Expert therapy area review of the key market players and deals highlights for leading areas of industry investment and development. These insightful reviews are based on the strategic data and insights from Thomson Reuters Cortellis™ Competitive Intelligence.

IN THIS ISSUE

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ABSTRACT

Depression represents a huge pharmaceutical market opportunity. There are approximately 350 million people worldwide with depression, and it is the leading cause of disability in the world. In the U.S., 9.1 percent of the population suffer from depression. Globally, fewer than half of depression sufferers receive treatment for their illness, and in some countries this figure falls to fewer than one in 10. The high incidence rate, combined with limited market penetration, makes depression a high potential market for pharmaceuticals. However, companies developing drugs for depression also face a number of serious challenges. Psychosocial treatment options remain the preferred first-line therapy ahead of medication—and when it comes to drug treatment, the abundance of generic options available has significantly contributed to halving the value of the branded antidepressant market over recent years. Another hurdle faced by new drugs is the requirement that all antidepressants carry a black-box warning regarding the increased risk of suicide in children, adolescents and young adults, which limits their use in this population. Switching between medications presents both an opportunity and a challenge, as a significant number of patients will switch away from their first medication within the first year of treatment. The lack of complete understanding of why depression occurs also makes this area a difficult one, although it opens the door for the development of drugs with novel mechanisms of action.
SECTION I

INTRODUCTION

The American Psychiatric Association defines depression, or major depressive disorder (MDD), as a chronic medical illness “that affects how you feel, think and behave causing persistent feelings of sadness and loss of interest in previously enjoyed activities.” According to the American Psychological Association, the condition is the most common mental disorder and symptoms include “a lack of interest and pleasure in daily activities, significant weight loss or gain, insomnia or excessive sleeping, lack of energy, inability to concentrate, feelings of worthlessness or excessive guilt and recurrent thoughts of death or suicide.” In the U.S., the Centers for Disease Control and Prevention state that 9.1 percent of the population has depression. Globally, World Health Organization (WHO) figures show that 350 million people have depression, and that the condition is the leading cause of disability worldwide. Despite the prevalence and significant impact of this disease, less than 50 percent of those affected receive treatment—in some countries it is less than 10 percent (see Figure 1). The WHO attributes this to a lack of resources, healthcare professionals and accurate diagnoses, plus the social stigma that many people attach to mental disorders. While these factors are significant barriers to drug penetration into a large untapped market, they also represent an opportunity for drug companies to address via educating patients and the general population.

“Depression is the leading cause of disability worldwide, and is a major contributor to the global burden of disease.”

World Health Organization
SPOTLIGHT ON... DEPRESSION

350 million people worldwide have depression. 9% of the US population has depression. Less than 50% of depressed people globally get treatment. In some countries, less than 10% get treatment.

FIGURE 1: DEPRESSION REPRESENTS A LARGE MARKET OPPORTUNITY
Depression has been treated with a number of blockbuster drugs, but these have been severely impacted by patent expiration. At its peak in 2003, the branded depression drug market was worth almost $15 billion, but by 2012 the market had lost almost a third of its value, with sales of $9.560 billion reported that year (see Figure 2). Consensus forecasts from Thomson Reuters Cortellis™ Competitive Intelligence anticipate an even steeper decline from 2013 to 2014, with 2014 forecast sales of $5.720 billion. The pharma companies have as yet been unable to produce new products that significantly differentiate themselves from generic formulations, resulting in the drop in market revenue we now see.

In 2003, sales of Zoloft (sertraline), Paxil/Paxil CR (paroxetine), Effexor/Effexor XR (venlafaxine), Celexa (citalopram), Wellbutrin SR and XR (bupropion), Lexapro (escitalopram), Prozac (fluoxetine) and Remeron (mirtazapine) totalled $14.755 billion. By 2012, all these drugs faced generic competition, and their combined sales had declined to $3.600 billion that year. Cymbalta (duloxetine) contributed a further $5.115 billion to the $9.560 billion 2012 total sales, having gained a 54 percent share of the market since its launch in 2004. However, the genericization of Cymbalta in December 2013 is expected to decimate its sales over the next few years, with consensus forecasts falling to $558.4 million by 2019. That year, the total value of the branded antidepressant therapeutic market is forecast to have fallen to $7.207 billion (see Table 1).
Generic competition is the major sales threat that branded antidepressants face, although it is by no means their only challenge (see Figure 3). Unlike many medical conditions, drug therapy is not the preferred first-line treatment for depression. The WHO recommends psychosocial treatments, such as cognitive behavior therapy, interpersonal psychotherapy or problem-solving treatment, as the initial approach for mild depression. For moderate-severe depression, drugs should be used alongside psychosocial therapy. The WHO’s advice is that antidepressant medication should not be used in children, and in adolescents should only be used with caution and not as a first-line therapy, as the drugs are associated with an increased risk of suicidal thoughts, feelings and behavior in these populations. Since October 2004, the Food and Drug Administration (FDA) has mandated that all antidepressants carry a black-box warning to this effect, and in May 2007, this was expanded to include young adults aged 18 to 24 years of age. However, the required warnings also carry the reminder that “depression and other serious psychiatric disorders are themselves associated with increases in the risk of suicide,” thus the risks from the disease versus those from the medication must be weighed when considering the use of antidepressants for adolescents and young adults. American Psychiatric Association estimates put the lifetime risk of suicide in people with depression between 2.2 and 15 percent, depending on the population studied, whereas an FDA meta-analysis of 372 randomized antidepressant trials conducted by 12 pharmaceutical companies in 99,839 subjects over 20 years showed the absolute suicide risk in patients taking investigational antidepressants was 0.01 percent, albeit over short trial durations typically of four to 12 weeks. Nevertheless, the off-putting effect of the black-box warning for potential patients and their physicians, in addition to the increased need to monitor patients in the early weeks of treatment when the risk is greatest, is another hurdle that drug developers must overcome in the marketing of their products.

