

## Developing Prefilled, Size Efficient and Disposable Patch Pump Technology, SteadyMed Therapeutics, Inc. is focused on the Commercialization of their family of PatchPumps® that can be Customized to Deliver Liquid Drugs Subcutaneously in a Controllable Manner to Treat Rare Disease with Minimal Investment

Healthcare  
BioPharmaceuticals  
Pharmaceuticals  
Drug Delivery Therapeutics

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Jonathan M.N. Rigby  
CEO

### BIO:

Jonathan has been working in the pharmaceutical, biotech and drug delivery industry for over 20 years. In Mid 2011 he joined SteadyMed Therapeutics as the CEO to drive the strategic direction of the company and the associated financing, development and commercialization of its novel PatchPump® enabled Drug Delivery Therapeutics Programs. In August 2006, Jonathan co founded Zogenix (NASDAQ: ZGNX) and played a key role in its subsequent raise of ~\$250 MM venture financing, launch of its first product, SUMAVEL DosePro, in the U.S. in 2010 and an IPO later the same year. Prior to Zogenix Jonathan co-led the management buy out of the DosePro™,

single use, disposable, needle free delivery technology and associated assets from Aradigm Corporation, where he worked as Vice President Business Development. Earlier in his career Jonathan worked as the Head of Business Development and Head of UK Sales for Profile Therapeutics (Phillips), and held various sales, marketing and managerial positions with Bristol Myers Squibb and Merck. Jonathan is a frequent speaker at industry conferences in the drug delivery sector. Jonathan earned his undergraduate degree in Biological Sciences with Honors from Sheffield University, U.K. and an MBA from Portsmouth University, UK.

### SteadyMed Therapeutics, Inc.

SteadyMed Therapeutics, Inc. is a private, venture funded, Drug Delivery Therapeutics Company. We are leaders in the development and commercialization of prefilled, size efficient and disposable patch pump technology.

Our family of PatchPumps® can be customized to deliver liquid drugs subcutaneously, including biologics, with a wide range of volumes and viscosities, in a consistent and controllable manner.

Interview conducted by:  
Lynn Fosse, Senior Editor  
CEOCFO Magazine

**CEOCFO:** Mr. Rigby, what is SteadyMed?

**Mr. Rigby:** SteadyMed is a commercially focused, drug delivery therapeutics company, which means that we have a platform drug delivery tech-

nology that we are developing with our own pharmaceutical products to take all the way through to commercialization ourselves. In parallel with that we are licensing our platform technology to Biopharmaceutical companies.

**CEOCFO:** What is your technology?

**Mr. Rigby:** Our technology is called PatchPump® and this is the world's only prefilled single-use, disposable, high volume subcutaneous delivery system that is electronically controlled with a preset dose. In essence, it is a compact electromechanical pump into which we pre-fill small molecules or biologic drugs. We then exploit our technology called the ECell®, which is an expanding battery that compresses a reservoir within the PatchPump to deliver drugs into the subcutaneous layer of the skin for systemic absorption and therapeutic effect.

**CEOCFO:** What types of drugs would be appropriate for your technology?

**Mr. Rigby:** One of the key benefits of our technology is that it is applicable to a broad range of different types of drugs. More specifically, if you look at biologic drugs that are in development, there are around five hundred between Phase 1 and commercial launch. About half of those come in large volumes, high doses and high viscosities. Those drugs are applicable and amenable to delivery by the PatchPump. In addition, we are developing our own high-value small molecule product for an Orphan indication (a rare life threatening disease) for delivery by the PatchPump.

**CEO CFO:** Regarding the class of drugs that you will be working with, has the medical community been looking for a better means of delivery, and what would you be replacing?

**Mr. Rigby:** Yes, the system that we are looking to replace is large, cumbersome, complicated, bulky and inconvenient. The patient has to transfer drugs from a vial via a complex system into the pump that is currently used as well as having to program the dose themselves. Our goal is to improve the quality of life of these very sick patients by replacing that system with a simple, convenient PatchPump that comes to the patient prefilled with drug and preprogrammed with the desired dose, making it much easier, more discreet, more convenient and potentially reducing user error.

**CEO CFO:** What are some of the conditions for which people would need this regularly?

**Mr. Rigby:** There is a disease called pulmonary arterial hypertension (PAH). This is a rare disease, which affects around 35,000 to 40,000 patients in the United States. It is a very serious condition and if these patients are not treated, unfortunately the prognosis is poor. There are drugs delivered subcutaneously to treat this condition and our goal is to improve the delivery of these therapeutics in these very sick patients.

**CEO CFO:** Where are you in the development process?

**Mr. Rigby:** We are finalizing the design and performance of our platform. We are currently putting in place small-scale commercial manufacturing. We are planning to do our pivotal trials for our lead drug 2013 with the goal of launching that product on the

market in the US in 2014 ourselves and in Europe around the same time with a partner company.

**CEO CFO:** Does SteadyMed Therapeutics have adequate funding for the next steps?

**Mr. Rigby:** We are very fortunate. We recently closed a \$10.4 million round of financing on top of \$2.4 million earlier in the year. We are capitalized to go through a pivotal inflection point i.e. the filing of our first New Drug Application (NDA) for our lead product, so financing the company, with such an attractive commercial opportunity, should not be a problem.

**CEO CFO:** How will the licensing work for you?

**Mr. Rigby:** If you look at our industry, most of the drugs in development are

evaluations with a number of biopharmaceutical companies that are looking to PatchPump as a platform technology for delivery of their pipeline biologic products.

**CEO CFO:** You have a long history in the industry. What important lessons are you able to bring to the table at SteadyMed?

**Mr. Rigby:** I would say the ability to really identify an unmet market need, being able to identify a pathway where from a technical and regulatory perspective as well as a financial perspective, you are able to follow and take your own products to market. One of the key things I have learned is that partnerships and licensing is a great model, but that model alone is very high-risk. Partners, come and go, so being able to develop and leverage

our own technology to develop our own drug product and take it all the way to market, is key. I have done this with success before.

**CEO CFO:** Why should the business and investment community pay attention to SteadyMed Therapeutics?

**Mr. Rigby:** SteadyMed should stand out because we have a truly unique technology to capitalize on the delivery needs of biopharmaceutical products. Secondly, they should be watching us closely because we have a great strategy where we can commercialize our own high value drug product to treat a rare disease with minimal investment, minimal risk and large returns. Lastly, our business model affords multiple exit opportunities and allows us to become a profitable commercial entity in the US and Europe in the near future.

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**- Jonathan M.N. Rigby**

biologic products. The companies that are developing these drugs are facing some delivery challenges in so much that about half of them are in high volume, high doses, and they can be highly viscous. For drugs that are delivered in small volumes, i.e. less than one milliliter, there are plenty delivery systems for biopharmaceutical companies to choose from, including auto-injectors and needle-free injectors. Once you get over the one-milliliter volume, there are very few delivery systems that can deliver these biologics. The only one that is available to biopharmaceutical companies, which is prefilled with drug is the SteadyMed PatchPump. We are actively engaged in discussions and

