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New Patents Could Sustain Allergan Restasis Franchise Until 2024

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In its most recent quarterly results, Allergan (NYSE:AGN) stated that its Restasis product had \$239.3M in net sales for the three months ended September 30, 2013, and \$662.4M in net sales for the nine months ended September 30, 2013. Allergan gave guidance that it expected Restasis to have net sales for the full year of 2013 of \$900-920M. This is roughly 15% of Allergan's total expected annual product sales. Thus, Restasis appears to be a very important product to Allergan.

Restasis is a drug that was approved by the FDA in December 2002. Its active ingredient is cyclosporine (0.05% strength) and it is an ophthalmic emulsion. Allergan stated in its most recent 10-Q that "The U.S. Patent covering Restasis will expire in May 2014." Indeed, the FDA's Orange Book listing of patents for Restasis currently contains only one patent, U.S. Pat. 5,474,979 ("the '979 patent"), which expires on May 17, 2014. Fear of generic competition for Restasis sent Allergan's shares down more than 10% last summer when the FDA issued guidance for how generic forms of Restasis could be developed.

This morning, the U.S. Patent and Trademark Office issued a new patent to Allergan for "Methods of Providing Therapeutic Effects Using Cyclosporin Components." This is the second patent the Patent Office issued in as many weeks from the same family of applications that date back to September 2003. There will be a third patent from the family issued next week and at least two more issued in the near future. Specifically, on December 31, 2013, the PTO issued U.S. Pat. No. 8,618,064 ("the '064 patent"), and today the PTO issued U.S. Pat. No. 8,629,111 ("the '111 patent"). Any patents issued from this family, including the '064 and '111 patents, will have a term that extends to at least 2024, a decade longer than the only current Orange Book patent for Restasis that expires in a few months.

While the '064 patent claims, "A method of treating or preventing corneal graft rejection ...," which may not effectively protect Restasis from generic competition, the brand new '111 patent issued this morning broadly claims, "A topical ophthalmic emulsion for treating an eye of a human comprising cyclosporin A in an amount of about 0.05% by weight"

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Thus, it seems to be a broad patent that Allergan can list in the Orange Book and assert against any potential generic challenger to Restasis. Indeed, Allergan filed an 8-K with the SEC this morning stating, "The Company has submitted the '111 Patent for listing in the United States Food and Drug Administration (the "FDA") publication Approved Drug Products With Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The '111 Patent will expire in August 2024."