“The real killer in this story is untreated depression, and the possible risk from antidepressant treatment is dwarfed by that from the disease.”

Dr. Richard A. Friedman and Andrew C. Leon, Ph.D., Weill Cornell Medical College

Nor is the marketing struggle over once a patient has begun taking a prescribed antidepressant. It has been stated that two thirds of patients fail to respond to initial treatment, and a significant number (estimates vary between 16 and 40 percent or more) switch to a different antidepressant, often within a few months of treatment initiation. The converse of this risk of losing first-line patients is the opportunity to gain second-line subjects as they switch away from their first medication. Thus not only is a drug’s efficacy important, but also factors such as side-effect profile and tolerability, as patients have a number of choices in the antidepressant field to choose from. This is particularly true as earlier antidepressant drugs were often associated with quite limiting side effects.

“While initial treatment is ineffective in about two thirds of patients, patients who have not responded to such initial treatments can be managed effectively.”

Dr. Larry Culpepper, Boston Medical Center
THE BIOLOGY OF DEPRESSION

The treatment of depression is made more complicated by the fact it is not fully understood. While neurostimulatory drugs are often effective, the reason for this is not entirely clear, nor have the biological causes of depression been elucidated. Potentially, this opens the field for the development of drugs with novel mechanisms of action, although the majority of current medications focus on altering the level of the monoamine neurotransmitter serotonin (SHT) in the brain. Other monoamine neurotransmitters targeted by antidepressants drugs include norepinephrine (noradrenaline) and dopamine.

Nerve impulses are conducted through the synaptic clefts between one neuron and the next via chemical neurotransmitters that are released from the presynaptic cell and which trigger a response in the postsynaptic cell by binding to receptors on its cell surface. The neurotransmitter can also bind autoreceptors on the presynaptic cell surface that trigger a reduction in the release of neurotransmitter via a negative feedback loop. Neurotransmitter remaining in the synaptic cleft is taken back up into the presynaptic cell, via a reuptake pump, and broken down by the enzyme monoamine oxidase (MAO). There are therefore a number of mechanisms by which drugs can influence synaptic neurotransmitter levels, with the aim of increasing the amount of transmitter free to bind to and activate the postsynaptic cell (see Figure 4).

MAO INHIBITION

MAO inhibitor (MAOI) drugs such as iproniazid inhibit the breakdown of monoamine neurotransmitters by MAO, resulting in greater levels of active neurotransmitter. These drugs were first used in the 1950s, but they are associated with significant side effects, including potentially fatal interactions with certain foods and medications, and their current use is therefore limited. The reversible inhibitor of MAO A (RImA) drugs, such as moclobemide, have a reversible, and therefore safer, effect on MAO, but are still rarely used.

NEUROTRANSMITTER REUPTAKE INHIBITION

Blockade of neurotransmitter reuptake pumps, also first produced in the 1950s by tricyclic antidepressants such as imipramine and amitriptyline, increases the concentration of active neurotransmitter in the synaptic cleft, thus enhancing postsynaptic cell activation. These drugs principally block the serotonin and norepinephrine reuptake pumps, increasing serotonin- and norepinephrine-mediated neuronal signalling. Due to their side effect profile, the tricyclics have been largely eclipsed by the selective serotonin reuptake inhibitors (SSRIs), of which Prozac was the first on the market in 1988, and later generations of serotonin-norepinephrine reuptake inhibitors (SNRIs).

FIGURE 4: NEUROTRANSMITTER TARGETS FOR DEPRESSION
SPOTLIGHT ON... DEPRESSION

RECEPTOR-MEDIATED MECHANISMS
Blockade of the negative feedback loop autoreceptors on the presynaptic cell by receptor antagonists can be used to prevent reductions in neurotransmitter release. The presynaptic 5HT 1A, 1B and 1D receptors are of this type, and some newer antidepressants utilize this approach as part of their mechanism of action. Direct activation of postsynaptic cell receptors by agents that act as agonists at these receptors is another method used by a number of antidepressant agents. This type of receptor includes the postsynaptic 5HT 1A type.

STRENGTHS AND WEAKNESSES OF KEY ANTIDEPRESSANTS
SSRIs currently form the mainstay of depression treatment, although the newer SNRI agents have been slowly gaining a share. Although there are a number of agents with alternate mechanisms of action, these are in the minority of the antidepressants currently on the market. Several of the key drugs on the market are discussed below (see Figure 5).

DRUGS LAUNCHED IN THE 1980S
WELLBUTRIN, WELLBUTRIN SR AND WELLBUTRIN XR
In 1985, Glaxo Wellcome (now GlaxoSmithKline; GSK) launched its norepinephrine and dopamine reuptake inhibitor Wellbutrin in the U.S., followed in 1997 by a sustained-release formulation, then in 2003 by an extended-release version. Wellbutrin XL is also indicated for preventing seasonal depression in patients with seasonal affective disorder. All three formulations require dose titration, and it was only by the third formulation that the drug was able to be dosed once daily, with the original and SR forms requiring three- and two-times daily dosing, respectively. In four- and six-week clinical trials, Wellbutrin improved scores on the Hamilton depression rating scale (HAM-D), HAM-D depressed mood subscale and clinical global impression (CGI) severity scale compared with placebo. The long-term use of Wellbutrin was not evaluated. Wellbutrin SR and XR were shown to have similar bioavailability to Wellbutrin. Wellbutrin SR was additionally shown to reduce the risk of relapse when assessed in an open-label 44-week extension to an eight-week trial.

