release, that we can achieve good stability and that we can get very good vaccine responses. In particular, we have shown that the technology works in humans and that they like it.

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Q9. There have been three very significant developments at Glide Pharma recently: the awarding of a large grant from the UK Biomedical Catalyst at the end of 2012 for the
development of a new parathyroid hormone (PTH) product; the completion of a £14 million funding round at the end of February; and the appointment of a new Chief Executive Officer at the beginning of March. These are exciting times for the company. Can you tell me how these recent successes have positioned Glide for the next chapter in its story?

Yes, a couple of months ago we were awarded a £2.3 million pound grant from the Biomedical Catalyst, which is run by the UK Medical Research Council and the Technology Strategy Board, for the development of a PTH product. This is very important not only because this is a product development project that we have been eager to do, but also because when it came to the more recent investment round, we were able to say to investors that part of the funding would be matching the existing grant. The key purposes of the recent large investment funding are to demonstrate the manufacturing capability and also then to take our first products through into clinical trials.

Mark Carnegie-Brown coming on board as our new Chief Executive is an important part of this process. He will build the management team that will help him take the company through these next stages. He has extensive operational experience in the pharmaceutical industry and is well positioned to move the company forward from where we are now to bring the first products to market.

Up until now we have kept the number of employees to a minimum. At the point of the recent funding we were just twelve people. We have three new staff members starting in March and two more in April. We’re entering a period of scale up in order to manage both the PTH project and the other internal technology development programmes.

Q10. Can you tell us about the company’s business model and strategy, including key milestones and the planned timeframe for reaching them?

The technology is heavily patent protected. We have granted patents in most of the territories around the world and more patent applications coming through. This makes the technology applicable for the lifecycle management of drugs that are coming off-patent or which simply require a better delivery system, in addition to being suitable for new drugs coming onto the market, or for creating differentiated generic drug products.

We want to take our own pipeline forwards, firstly because it gets our first products to market more quickly and initiates a revenue stream and, secondly, this also demonstrates the commercial viability of the technology and that then mitigates the risk from the point of view of prospective pharmaceutical partners. When pharma companies can see products moving through the clinic and through the regulatory process then we are better positioned for larger licensing agreements with big pharmaceutical companies.

Because we can achieve bioequivalence with a subcutaneous injection with a needle and syringe, it means that we can select drugs that are coming off patent or that are off patent, reformulate them into a solid dosage form with all of the benefits we’ve talked about, and take them through the preclinical and clinical process. We will license them out at a later stage to partners as we are not going to do the sales and marketing, but we can add value to these products. To demonstrate the manufacturing process we have to put a real drug through it. We believe it should be one that is commercially viable and that we are adding value to. The PTH project is a great example.

Q11. How will the Glide SDI change the pharmaceutical industry?

We believe the Glide SDI has the potential to change the pharmaceutical industry by bringing out products that patients are happy to have administered or administer themselves, which will change their lives and change the way they take injectable drugs. Obviously it holds true that if a drug can be taken as a tablet then it will be. But for drugs that need to be injected we believe that this will be the patient-preferred way of doing things.

If we look beyond the developed world, into the developing world, we can potentially make a big impact. If you can get away from cold-chain storage, and you can get away from needles, and you can do it at low cost (we have a low cost disposable component), then you can really start addressing vaccination in the developing world. In this context our technology could have a phenomenal impact on the landscape for the pharmaceutical industry.

For now we have got to focus on the simple, immediate-release formulations. We now have the funding in place and we are focused on getting first products to market and into patients’ hands.

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Dr Charles Potter is the inventor of the Glide technology and founder of Glide Pharma. He holds an engineering degree and PhD from Cambridge University. He spent six years undertaking research within the Transplant Unit at Papworth Hospital, a specialist cardiothoracic centre, where he gained extensive medical experience. Charles has worked in four other successful start-up companies including nearly six years at PowderJect Pharmaceuticals where he saw the company grow from just five employees to over 3,000.

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