



Issue: August 20, 2012

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For Affinium Pharmaceuticals, Ltd., taking the Path of a Safe, Potent, Targeted Spectrum Antibiotic will be Revolutionary, with their Lead Clinical Compound AFN-1252 Focused on Both Oral and IV Treatment of Staphylococcal Infections, including MRSA and other Drug-Resistant Strains

Healthcare Pharmaceuticals (Private)

Affinium Pharmaceuticals, Ltd.

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Owen Roberts Chief Financial Officer (oroberts@afnm.com)

BIO:

Owen G. Roberts, CFA is the Chief Financial Officer and a founding executive of Affinium. In 1998 he helped create Borealis Biosciences, one of two companies which would merge to form Affinium in 2000. In his capacity as head of Affinium's financial operations, Mr. Roberts has raised over US\$55 million of international private

equity, over US\$25MM in secured and convertible debt, negotiated inlicensing, asset purchases and collaboration agreements with global pharmaceutical companies, and in 2007 lead the company's current US\$18MM Series A financing. Prior to joining Affinium, Mr. Roberts spent over 10 years as a corporate finance executive with major US financial institutions where he led the structuring of debt for major North American clients. A graduate of McGill University, Mr. Roberts is also a Chartered Financial Analyst.

Company Profile:

Affinium is a specialty pharmaceutical company developing a novel class of antibiotics that target the bacterial fatty acid synthesis (FASII) pathway. AFN-1252, our lead clinical compound, is a highly-potent, small molecule antibiotic for both oral and IV treatment of staphylococcal infections, including MRSA and all other drug-resistant strains.

Established in 2000 to commercialize its structure-guided drug development expertise, Affinium has focused since December 2002 on small molecule antibacterials which inhibit the FASII pathway and has built an international patent portfolio of more than 1,700 compounds, targets and assays in this new therapeutic class. Affinium's first clinical candidate, AFN-1252, has demonstrated excellent tolerability in multiple phase 1 clinical trials with an oral formulation. A Phase 2 oral clinical trial and preclinical development of an IV formulation for AFN-1252 are ongoing.

Affinium is headquartered in Austin, Texas, with operations in Toronto, Ontario. Affinium is interested in worldwide out-licensing of AFN-1252 and other active small molecules that exhibit in vitro antibacterial activity against additional relevant pathogenic bacteria.

Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine

CEOCFO: Mr. Roberts, what was the vision when Affinium was founded? Mr. Roberts: Originally, back in 2000-2001 when Affinium founded as a structural proteomics company. Our goal at that time was to solve the three-dimensional structures of multiple proteins around certain therapeutic areas. Our first therapeutic area of interest was in antibiotics and specifically the protein structures of staphylococcus aureus. We continued on that path until about 2002 when that business model really fell out of favor and it was obvious that the competition from academia, would not allow us to earn sufficient returns on the services and databases we were providing to reinvest enough capital in the company and stay at the cutting-edge. At that time, we also started converting ourselves into a therapeutic company. And as we had the strength in antibiotics from our initial projects we moved into antibiotics as our first therapeutic area.

CEOCFO: What is happening today? **Mr. Roberts:** Well since 2002 when we became a therapeutics company, we commenced work on antibiotics specifically for staphylococcus

aureus. We have moved that program through steadily, from the early discovery phases into preclinical work in 2005-2008 and then into the clinic in 2008-2009. Right now our lead clinical program which is AFN-1252 is a very potent oral and IV anti-staff drug that can be used for a wide variety of infections as monotherapy for confirmed staphylococcal infections, or in combination therapy when staphylococcus is suspected. Right now, we have a Phase 2 trial ongoing in which we are about 40 percent completed. Our IV program is working through preclinical studies with the expectation that we will have our IND filed at the end of this year or first quarter of next year.

CEOCFO: What does your drug do that others do not?

Mr. Roberts: There are several key differentiators. One, our drug is highly potent. It is potent against all staph strains and any resistance mechanisms. It is a new class, new mechanisms.

nism action. There haven't been any new classes of antibiotics since oxazolidinonels were introduced about twenty years ago. This will be the first

new class. It is also very selective. It targets only staphylococci. Therefore, it is less likely to cause antibiotic induced diarrhea, or candidiasis. Therefore, it will be much safer. It has no activity against human enzyme targets, so it should have fewer sideeffects. With the oral and IV formulations, patients can start an IV in the hospital and provide positive pharmaco economics allowing the physician to quickly to get the patient out of the hospital and onto the oral antibiotic. Dosing flexibility along with its excellent tolerability will give AFN-1252the opportunity to be used for very serious staph infections that sometimes take extended periods of time and therapy.