All forms of the drug are associated with a small (0.4 percent) risk of seizures, and the XL formulation may require concomitant use of a sedative-hypnotic in the first week to reduce agitation, motor restlessness and insomnia. Dose reduction is required in subjects with hepatic or renal impairment. However, the Wellbutrin portfolio made sales of $2.109 billion at its peak in 2006, declining to $274.3 million by 2012.

PROZAC
Eli Lilly’s once-daily Prozac was the first of the SSRI drugs, entering the U.S. market in 1988, and has subsequently gained iconic status. Approval for depression was based on data from a number of studies assessing both the response to initial treatment and the drug’s effect on relapse rate. In five- to six-week studies in depressed patients over 18 years of age, Prozac achieved significantly improved HAM-D scores compared with placebo; subscores for depressed mood, sleep disturbance and anxiety were also improved significantly. Similar results were obtained in two six-week trials in patients aged over 60, and in two eight- to nine-week studies in pediatric subjects aged eight to 18. The drug was also shown to decrease the rate of relapse in a 50-week study in which participants received open-label treatment with Prozac for 12 weeks, followed by 38 weeks of blinded treatment with Prozac or placebo. Weekly rather than daily Prozac dosing was also shown to reduce relapse rate compared with placebo. Reduced dosing is recommended in the elderly and those with impaired hepatic function.

Prozac, which is one of the very few antidepressants approved for pediatric use (from age eight), also benefits from a broad label, in that in addition to depression it is approved for a number of other mental health conditions that have increased its sales and the awareness of the brand. These include obsessive compulsive disorder (OCD; including for pediatric patients from age seven upwards), bulimia nervosa, panic disorder with or without agoraphobia, and premenstrual dysphoric disorder (PMDD; under the brand name Sarafem). Prozac is also approved for use in combination with the adjunctive antidepressant agent olanzapine for the acute treatment of depressive episodes associated with bipolar I disorder and the acute treatment of resistant depression that has not responded to two prior therapies. Sales of Prozac reached $2.8 billion at their peak, but have declined significantly since generic entry in 2001. Sales in 2012 were $180.1 million, and consensus sales forecasts for 2019 are just $86.5 million.
CELEXA

The initial launch in a European country of the SSRI Celexa, developed by H. Lundbeck and marketed in the U.S. by Forest Laboratories, followed Prozac by only a few months (in 1989), but its U.S. market debut was a decade after that of Prozac (in 1998). With its more limited label of just depression in the U.S. and depression, OCD and panic disorder in Europe, its sales never matched those of its predecessor. Celexa’s peak sales were $2.111 billion in 2002, falling steeply to $337 million within three years as generics entered the market, and to $14.8 million by 2012. In two four- to six-week pre-approval studies, the drug improved HAM-D, HAM-D depressed mood subscale and CGI severity scale scores. However, no significant difference versus placebo was seen in three other depression studies. Longer-term studies demonstrated the ability of Celexa to reduce relapse rate. The maximum dose of the drug is limited in elderly patients and subjects with hepatic impairment.

DRUGS LAUNCHED IN THE 1990S

PAXIL AND PAXIL CR

The third SSRI on the market, GSK’s Paxil, achieved greater sales than either Celexa or Prozac. It was launched for depression in Europe in 1991 and in the U.S. in 1996, and subsequent approvals have given it a broad label for the additional indications of OCD, panic disorder with or without agoraphobia, social anxiety disorder (SAD), generalized anxiety disorder (GAD) and post-traumatic stress disorder (PTSD). In 1999, a controlled-release formulation of the drug, Paxil CR, gained U.S. approval for depression, which was later followed by approvals for panic disorder and SAD. Both formulations are dosed once daily. Peak sales for Paxil/Paxil CR, which were $3.089 billion in 2002, exceeded those of Prozac and Celexa. A generic version of Paxil was launched “at risk” in 2003, and although sales declined significantly, 2012 sales of Paxil/Paxil CR still exceeded the half-billion mark, at $592.7 million. Consensus forecast sales for 2019 are $215.9 million. Like the drugs described above, Paxil demonstrated its efficacy in both short-term studies and longer-term relapse-prevention trials. Although three placebo-controlled trials were conducted in children with depression, the results were not sufficient for the drug to be approved for pediatric use. As with other antidepressants, the maximum dose of the drug is limited in elderly patients and subjects with hepatic or renal impairment.

ZOLOFT

Another former blockbuster SSRI, Pfizer’s Zoloft, entered the U.S. and European markets in 1992, proceeding Paxil by a year in Europe, but preceding it by four years in the U.S. Zoloft was launched first for depression, with approvals in subsequent years for panic disorder with or without agoraphobia, OCD (including in children from six years of age), PTSD, PMDD and SAD. Its sales reached their peak in 2004 at $3.361 billion, exceeding even Paxil. The drug was genericized in 2006, and by 2012 sales had declined to $541 million. Sales of $350.5 million are forecast for 2019. Caution is required when treating patients with hepatic impairment, in whom doses should be lower or less frequent.
SPOTLIGHT ON... DEPRESSION

EFFEXOR AND EFFEXOR XR
In 1994, Pfizer launched Effexor as the first of the newer SNRIs on the market, and followed this three years later with an extended-release formulation, Effexor XR, that reduced Effexor’s dosing frequency from two or three times a day to the once-daily schedule common to previous antidepressants. Clinical studies of the Effexor/Effexor XR were similar to those of their predecessors. With a broad label, including GAD, SAD and panic disorder, Effexor/Effexor XR followed the trend of exceeding the peak sales of its predecessors on the market. It achieved sales of $3.928 billion in 2008, two years after the genericization of Effexor and two years before the entry of Effexor XR generics. Sales in 2012 were $541 million with forecasts that they will fall to $209.2 million by 2019. Significant dose reduction is recommended in subjects with hepatic or renal impairment.

