IN brief

Amylin's three-party good-bye

The buyout of Amylin Pharmaceuticals by Bristol-Myers Squibb (BMS) completed in August called for BMS to pay \$31 per share and gather up ownership of Amylin for about \$5.3 billion. But the uniquely structured deal also brought in a third party (London-based AstraZeneca) and added a \$1.7-billion payout by BMS to cover both Amylin debt and a contractual obligation to Eli Lilly, putting the total deal value at \$7 billion.

New York-based BMS immediately packaged Amylin's products together into a new collaboration with AstraZeneca, in which the latter pays the now wholly-owned subsidiary Amylin \$3.4 billion, and any forthcoming profits and losses are split equally between AstraZeneca and BMS. The assets in the collaboration are Amylin's GLP-1 agonists, Byetta (exenatide) and Bydureon (exenatide extended release); metreleptin, being reviewed by the FDA for diabetes and/or hypertriglyceridemia in rare forms of inherited or acquired lipodystrophy; and Symlin (pramlintide acetate), approved for type 1 and 2 diabetes in patients with inadequate glycemic control already taking meal-time insulin. The three approved products combined to sell about \$830 million worldwide in 2011.

The side payments to Indianapolis-based Eli Lilly in the buyout stem from Amylin's initial development and commercialization partnership for Byetta with Eli Lilly, signed in 2002, with a total potential value of \$300 million. But in May 2011, Amylin sued Lilly for engaging in anticompetitive acts and for breaching that original 2002 agreement, as Lilly earlier in the year had formed a collaboration with Boehringer Ingelheim in Ingelheim, Germany. The two companies were to jointly develop and commercialize two oral diabetes agents, Boehringer Ingelheim's linagliptin and BI10773, and Lilly's two basal insulin analogs, LY2605541 and LY2963016, with an option to co-develop and co-commercialize Lilly's anti-TGF- β monoclonal antibody. Lilly planned to use the same sales force to sell both exenatide and the direct competitor Boehringer Ingelheim's linagliptin, and this is the detail that caused Amylin to file suit. The issue was resolved when Lilly and Amylin ended the alliance and Amylin regained rights to exenatide. Having full rights made Amylin an attractive acquisition target, except that the breakup called for Amylin to, among other things, pay 15% of global sales of exenatide until the sum reached \$1.2 billion, plus interest. Any potential suitor needed to take on that long-term financial commitment, and thus, BMS's multiparty buyout deal, with money flowing in three directions.

Brady Huggett

Industry cautiously welcomes Supreme Court decision on healthcare overhaul

This summer's ruling by the US Supreme Court to uphold President Barack Obama's healthcare reform law has been welcomed by the drug industry. Industry executives say The Patient Protection and Affordable Care Act (PPACA), which requires most Americans to obtain health insurance and includes a handful of provisions that affect drug development, isn't perfect and may not ultimately benefit biotech's bottom line, but the ruling at least ends a highly fractionalized and protracted battle. "The biggest enemy of the economy and our industry is uncertainty," says Ron Cohen, founder of Acorda Therapeutics in Ardsley, New York.

"It's good that we have closure." At the same time, companies are scrambling to ensure that they will be compliant with the law's provisions on reporting physician payments.

The PPACA legislation was enacted in 2010, but was promptly challenged by 26 states and a trade group for small businesses. In a 5–4 decision on June 28 this year, the Supreme Court deemed the law constitutional, upholding it almost in its entirety. The court based its decision on the US Congress's power to impose taxes. The law requires individuals to obtain health insurance by 2014 or pay a penalty, and that financial penalty "may reasonably be characterized as a tax," Chief Justice John Roberts wrote in the majority opinion. "Because the Constitution permits such a tax, it is not our role to forbid it, or to pass upon its wisdom or fairness," he wrote.

A few key provisions stand out for innovative biotech companies. Most notably, drug makers' markets should expand as more Americans become insured and gain access to medicines. Small companies developing therapeutics also receive grants and tax credits for their projects, which may prove crucial for cash-starved startups (**Box 1**). What's more, innovative drugs will receive 12 years of exclusivity against competition from biosimilars. The language demarcating extra exclusivity for biologics should provide innovative companies, and the investors who place their money in them, with more certainty, say industry executives. At

the same time, PPACA now at least provides a legal framework for the US Food and Drug Administration (FDA) to come up with a pathway for biosimilars manufacturers.

How much the drug market will expand in 2014 when PPACA comes into force is unclear.

Although the general population remains generally split on the healthcare reform, most in biotech industry view it as a positive.

More than 53 million Americans are uninsured, and the healthcare reform law aims to cover more than half of them. To that end, the law expands Medicaid to include people at or below 133% of the federal poverty level. This bodes well for companies like GlycoMimetics in Gaithersburg, Maryland, which is developing a small-molecule drug to treat vasoocclusive crisis of sickle cell disease. Most people with the disease access treatment through Medicaid and Medicare, says Rachel King, CEO of GlycoMimetics. An expansion of Medicaid would be a way to give more people access to the company's drug candidate, if it is approved.

But although the Medicaid expansion was initially mandatory for states, the Supreme Court in its decision deemed the provision overly coercive, and effectively made the program voluntary for states. Kings says she is concerned that if states opt out, that will limit patients' access. Indeed, several state governors have already said publicly they would not participate in the expansion, even though the federal government would pay for 100% of the additional costs through 2020. The US Congressional Budget Office in July estimated that in 2022, 3 million fewer people would be insured due to state opt-outs.

Also offsetting the benefits of a bigger roster of insured Americans are the \$80 billion in rebates and fees drug makers must pay on their commercialized products to help fund the plan. "In that sense, it costs us money. But on