

A man in a dark suit stands on a white circular platform, looking up at a tall, dark ladder that reaches up to a bright skylight in a dark room. The scene is dramatically lit from above, creating strong shadows and highlights.

Market Outlook 2010

For this annual feature, Financier Worldwide has again gathered the opinions of the corporate advisory and dealmaking community to explore their insights into current and emerging trends as we enter the new year.

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SECTOR ANALYSIS

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► FDA'S NEW ENFORCEMENT INITIATIVE FOR 2010

On 6 August 2009, Commissioner of Food and Drugs at the US Food & Drug Administration (FDA), Margaret A. Hamburg, announced FDA's new enforcement initiative for 2010, designed to "prevent harm to the American people through swift, aggressive, and effective enforcement of FDA laws and regulations". She explained that FDA enforcement actions years "have been hampered by unreasonable delays" and "in some cases, serious violations have gone unaddressed for far too long".

FDA's announcement follows pressure from Congress to 'clean up' FDA and the commitment from the Obama Administration to reinvestigate the agency, which had been accused of permitting stakeholders to influence scientific decision-making and of letting alleged violations languish too long without action.

A few components of the enforcement initia-

tive have already proved, and will continue to prove, significant for companies intent on full compliance with FDA regulations. First, FDA will require companies to respond to significant FDA inspection findings within 15 days. If no response is forthcoming within 15 days, the agency says it will go ahead and issue a warning letter – which is a public document – or take other appropriate enforcement action. Considering the scope of many FDA inspections, particularly when multinational companies are at issue, 15 days to respond is scant time to marshal the evidence frequently required to rebut or explain inspection findings, much less resolve outstanding issues with the agency. As a practical matter, substantive responses to inspection findings can take weeks or months.

Second, FDA will no longer require its Office of Chief Counsel to review warning letters before they are issued. This means that going forward we can expect more warning letters to be issued, and we can expect them to be issued more quickly than in the past.

Third, FDA has said it may not even wait to issue a formal warning letter before it takes enforcement action. This is a radical change from

previous procedure and raises not insubstantial questions of administrative law, including potentially limiting a company's appeal options and potentially improper reputational damage – particularly if the warning letter had not been subject to internal FDA legal review. If FDA follows through on its enforcement commitment, which appears to be the case, the impact on industry could be dramatic.

Having said that, there is one potential benefit under the new initiative, i.e., that FDA has said it will institute a formal 'close-out' procedure that will notify the public that violations raised in a warning letter have been fully corrected. Of course, the public's memory is short, and much as few people read corrections in a newspaper, the reputational value of the close-out notice may not outweigh the damage done by a warning letter, particularly if the warning letter raises issues that turn out to be unfounded. ■

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SECTOR ANALYSIS

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► POWER, GAS E&P IN ROMANIA

The prospects for power and gas exploration and production sectors in 2010 look good. Several major power projects are underway. CEZ started works on windfarm projects with a final capacity of 600 MW. The estimated costs are about €1.1bn. The European Investment Bank recently approved credit facilities of €200m to finance the first stage of the project. Iberdrola also plans to develop a windfarm project with a first stage capacity of 600 MW, and a final capacity of 900 MW. Both projects are developed in Dobrogea, a region of Romania ranked second in Europe, after northern Germany, as a source of wind energy.

Iberdrola and CEZ are also participating in the construction of two nuclear reactors at the existing nuclear power plant in Cernavoda. This project is developed by Nuclearelectrica SA, a joint venture in which the Romanian State holds 51 percent, and CEZ, Iberdrola, Enel, GDF Suez, RWE Power, and ArcelorMittal hold 49 percent. Discussions are underway to reduce the State's partici-

pation to 20 percent. The estimated costs of this project are of €8bn. In January 2010, Craiova Energy will launch a tender for the construction of a thermal power plant with a capacity of 500-600 MW, at estimated costs of €650m. The development vehicle will be a joint venture in which the foreign investors will hold 51 percent. Hidroelectrica SA, the state-owned hydro power producer launched a tender in November 2009, for consulting services regarding the selection of investors, and the setting up of a legal vehicle for the construction of a hydro power pumped-storage project.

Other long term projects include a hydro-power plant on the Danube, which will be developed jointly by Romania, and Bulgaria, with the probable participation of Serbia, and a nuclear plant which will be located in central Transylvania.

With assistance from IFC, a consortium led by Nordpool designed and assisted the implementation of an electricity trading platform located in Bucharest. Trading licences were issued to EON Romania, ENEL Energie, CEZ, Merrill Lynch Commodities, Statkraft, and Gazprom Marketing & Trading, among others. Romania has the largest electricity production capacity in South Eastern Europe. The strong interest shown by major electricity producers and traders shows that the Bucharest

trading platform has the potential to become the most important power exchange in South Eastern Europe.

According to official estimates, Romania has reserves of 185 billion cubic metres of gas, and 75 million tons of crude oil. The most significant gas discovery of 12 billion cubic metres is on a block in the Black Sea continental shelf concessioned to Sterling Resources Ltd. There are indications that further significant gas reserves are on the Black Sea continental shelf. Exxon is currently drilling on an OMB concession on the Black Sea continental shelf. Commercial discoveries were also made in a block concessioned to Aurelian in north-east Romania. In the last couple of years other commercial discoveries were made by Wintershal and Toreador. On 18 November 2009, the National Agency for Mineral Resources, published the Tender Notice for the tenth bidding round for concessions of oil and gas exploration and production. Many oil and gas investors are expected to attend the tender.

All of these energy and gas sector projects will generate major project finance deals to raise the necessary funds for their completion. ■

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