REMERON
Schering-Plough (now Merck & Co) entered the field in 1994 with Remeron. In a change from the run of SSRI/SNRIs, Remeron increases noradrenergic and serotonergic neurotransmission via antagonism of presynaptic alpha-2 adrenergic receptors which are linked to the negative feedback loop that controls neurotransmitter release. However, Remeron’s label is limited to just depression, which is reflected in its limited sales. They reached their peak of $677.9 million in 2002, and by 2012 had declined to $232 million, with a further decline to $131.5 million forecast for 2019. Caution is advised when used in elderly subjects or patients with hepatic or renal impairment.

DRUGS LAUNCHED IN THE 2000S
LEXAPRO
Lundbeck and Forest followed up their earlier SSRI Celexa, a racemic mixture of the S- and R-forms of citalopram, with Lexapro, the S-enantiomer of citalopram. It was launched in the U.S. for depression in 2002, and for GAD in 2004. However, the FDA ruled the drug not-approvable for panic disorder and SAD due to issues relating to the supporting clinical data. Lexapro’s label is broader in Europe, where panic disorder, SAD and OCD are included in the approved indications. Despite this, Lexapro has one notable advantage over a number of its competitors, in that it is approved for use as an antidepressant in adolescents as well as adults, although the youngest age for use is older than that for Prozac, at 12 years of age rather than eight. Peak sales of Lexapro were $3.483 billion in 2010, followed by generic entry two years later, reducing 2012 sales to $1.340 billion. The maximum dose of the drug is limited in elderly patients and those with hepatic impairment.

CYMBALTA
Launched in 2004, Eli Lilly and Shionogi’s SNRI Cymbalta achieved multi-billion-dollar sales that exceeded those of its competitors, although not all of the sales were for depression. The drug is also approved for diabetic peripheral neuropathic pain (DPNP), chronic musculoskeletal pain and fibromyalgia pain, as well as depression and GAD, and the sales for both depression and pain are presented here (sales for its further use in urinary incontinence are not covered in this report). Cymbalta sales peaked at $5.115 billion in 2012, but generic entry in December 2013 is expected to see sales drop to a forecasted $558.4 million in 2019. The drug is contraindicated in patients with any hepatic insufficiency or severe renal impairment.
PRISTIQ

Pfizer’s SNRI Pristiq (desvenlafaxine) was launched in the U.S. in 2008, but efficacy concerns raised in Europe resulted in the withdrawal of a European filing. The drug had also been filed for U.S. and EU approval for treating vasomotor symptoms of menopause, but both filings were withdrawn after the regulatory agencies requested additional data regarding the risk of serious adverse cardiovascular and hepatic effects. Trials for fibromyalgia and DPNP had been conducted, but development for those indications was later dropped. Renal or hepatic impairment require dose limitation. The restrictions of the drug’s label are reflected in its sales, which were $630 million in 2012, after four years on the market. Sales are forecast to continue rising at least until 2019, but are still only expected to reach $923 million that year. Pristiq’s patent protection expires in 2022. More optimistically, a phase IV trial for SAD is being conducted, with data expected in January 2014.

DRUGS LAUNCHED IN THE 2010S

VIIBRYD

2011 saw the market entry of an antidepressant with a different mechanism of action from its predecessors. Forest’s Viibryd (vilazodone) inhibits serotonin reuptake, but also acts as a 5HT 1A partial agonist, with the aim of hastening the onset of therapeutic action by blocking negative feedback via the presynaptic 5HT 1A autoreceptors. Antidepressants typically take two or more weeks to show an effect, and it has been hypothesized that this is due to the time it takes for the autoreceptors to desensitize to the increased levels of serotonin in the synapses. Blockade (via partial agonist or antagonism) of 5HT 1A receptors would potentially enable this delay to be bypassed, and indeed in two eight-week trials, the drug showed significant effects relative to placebo as early as the first week. No dose adjustments are needed in the elderly or those with renal or hepatic impairment. However, these advantages may be offset by the need to titrate the dosing of the drug over two weeks, and its narrow therapeutic range whereby its upper therapeutic dose limit is close to that which produces intolerable side effects. Viibryd’s sales were just $162.5 million in 2012, with forecasts remaining below $500 million into 2019 when patent coverage will expire. The drug is currently indicated only for depression, but clinical studies for SAD and GAD are underway.

BRINTELLIX

Lundbeck and Takeda’s novel-mechanism drug, Brintellix (vortioxetine), shows much more market promise than Viibryd. It has a complex multimodal mechanism of action based on antagonism of the 5HT 1D, 3 and 7 receptors, partial agonism of 5HT 1B and agonism of 5HT 1A, plus inhibition of serotonin reuptake. The drug was approved in the U.S. and Europe in 2013 and is forecast to make sales of $1.739 billion by 2019, with three years of exclusivity remaining until patent expiration in 2022. Brintellix requires dose titration and is not recommended in severe hepatic impairment. However, it can be used in mild to moderate hepatic impairment and all stages of renal impairment (including end-stage renal disease) with no dose limitation. Phase III trials for GAD are being conducted.

FIGURE 7: SALES OF SELECTED ANTIDEPRESSANTS LAUNCHED IN THE 2000S

Lexapro (escitalopram)  Cymbalta (duloxetine)  Pristiq (desvenlafaxine)
SPOTLIGHT ON... DEPRESSION

Also launched in 2013 in the U.S. was Pierre Fabre and Forest’s SNRI Fetzima (levomilnacipran). However, there are no plans for an EU filing, and although trials in other indications such as anxiety and fatigue have been conducted, these are no longer in development, although a trial for increasing post-stroke recovery is underway. Sales forecasts are low, taking six years to reach just $325.9 million by 2019, leaving four years before Fetzima’s patent coverage expires in 2023. Like Brintellix, the drug requires dose titration. Additionally, dose reduction is required for moderate or severe renal impairment, and the drug is contraindicated in end-stage renal disease. However, it can be used in all stage of hepatic impairment without dose alteration.

