From Little Things, Big Things Grow— iCeutica's Product Pipeline is Blossoming

October 17th, 2013

Even for a company that likes rapid drug development, the cascade of events rolling out from iCeutica is exhilarating.

"We are an engine of new product creation," explained CEO Matt Callahan, describing what he called an exciting time for the company.

"We are expecting feedback from the FDA on our first partnered product, Zorvolex™, in the October time frame. This represents a major milestone for us, a validation of our SoluMatrix technology, but also of our business model for developing products with partners to move them rapidly to market."

Zorvolex is an improvement to the well-known drug diclofenac, a nonsteroidal medicine used by patients with arthritis for pain relief and to reduce swelling.

Another product developed in partnership with Iroko Pharmaceuticals in Philadelphia has now reached the New Drug Application (NDA) stage and another NDA is near submission on a third product partnered with Iroko.

At BioPharm America in Boston, iCeutica announced positive top-line results from its Phase I trial of ICE 1201, a submicron version of the muscle relaxant metaxalone, which is indicated for the treatment of acute, painful musculoskeletal conditions. Trial results demonstrated that the variability of the drug which is associated with increased CNS depression can be removed and that the improved SoluMatrix metaxalone has better oral bioavailability and more rapid absorption when compared to the currently marketed metaxalone product, SKELAXIN®.

Deep pipeline for partnering

Callahan is now setting meetings for November at BIO-Europe® 2013 in Vienna where he will present a portfolio of products which are either already in, or poised to enter clinical development in four therapeutic areas, including products for prostate cancer, migraine, lung cancer, leukemia, asthma, and COPD.

“We have shown the potential of the SoluMatrix technology for creating branded medicines with important clinical benefits and rapid pathways to market,” he said. “Now we’re keen to talk to people about partnering those products and their own ideas for applying this technology.”

iCeutica is built around a proprietary platform for transforming products with bio-availability challenges into new branded medicines with new patent protection.

But even though the technology is important to transforming the products, the critical focus is on the business case for each product.

“Payers do not reimburse technologies,” said Callahan. “The technology is important because it gives the improvement to the drug, but at the end of the day, you have to convince yourself and a partner that patients will see a real benefit, that payers are prepared to pay for that benefit, and that physicians understand the benefit and are ready to prescribe this significantly improved product.”

“The old model of having a technology and just running things through as a service does not create any value,” he said. “What creates value is products that get through clinical development and onto the market. Not many companies have both the technology and the capability to both conceive and execute on product development.”

At iCeutica an internal team analyzes the potential for a candidate program. After gathering data around the drug, the team interviews key opinion leaders in the targeted therapeutic space as well as panels of health insurance groups, physicians and patient advocacy groups to gather their opinions on the potential product.

Improving bio-availability

According to diverse industry studies, approximately 40% of the drugs that are now in clinical development and 25% of drugs currently being marketed have issues of bio-availability of the chemical entity.

“There is no end of products we can work with,” said Callahan.

The key for iCeutica is identifying where increasing bio-availability will improve the drug and whether that improvement provides a real clinical benefit and a reimbursable differentiation when compared with the original product.

The innovation of the SoluMatrix platform is an ability to make particles of drugs that are less than one micron in size.

“We work in the nano scale, and when you make things that small, they have much more surface area and dissolve much more quickly. By bringing a drug particle down so small we can improve the bio-availability of that drug, as well as imparting a range of different benefits,” Callahan explained.

For example, faster dissolution means pain drugs work more quickly, the dose of a cancer therapy can be reduced so that a patient can be given less drug to achieve the same effect, and potential side effects of a drug can be reduced or eliminated, because there is less of the drug unused in the body.

Balancing risk with partners

Because there are multiple projects the company can take on, Callahan said the team is careful about selecting programs.

“We look for projects that are very attractive from a partnering perspective, or which have very attractive markets where we can execute to get our improved product to the market in two to three years,” he said, adding, “The development cycle is very, very short, and the capital required for investment is much lower than for a traditional NCE development.

“We are in a comfortable position having generated money from milestones and now with royalties from the products that we can reinvest in our own clinical programs,” he said, “which gives us the ability to co-invest with a partner on a clinical program. It is fairly unique for a company of our size and our age.”

Balancing risk with a partner is a multifaceted proposition covering discussion of risk in capital management, the technical risk for the reformulation, and then the risk of getting a product into the market in a timely fashion to address a particular need.

Callahan and the iCeutica team will be on the hunt in Vienna for partners.

“On one hand we are constantly stimulated by some of the products that partners bring us where we see a real opportunity to create very valuable products that solve a problem for patients,” he said.

Meanwhile, “pharmaceutical companies are waking up to the idea that within their portfolio there are products that can be improved,” he said, adding that a reformulation with SoluMatrix adds a patent protection that extends by 18 to 20 years the life span of products.

“This is obviously very valuable for products doing more than a billion dollars annually,” Callahan said, “but equally there are opportunities in the fifty to one hundred million dollar range that don’t get attention which can be very profitable, if you can move quickly.”

A priority in Vienna will be meeting with potential partners for the products iCeutica has advanced on its own initiative to the clinical development stage.

Given the dearth of products coming out of pharma pipelines, the SoluMatrix engine at iCeutica is bringing new life to products which are now nearing first approvals and commercial launch.

“We are not going to run out of things to do,” said Callahan