

Five minutes with...

Al Altomari of Agile Therapeutics

Al Altomari is president and CEO of Agile Therapeutics, a privately-held Princeton, New Jersey firm targeting the \$4bn female contraceptive market. It is currently developing a once-weekly, low-dose combination contraceptive patch, incorporating the firm's Skinfusion transdermal drug delivery technology



Al Altomari

Clinica: Why has Agile decided to focus exclusively on the female contraceptive market?

Al Altomari: Our patch technology can be applied across a range of therapeutic areas. However, we decided to focus initially in the female contraceptive market because we believe our contraceptive patch product AG200-15 will fulfill a currently unmet need for a more convenient low-dose combination hormonal contraceptive that is safe and effective. The current market is

large, well-established and grosses over \$4bn annually, with the "contraceptive population", or women of childbearing age, expected to grow 5.5% in this decade. Key players in the female hormonal contraceptives market right now include Bayer, Merck, Warner Chilcott, Teva and Pfizer; [Johnson & Johnson's] Ortho Evra is the only commercially available contraceptive patch currently on the market.

Clinica: How does Agile's contraceptive patch distinguish itself from its rivals?

AA: Unlike Ortho Evra, which utilises norelgestromin and ethinyl estradiol, AG200-15 contains the active ingredients levonorgestrel (LNG) and ethinyl estradiol (EE), both of which have a well-established history of efficacy and safety in combination [oral] contraceptives. Another key differentiator between AG200-15 and Ortho Evra is that in a pivotal pharmacokinetic study comparing AG200-15 to a low-dose oral contraceptive, AG200-15 was shown to deliver an EE dose comparable to an oral dose of 30µg/day. On the other hand, since its market launch, Ortho Evra has been re-labelled at the request of the FDA due to an EE dose that exceeded that of low-dose oral contraceptives and this has raised safety concerns.

As opposed to oral contraceptives, which women are required to take daily to prevent pregnancy, the AG200-15 patch is applied once weekly for three weeks. It may be applied to the abdomen, buttocks, or upper torso, is soft and flexible with a cloth-like, silky feel, and designed to provide excellent adhesion, comfort, and appearance.

Clinica: Agile was founded in 1997 and your key products are still in clinical trials, albeit at an advanced stage. Are

these long timelines typical for a speciality pharma company such as Agile?

AA: We look at Agile's evolution as having two phases. When the company was initially established, we were research-focused. It took several years and a lot of experimenting to determine which was the best pharmaceutical product for delivering the right dose of both ethinyl estradiol and levonorgestrel over seven days. At the same time we had to ensure the patch would adhere to the skin with little irritation. Once we pinpointed AG200-15, we transitioned to a company with a commercially viable product. The development of AG200-15 has been accomplished in a rapid time frame.

We expect to close out our AG200-15 Phase III study in late 2011 and to file our new drug application (NDA) with the US FDA in the first quarter of 2012. This means that the timeline from the point where we identified our lead compound to filing our NDA will have been five years. When you look at other pharmaceutical and speciality pharmaceutical companies, this timeline is rapid for new drug development.

Clinica: What have been the biggest challenges for a CEO in trying to keep the momentum going in a venture-backed company?

AA: From my perspective, it is important to identify the right talent. We've surrounded ourselves with employees and key advisors who understand what it takes to bring a product to market. I feel that we have a team of the best possible individuals to be successful.

I've also found it is important to set clear and measurable milestones with your investors. Once you have these in place, it is a matter of executing them on time and under budget.

Clinica: You spent over a decade at Johnson & Johnson. What have been the key lessons you learnt there that have been invaluable in your experience leading other companies?

AA: The two key things that I have taken from my experience at Johnson and Johnson and applied to the rest of my career are the principles of "playing to win" and setting high standards. What I mean by "playing to win" is that you have to go into each opportunity and strive to become the market leader. Our goal is not to bring a good product to market but to take the time to develop a great product.

Al Altomari was talking to Tina Tan.

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