ANTIDEPRESSANTS IN DEVELOPMENT

There are three notable drugs in development for depression, all with mechanisms of action that differ significantly from those drugs described above. As none of them have yet reached phase III development, their futures remain uncertain, although the data to date and current sales forecasts will be discussed (see Table 2).

ALKS-5461

Alkermes’ ALKS-5461 is a fixed-dose combination of the mu opioid receptor antagonist samidorphan and the kappa opioid antagonist, ORL1 partial agonist and mu opioid partial agonist buprenorphine that has been designed to act as a non-addictive kappa opioid antagonist for treatment-resistant depression. In a seven-day phase I/II trial completed in 2012, ALKS-5461 significantly reduced depressive symptoms in patients who had inadequate responses to either an SSRI or an SNRI. Similar data were reported from a four-week phase II trial in 2013, with a HAM-D score reduction of 5.3 points compared with 2.1 points for placebo. A pivotal phase III program, comprising three studies in 1,500 patients, is planned to start in the first quarter of 2014. The first sales for this drug are forecast for 2016 ($25 million), rising to $350 million by 2019, and Alkermes is looking to outlicense the drug.

RG-7090

Also expected to make its first sales in 2016 is Roche’s metabotropic glutamate 5 receptor (mGluR5) antagonist RG-7090. As yet, no phase II data have been reported for this drug, although results are expected during 2014 from phase II trials for depression and fragile X syndrome, a genetic condition resulting in a spectrum of intellectual disabilities. Forecast sales for 2019 reach $107.3 million.

RG-1578

Roche’s other mGluR antagonist for depression, RG-1578, works via antagonism of the mGluR2 and 3 receptors. In 2014, data from a phase II trial of RG-1578 as an adjunct for depression are expected. Sales are expected to climb from $57.4 million in 2017 to $679.2 million by 2019.
DRUG, DEVELOPER AND MECHANISM OF ACTION

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<tr>
<th>ALKS-5461 (samidorphan plus buprenorphine), Alkermes</th>
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<tr>
<td>• mu opioid receptor antagonist (samidorphan); kappa opioid antagonist, ORL1 partial agonist and mu opioid partial agonist (buprenorphine)</td>
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<tr>
<td><strong>KEY FACTS</strong></td>
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<td>The drug is designed as a non-addictive kappa opioid antagonist for refractive depression. Positive phase II data were obtained in 2013, and a three-trial phase III program is planned for 2014. First sales are forecast for 2016, rising to $350 million by 2019. Development partners are being sought.</td>
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<tr>
<td><strong>INDICATIONS UNDER DEVELOPMENT</strong></td>
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<td>Positive phase II depression data obtained; phase III development planned to start in early 2014.</td>
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<th>RG-7090, Roche</th>
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<tr>
<td>• mGluR5 antagonist</td>
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<td><strong>Phase II data are expected imminently.</strong> Like ALKS-5461, first sales are forecast for 2016, although they are forecast to reach only $107.3 million by 2019.</td>
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<td><strong>Phase II for depression and fragile X syndrome are anticipated.</strong></td>
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<tr>
<td>• metabotropic glutamate 2/3 receptor (mGluR2/3) antagonist</td>
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<tr>
<td><strong>Phase II data are expected in the first half of 2014.</strong> Sales are forecast from 2017, with forecasts reaching $679.2 million by 2019.</td>
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<td><strong>Phase II for depression.</strong></td>
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**TABLE 2: THE MAIN DRUGS IN THE DEPRESSION PIPELINE**

**CONCLUSION I**

Although depression is potentially a huge market opportunity, market penetration still remains low 25 years after the debut of the iconic antidepressant Prozac. In part, this is because psychosocial therapies tend to be preferred in the first line, especially in young people. The lack of available treatment resources, plus the stigma of mental illness, also prevents some patients from receiving or seeking appropriate care. The drugs themselves must also bear some of the responsibility. Recent analyses have suggested that in mild depression, medication may have minimal benefit, although its effect is substantial in severe depression. While the current medications of the SSRI and SNRI type have significant advantages over their predecessors, the MAOIs and tricyclics, there is very little to choose between these drugs in terms of efficacy. SSRIs tend to be preferred as a first choice, with SNRIs gaining modest ground. The vast majority of these drugs are now available as generics, which has contributed to a predicted halving of the value of the branded antidepressant market from 2003 to 2019. Interestingly, the three most notable drugs in the antidepressant pipeline are all different in their mechanism of action from the drugs already on the market. With only minimal data currently available for these agents, it remains to be seen how they will fare in large-scale efficacy trials.
SECTION II

DEAL HIGHLIGHTS

Deals coverage on Cortellis Competitive Intelligence indicates that around 535 deals have been forged since the mid-1980s for depression and depression-related diseases, including MDD. The following section reviews the licensing portfolio of a number of depression treatments on the market, as well as certain significant and promising therapeutic candidates within the field, as featured in Cortellis Competitive Intelligence. Other notable and high-value deals are also highlighted to give an insight into the depression market.

There has been considerable partnering activity in the field of depression, with analysis showing considerable interest from “Big Pharma.” However, it is Denmark-based H. Lundbeck that is predominant in licensing out drugs or technology, forming 22 partnerships (Figure 10). Lundbeck develops drugs with the main focus on the treatment of CNS disorders, including depression, and is involved in 157 deals covering a range of therapeutic areas particularly depression, Alzheimer’s disease and anxiety disorders. GSK has been almost as active, with 21 agreements formed, followed by Eli Lilly with 17.