CEOCFO: Is the speed and the lack of side-effects the most important aspect, and how does it act in the body?

Mr. Roberts: Our drug is a Fabl inhibitor. The bacterial pathway for creating fatty acids is very different from a human system, which is the FAS II system for creating fatty acids. Our

antibiotic inhibits the Fabl enzyme which is a critical step in the synthesis of fatty acids in staph aureus. Fabl is unique to staph aureus and a select other set of bacteria. This is what gives it the selectivity such that AFN-1252 will not disrupt other important and beneficial bacterial flora inside the human body. Additionally, since there are no other antibiotics that targets the Fabl directly; there is currently no resistance to this class of therapeutics.

CEOCFO: We know staph is a problem and people are working on it. Are there many competing ideas and concepts? What makes you feel confident Affinium has chosen the right path?

Mr. Roberts: The antibiotic world is kind of at a fork in the road. For years, industry has been developing broad spectrum antibiotics. If someone has an infection they take a broad spectrum antibiotic which hits many bacteria. That both helps cure the

"We believe taking the path of a safe, potent, targeted spectrum antibiotic will be revolutionary" - Owen Roberts

actual infection but also has a lot of off-target effects including resistance, or as I mentioned before, the reduction of good flora that you have in your body that you need specifically in your intestines. At this fork in the road we can chose to continue to develop third and fourth generations of different classes of antibiotics, each one improving slightly on the potency, and side-effect profile. However, the law of diminishing return is starting to occur down this path. We are taking a different path at this fork. We believe taking the path of a safe, potent, targeted spectrum antibiotic will be revolutionary, because now we are only going to treat the bacteria causing the infection. This is a different mindset and not everyone will be accepting of it. There are some very good companies working on very good fourth and fifth generation class with existing antibiotics and there will be a market for broad spectrum drugs. Broad spectrums are not going to disappear. However, there is a very important place for a targeted spectrum therapeutic. In our case, when you know

that you have a confirmed staph infection, often because the initial broad spectrum has failed because of class resistance, or with a deep-seated infection or some other kind of infection where you are aware that it is staph.

CEOCFO: Has the medical community started to take notice or is it still too early?

Mr. Roberts: We believe the medical community has definitely started to pay attention to this. In fact, modern antibiotics stewardship policies are already promoting the use of the narrowest spectrum agents possible. This is becoming a policy of the IDSA. They themselves are questioning, "why we are using broad spectrum antibiotics which have so much offtarget side effects and cause resistance pressure on the other flora on the body". If you come in with a staph infection and you get treated with a broad spectrum antibiotic, what you can have is off-target resistance pressure created. That is the significant

problem with broad spectrum drugs. Whereas, from our perspective people are starting to understand the benefits of narrow spectrum antibiot-

ics. Doctors are excited about that, here for the first time they have the chance that if someone has a staph infection, they can just to treat them for the staph infection.

CEOCFO: Development is always expensive. Is Affinium Pharmaceuticals funded to get to the next level? Mr. Roberts: We have been very lucky to get great support from our existing investors. We just closed a \$17 million financing in August of 2011. We closed the second and final tranche of that financing in March of this year. This is more than sufficient funds to take us through what we believe is the critical value inflection of completing our Phase II oral study. developing and completing Phase I IV studies early next year, and to do important animal studies that will help build out the case of how you can use AFN1252 for important therapeutic indications, particularly long-term usage of the antibiotic.

CEOCFO: What are your plans for commercialization?

Mr. Roberts: Our company was built to be partnered or sold. We have been run as a virtual company. We have two people located up here in Toronto full-time. One person, our chief medical officer is located in Austin Texas. We use a number of consultants throughout North America and through Europe as well who are very important in assisting us in developing and doing our clinical and preclinical development. We do not see taking this company through to full commercialization while we look to partner or sell the company outright

in the next eighteen or twenty-four months.

CEOCFO: Why should investors pay attention to Affinium Pharmaceuticals today?

Mr. Roberts: First off, staph infections kill more people than AIDS or influenza in North America. It is a very serious disease. There is an incredible medical demand for improvements and new drugs which are more potent, safer, and flexible. Secondly, we believe this will be the first targeted spectrum antibiotic on the

market and this could have a significant change. When people see how this product is utilized by the medical community and is very profitable, it will be beneficial to other investors to look at other companies that are developing narrow or targeted spectrum antibiotics for other very important diseases. Therefore, there will be other investment opportunities for companies that are developing antibiotics with the same targeted spectrum philosophy that we have.



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