

WE AIM TO STRENGTHEN OUR NEUROSCIENCE POSITION THROUGH FURTHER GROWTH OF THE *SEROQUEL* FRANCHISE, BRINGING NEW VALUE TO PATIENTS AND DOCTORS WITH *SEROQUEL XR* AND BY THE SUCCESSFUL INTRODUCTION OF A RANGE OF LIFE-CHANGING MEDICINES AIMING TO MEET SIGNIFICANT MEDICAL NEED IN PAIN CONTROL, NEUROLOGY AND PSYCHIATRY.

PRODUCTS

Seroquel is a leading atypical anti-psychotic for the treatment of schizophrenia and bipolar disorder. During their lives, about one person in every 100 will suffer from schizophrenia and about one in 20 will suffer from bipolar disorder. Launched in 1997, we estimate that *Seroquel* has been prescribed to more than 25 million patients worldwide. *Seroquel XR* was launched for the treatment of schizophrenia in the US in 2007. It is an extended release formulation that offers patients and doctors a once-daily schizophrenia treatment that can be given at the effective dose range by the second day of treatment. Its clinical development programme and planned regulatory filings extend through bipolar disorder to major depressive disorder (MDD) and generalised anxiety disorder (GAD).

Seroquel remains the most commonly prescribed atypical anti-psychotic in the US, where it is the only anti-psychotic approved as monotherapy treatment for both bipolar depression and bipolar mania. Its benefit/risk profile includes proven efficacy across a range of symptoms in schizophrenia and bipolar disorder as well as a tolerability profile that is differentiated from competitors.

In November 2007, the US Food and Drug Administration (FDA) approved *Seroquel XR* for the prevention of relapse in schizophrenic patients already benefiting from *Seroquel XR* treatment. Regulatory submissions for *Seroquel XR* in the US for the treatment of bipolar mania and bipolar depression were made in December 2007. Data from the studies on which the filings were based will be presented at major scientific congresses in 2008. Regulatory submissions in the EU are planned in these areas in the first quarter of 2008.

Seroquel bipolar maintenance clinical study data were presented for the first time in 2007 at the European Congress of Psychiatry, in Vienna. They showed that patients receiving *Seroquel* plus baseline treatment (lithium or divalproex) experienced a 72% reduction in the risk of relapse when compared with those receiving baseline treatment alone and this reduction in risk was similar for both manic and depressed events. In July 2007, AstraZeneca submitted a supplementary new drug application to the FDA for a new indication for the use of *Seroquel* as an adjunct to a mood stabiliser for the maintenance of effect in patients with bipolar disorder, based on data from two similar clinical trials. Pooled data from the bipolar maintenance studies showed a greater incidence of blood glucose increases to hyperglycaemic levels in patients randomised to *Seroquel* and mood stabiliser than in patients randomised to placebo and mood stabiliser. Appropriate *Seroquel* labelling revisions have been submitted to regulatory authorities, with implementation subject to local regulatory requirements.

The large *Seroquel XR* clinical trial programmes for MDD and GAD are planned to enrol more than 7,000 patients in total. They progressed during the year, with completion of the majority of the studies and first presentation of both MDD and GAD data in December 2007 at major international congresses. We expect to make US regulatory submissions in these areas in the first and second quarters of 2008 and EU regulatory submissions in the third and fourth quarters of 2008.

AstraZeneca Pharmaceuticals LP, either alone or in conjunction with one or more affiliates, is defending more than 8,100 served or answered lawsuits involving approximately 12,350 plaintiff groups who have filed *Seroquel*-related product liability claims in the US and Canada. Although the nature of the alleged injuries is not clear from the face of most of the complaints and discovery of the cases is continuing, plaintiffs generally contend that they developed diabetes and/or other related injuries as a result of taking

Seroquel and/or other atypical anti-psychotic medications. Further information can be found in Note 27 to the Financial Statements on page 158.

In April 2007, we filed a patent infringement action in the US District Court for the District of New Jersey, seeking an injunction and other remedies against Sandoz, Inc, following receipt of a notice from Sandoz informing us that it had submitted an abbreviated new drug application (ANDA) to the FDA for approval to market a generic version of *Seroquel* 25mg quetiapine fumarate tablets. In June 2007, we filed a third patent infringement action against Teva Pharmaceuticals USA Inc. in the US District Court for the District of New Jersey following receipt of a notice from Teva that it had supplemented its ANDA for generic *Seroquel* tablets a second time, adding 50, 150, and 400mg tablets to the application.

As a result of the expiration of 30-month stays during which the FDA may not approve ANDAs, an 'at risk' launch by Teva of 25, 100, 200 and/or 300mg quetiapine fumarate tablets may occur in the US in 2008. We continue to have full confidence in our intellectual property protecting *Seroquel* and will vigorously defend and enforce it. Details of the litigation against generic drug manufacturers in respect of *Seroquel* are set out in Note 27 to the Financial Statements on page 158.

Zomig is available in a unique range of formulations, offering physicians a choice of ways to provide rapid relief for migraine patients. *Zomig* remains the prescription market leader in Europe. *Zomig* Nasal Spray delivers fast pain relief, offering migraine patients with nausea and vomiting an alternative route of administration and now accounts for 7% of *Zomig* global sales. *Zomig* Rapimelt is a melt-in-the-mouth formulation offering patients a convenient, orange-flavoured tablet that can be taken without liquid whenever a migraine attack strikes. *Zomig* Rapimelt now accounts for more than 37% of *Zomig* global sales.

Diprivan is the world's best-selling intravenous general anaesthetic. More than 90% of total *Diprivan* sales consist of *Diprivan* EDTA, a microbial-resistant formulation, which is approved in the majority of markets. The EDTA formulation was approved in France in September 2007.

Naropin was approved during the year in the Czech Republic, Mexico, Australia and Finland for extended use in paediatric patients to include neonates and infants aged below one year old.