FORECAST-RELATED DEALS

CYMBALTA FACING DEPRESSED OUTLOOK FOLLOWING $400 MILLION DEAL TERMINATION

There are quite a few treatments battling it out for a significant share of the depression market. One treatment facing an uncertain future is Eli Lilly’s Cymbalta (duloxetine). The SNRI, launched in the U.S. in 2004 for MDD, was providing over $5 billion in revenue in 2012, but figures are expected to drop to the half a billion mark in 2019. The drug was the focus of numerous partnerships prior to its availability, and in December 2002 Eli Lilly began an eight year journey with Boehringer Ingelheim. The parties would jointly develop and commercialize duloxetine worldwide, excluding Japan, for stress urinary incontinence (SUI) (as Yentreve and Arixclaim in the EU) and worldwide, excluding Japan and the U.S., for MDD (as Cymbalta and Xeristar). However, following the withdrawal of a new drug application for SUI in January 2005 after the FDA indicated that it would not approve the drug based on the data submitted, in February 2006 the companies decided not to seek marketing approval for Yentreve in the U.S. It has, however, been approved in the EU and Canada.

It is also worth noting that by July 2005, the FDA had updated the safety sheets for certain antidepressants, including duloxetine, highlighting an increased risk of suicidal intentions, and in October 2005, the drug’s label was further updated for the contraindication of chronic liver disease, unbalancing the risk-benefit ratio. As a result, Eli Lilly intended to repurchase worldwide commercialization rights and future related...
urinary incontinence indications from Boehringer Ingelheim and would continue to market the drug for SUI outside the U.S. The companies would continue to co-market the drug outside the U.S. for MDD and DPNP and to develop it for CAD and fibromyalgia; this deal was expected to close by the end of 2006. By April 2010, Eli Lilly had re-acquired all Boehringer Ingelheim’s rights to the drug for all indications in regions outside the U.S. and Japan; Boehringer Ingelheim received $400 million upfront, and would receive sales royalties until 4Q12.

“Based on our collective experiences to date in the marketplace, both companies believe that the Yentreve/AriClaim opportunity is best suited and can be best commercialized in markets outside the U.S. with the support of one company.”

John Lechleiter, Ph.D., President & CEO, Eli Lilly & Co

Eli Lilly has also been involved in a number of other marketing and manufacturing agreements for Cymbalta. By 1996, Shionogi held Japanese rights for all indications to drug. In February 2007, Shionogi then signed an agreement to co-develop and co-market duloxetine in Japan for DPNP; Shionogi would remain the sole developer for depression. In 2004, Quintiles Transnational agreed to co-promote Cymbalta in the U.S. while sharing co-promotion costs and receiving sales commission; Quintiles’ obligation to co-promote the product expired in 2009. A manufacturing and supply agreement was established with Elan Corp in June 2004, under which Elan would supplement Eli Lilly’s manufacture of duloxetine capsules beginning in mid-2005. By August 2010, Eli Lilly and Handok Pharmaceuticals were co-promoting Cymbalta in Korea, and by February 2013, Evonik Degussa was manufacturing the API for duloxetine.

SEROTONIN-TARGETING BRINTELLIX TO MAKE H. LUNDBECK AND TAKEDA A FORCE TO BE RECKONED WITH

Continuing with serotonin inhibitors, Japanese giant Takeda teamed up with Lundbeck for the development and co-promotion of Lu-AA34893, Brintellix and Lu-AA24530 (tedatixetine) against mood and anxiety disorders (Figure 11). The September 2007 agreement covered the U.S. and Japan and included an option to add two additional compounds of the same class in early development if certain conditions were met. Following a U.S. launch in October 2013 and with the drug at an advanced clinical stage in Japan, 2019 sales for Brintellix are projected to be around $1.7 billion, meaning that Takeda’s large investment—a $40 million initial payment, up to $345 million in milestones with $40 million paid in December 2007 for initiation of a phase III MDD trial with Brintellix, royalties, and most of the remaining development costs—may be justified. The story is less positive for the other compounds included in this deal. Revenue for Lu-AA24530 is predicted to only hit slightly more than $100 million by 2019 after taking a back seat to Brintellix. Development of Lu-AA34893 was terminated in March 2010 after further preclinical analysis was required.

“Takeda’s experience in building up and leading one of the fastest growing companies in the U.S. combined with its market-leader position in Japan has made us confident that we have identified a fully-committed and highly-competent partner for our portfolio of compounds for the treatment of mood and anxiety disorders.”

Dr. Claus Braestrup, President, CEO, H. Lundbeck
## LU AA21004 (VORTIOXETINE) AND LU AA24530 FOR MOOD DISORDERS IN THE U.S. AND JAPAN

<table>
<thead>
<tr>
<th>Licensor</th>
<th>Lundbeck A/S</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Co-promotion and shared profits in the U.S. and Japan</td>
<td></td>
</tr>
<tr>
<td>• Joint development with responsibility for funding a minority of the remaining development activities</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rights to co-develop and commercialize</th>
<th>Lu AA21004 (vortioxetine) and LU AA24530 bisaryl sulphanylamines for depression, anxiety and mood disorders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic area:</td>
<td>Neurology</td>
</tr>
<tr>
<td>Technology:</td>
<td>Small molecules</td>
</tr>
<tr>
<td>Territory:</td>
<td>U.S./Japan</td>
</tr>
<tr>
<td>Stage at signing:</td>
<td>Phase II</td>
</tr>
<tr>
<td>License exclusivity:</td>
<td>Exclusive</td>
</tr>
<tr>
<td># Products/Options</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Licensee</th>
<th>Takeda</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Responsible for funding the majority of the remaining development activities</td>
<td></td>
</tr>
<tr>
<td>• Co-promotion and shared profits in the U.S. and Japan; responsible for booking sales</td>
<td></td>
</tr>
<tr>
<td>• Also received an option to other two compounds of the same class in earlier stages of development</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total announced size (USD): $385M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Committed payments:</td>
</tr>
<tr>
<td>Upfront: $40M</td>
</tr>
<tr>
<td>Equity: -</td>
</tr>
<tr>
<td>R&amp;D funding: -</td>
</tr>
<tr>
<td>Contingent payments:</td>
</tr>
<tr>
<td>Total milestones (up to): $345M</td>
</tr>
<tr>
<td>Pre-commercial: $345M</td>
</tr>
<tr>
<td>Sales-based: -</td>
</tr>
<tr>
<td>Back-end payment: Royalty</td>
</tr>
</tbody>
</table>

| Notes: |
| Share of the revenue generated in the U.S. and Japan and royalty payments on Takeda’s share of revenues |

**FIGURE 11: SNAPSHOT OF LUNDBECK AND TAKEDA’S AGREEMENT FOR LU-AA21004 (BRINTELLIX) AND LU-AA24530 (SOURCE: THOMSON REUTERS RECAP).**
OTHER HIGH VALUE DEALS

MERCK & CO AND DOV PHARMACEUTICAL MAKE A MARK WITH SEROTONIN UPTAKE INHIBITORS

In August 2004, a deal between Merck & Co and DOV Pharmaceutical (now Euthymics Bioscience) covered two candidates with serotonin, dopamine and noradrenaline uptake inhibition (Table 3). Merck & Co obtained exclusive worldwide rights to DOV-21947 (amitifadine hydrochloride) for all indications, and exclusive worldwide rights to DOV-216303 for the treatment of depression, anxiety and addiction, while DOV retained rights to DOV-216303 for other indications. DOV received a $35 million upfront payment and was to receive up to $300 million in clinical, development and regulatory milestones for multiple territories and approval of two indications along with up to $120 million upon achievement of certain sales thresholds. DOV had an option to co-promote the agents to psychiatrists and other specialists in the U.S. Prior to signing this deal, one of Merck & Co’s most advanced candidates for depression, aprepitant, a neurokinin-1 (NK-1) receptor antagonist, failed to demonstrate efficacy in phase III trials and its triple serotonin-2/3 and alpha-2 adrenoreceptor antagonist, mirtazapine, generated $451 million in revenue in 2004. In August 2005, DOV and Merck & Co amended the agreement, for DOV-21947 and DOV-216303. Planned clinical trials were to be conducted by DOV and not Merck & Co. DOV was to be reimbursed by Merck &Co for pre-agreed expenses and would receive a success premium, if the trials were successful. In addition, the amendment provided for the possible future expansion of the collaboration to include an additional triple reuptake inhibitor from DOV’s preclinical pipeline. This decision followed a review of data from preclinical studies in models of depression and a pilot phase I biomarker study in normal volunteers. In October 2006, DOV expressed its wish to terminate the agreement. If Merck & Co decided not to re-internalize the agent, then DOV would regain all rights. In December 2006, DOV regained exclusive rights to both treatments and DOV-21947 is in phase III trials while DOV-216303 appears to have been dropped from the development pipeline.

<table>
<thead>
<tr>
<th>Licensor</th>
<th>Licensee</th>
<th>Maximum projected value to licensor (USD million)</th>
<th>Drugs in active development for depression/MDD</th>
<th>Status</th>
<th>2012 sales (USD million)</th>
<th>Projected 2019 sales (USD million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Otsuka H. Lundbeck</td>
<td>Abilify</td>
<td>~ 1800.00</td>
<td>Abilify</td>
<td>Launched</td>
<td>5481</td>
<td>796</td>
</tr>
<tr>
<td></td>
<td>Brexpiprazole</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1158</td>
</tr>
<tr>
<td>Dainippon Sumitomo Pharma Takeda</td>
<td>Latuda</td>
<td>&gt;= 301.20</td>
<td></td>
<td>Launched</td>
<td>201</td>
<td>350</td>
</tr>
<tr>
<td>Otsuka H. Lundbeck</td>
<td>Bristol-Myers Squibb</td>
<td>&gt; 617.00</td>
<td>Abilify</td>
<td>Launched</td>
<td>5481</td>
<td>796</td>
</tr>
<tr>
<td></td>
<td>Brintellix</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1739</td>
</tr>
<tr>
<td>Merck KGaA</td>
<td>Cenaisance</td>
<td>&gt; 63.88</td>
<td>Viibryd</td>
<td>Launched</td>
<td>162</td>
<td>450</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>AspenPharmaCare</td>
<td>~ 272.29</td>
<td>Paxil</td>
<td>Launched</td>
<td>592</td>
<td>215</td>
</tr>
<tr>
<td>Pierre Fabre</td>
<td>Forest Laboratories</td>
<td>&gt; 75.00</td>
<td>Fetzima</td>
<td>Launched</td>
<td>n/a</td>
<td>325</td>
</tr>
</tbody>
</table>

TABLE 3: LICENSING AGREEMENTS FOR 5-HT PATHWAY TARGETING DRUGS WITH ACTIVE DEVELOPMENT FOR DEPRESSION/MDD, DRUG STATUS OF PHASE III AND ABOVE, MAXIMUM PROJECTED VALUE TO LICENSOR OF > $50 MILLION AND 2019 PROJECTED SALES FIGURES (SOURCE: CORTELLIS COMPETITIVE INTELLIGENCE).
ASTRAZENECA INVESTS $1.2 BILLION IN TARGACEPT FOR NICOTINIC RECEPTOR AGONISTS

Nicotinic receptor antagonists were identified by AstraZeneca as having potential in the depression market. Having signed a worldwide collaboration and license agreement in December 2009 with Targacept, AstraZeneca intended to target TC-5214 (dexamcycamyamine) against the alpha3beta4 nicotinic receptor in the hope of treating mDD. Targacept stood to receive an upfront payment of $200 million, development, regulatory and commercial milestones of up to $1.04 billion, plus significant double-digit royalties. It also retained an option for U.S. co-promotion of its drug to a limited target physician audience. Primary worldwide development costs would be shared 80:20 between AstraZeneca and Targacept, respectively. AstraZeneca would be responsible for worldwide commercialization and also assume Targacept’s manufacturing and supply agreements for TC-5214 with third parties. Both parties were planning to negotiate a potential multi-year research program to identify and develop further neuronal nicotinic receptor therapeutics for mDD. In January 2010, following the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act, the agreement was approved and Targacept received the upfront payment. However, in November 2011, the drug obtained disappointing top-line phase III results from its RENAISSANCE Program, failing to meet its primary endpoint of change in the Montgomery–Asberg Depression Rating Scale score after eight weeks. In March 2012 both parties announced that a filing for mDD would not be pursued. In 2012, Targacept took the strategic decision to reposition TC-5214 for overactive bladder where it is currently being evaluated in Phase II trials.

“Evotec has worked towards tackling the significant need for an effective treatment approach against depression... We are happy to team with Janssen Pharmaceuticals, one of the leaders in the field for the further development of our NMDA antagonists.”

Dr. Mario Polywka, COO, Evotec

Evotec’s decision to license out the two compounds followed a long relationship with Roche involving EVT-101. The company originally acquired an exclusive worldwide license in March 2004 to develop and market Roche’s extensive patent portfolio covering NMDA receptor NR2B-subtype selective antagonists, including EVT-101, EVT-102 and EVT-103, for CNS disorders including Alzheimer’s disease, neuropathic pain and Parkinson’s disease. Roche retained rights to reacquire the compounds in the future. In March 2009, the partnership included phase II development of EVT-101 to treat treatment-resistant depression and phase I development of EVT-103. If Roche were to exercise its buy-back option following the completion of phase II studies, Evotec would receive a $65 million lump-sum payment in exchange for returning the asset, as well as the entire EVT-100 family to Roche. Evotec would be eligible for further development, sales, and double-digit commercial payments. If the buy-back option was not exercised, Evotec would be granted exclusive worldwide rights to the entire EVT-100 series, as well as rights to all indications under revised terms from the original 2004 agreement. Roche would fully fund these
SPOTLIGHT ON... DEPRESSION

development programs. It was reported that the potential value of the agreement would exceed $300 million. However, by July 2011, Roche had returned rights to EVT-101 to Evotec after a U.S. phase II trial in MDD was stopped two months earlier (when Evotec retained all rights in the EVT-100 series including EVT-103) due to enrollment issues. Subsequently, clinical development was terminated and Evotec intended to not pursue further clinical development of EVT-101 without a partner. Following the announcement of Janssen as the new partner, a portion of payments given to Evotec by Janssen was to be shared with Roche.

ORTHOMCNEIL SEES ADDEX’S ALLOSTERIC MODULATOR PLATFORM AS SOLUTION FOR TARGETING METABOTROPIC GLUTAMATE RECEPTOR IN DEPRESSION

In a strategy to discover and develop allosteric GPCR modulators as treatments for anxiety, depression, schizophrenia and Alzheimer’s disease, Switzerland-based Addex Pharmaceuticals enlisted Ortho-McNeil Pharmaceutical’s (now Janssen Pharmaceuticals) expertise in psychiatry and neurology in combination with Addex’s allosteric modulator platform technology in a January 2005 exclusive worldwide collaboration. The ADX-2 program (of which ADX-71149 is the lead) is being developed for greater selectivity to metabotropic glutamate receptor 2. Addex would receive an undisclosed upfront fee and research funding for two years, as well as milestones and royalties. In June 2009, Ortho-McNeil initiated a phase I trial in central nervous system disorders triggering a EUR 1 million ($1.4 million) milestone payment to Addex and in May 2010, Addex revealed that it would be eligible to receive up to EUR 112 million (approximately $155.2 million) in milestones, and low double-digit royalties from Ortho-McNeil. In March 2011, a phase IIa trial for schizophrenia was initiated triggering a EUR 2 million (approximately $2.7 million) milestone payment to Addex. Although Addex never had any direct involvement for depression, its involvement has allowed Janssen to evaluate the program in phase II trials in patients with major depressive disorder and anxiety.

“We are delighted to be working with Ortho-McNeil...This partnership represents a strong validation of our discovery platform and highlights the value of Addex’s proprietary expertise in the allosteric modulation of G-Protein Coupled Receptors.”

Vincent Mutel, former CEO, Addex
CONCLUSION II

Considering the size of the depression market, there are surprisingly few standout deals in this sector, with many promising candidates not living up to expectations or finding value in other indications. Although the financial outlook for the depression market does not appear to be favorable, especially after heavy investment from partnering companies, such as for Cymbalta, there are other treatments on the horizon ready to generate fresh revenue for the licensees. These include Brintellix, which is expected to bring in billions of dollars after Takeda invested almost $400 million in its partnership with Lundbeck. Having Takeda on board, a leader in the Japanese pharmaceutical industry with strong regional links, Lundbeck should reap the rewards soon with an anticipated filing in Japan. There has been a large amount of investment in drugs acting on the serotonin pathway, however, drugs including Abilify and Paxil that were once market leaders now face a damaging future for the licensees. Abilify faces a reduced forecast in sales due to European and U.S. patent expiration in 2014 and 2015. Bristol-Myers Squibb’s EU and U.S. commercialization rights terminate in 2014 and 2015, respectively. Paxil has already lost U.S. and European patent protection and has the burden of a black-box warning highlighting increased risk of suicidal thinking and behavior, reflecting GSK’s decision to divest the product to Aspen. However, Lundbeck and Takeda stand to benefit from billion dollar revenues in the form of brexipiprazole and Brintellix, respectively.
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