Bio pioneer's

Tony Hooper, EVP, global commercial operations for Amgen

Amgen entered 2013 with two of its oldest brands staring down the patent cliff—erythropoietin drugs Epogen and Neupogen—and bracing for Neulasta to follow in 2015. It paid the US government $24.9 million to settle claims that it gave kickbacks to long-term-care pharmacy providers to influence them to prescribe anemia drug Aranesp, which followed a $762-million payment in December 2012 to settle another False Claims Act case. It prepared for the inevitable arrival of so-called biosimilars. Atop its corporate masthead, there was a new CEO and a new head of R&D; 160 staffers were laid off.

If you looked at that news in a vacuum, you'd think the only awards for which Amgen might compete would be Most Beleaguered Company. Instead, due to the skill, nimbleness and unflagging energy with which it tackled these challenges—not to mention a rich product pipeline, a surge in 2013 sales and a forward-minded growth strategy—Amgen is *MM&M*'s Company of the Year, the first biotech firm to be so honored. Since Amgen is the sole remaining fully integrated developer, manufacturer and marketer of biotherapeutics left to have emerged from the biotech sector of pharma, that's no small feat.

In advance of the patent expirations on Epogen and Neupogen, which together generated $3 billion in US sales in 2012, Amgen faced pressure to prepare for the loss of a substantial chunk of revenue. The company did so by effecting a series of canny moves, some strategic and some tactical. The $10.4-billion purchase of Onyx Pharmaceuticals, announced over the summer and finalized Oct. 1, boosted Amgen's

PHOTO LEFT: KEVIN LOCK

brand clinic

2013 PRODUCT SALES* (US EXPIRY)

Neupogen/ Neulasta
$4.4B
(2013/2015)

Enbrel
$3.4B (2028)

Aranesp
$1.4B (2024)

Epogen
$1.4B (2013)

Xgeva
$733M (2017)

Prolia
$508M (2017)

* Global, 9 mos. to Sept. 2013
Source: The company

Above: Amgen's BuildingBiologics.com uses infographics and videos to convey the nuances of biologics manufacturing; below: Prolia sales (left) rose after the company started re-running its Blythe Danner (right) ads on TV.

already strong presence in the lucrative cancer drug market. Against steep odds, Amgen orchestrated a resurgence of the firm's denosumab franchise (Prolia and Xgeva). One of its most enduring brands, rheumatoid arthritis drug Enbrel might be referred to as "mature," but Amgen grew third-quarter sales by 7% year-over-year (primarily due to price). The company also saw year-on-year gains for Xgeva (up 5%) and Prolia (up an astonishing 62%).

To hear Tony Hooper tell it, the secret to Amgen's success lies in its approach: a patients-first mission, an insistence on commercial excellence, and the establishment of cross-functional partnerships that bring marketing into the development process sooner rather than later. "Amgen is a science-based organization—and this applies to all functions, not just R&D," says Hooper, the company's EVP, global commercial operations, in response to e-mailed questions. "At the core we continue to focus on unmet needs in patients with serious illness."

As for its other audiences, Hooper believes that meeting and exceeding

2013 HIGHLIGHTS

■ Biologics boosted global sales by 11% for the first nine months of the year, with osteoporosis shot Prolia up 62% year-on-year (Q3)

■ In advance of patent expiries on anemia drugs Epogen ('13) and Aranesp ('24), secured long-term dialysis supply contracts

■ After locking up exclusivity until 2028 and assuming US selling from Pfizer in 2012, Amgen's Enbrel profit share ended in Oct., replaced by 12% royalty

■ Stood ground against biosimilars threat while joining fray with own biosimilars pipeline, including versions of Herceptin and Humira

■ Completed $10.4B acquisition of Onyx, and built a presence in 75 countries, establishing a future growth platform

Amgen hiked consumer ad spend for anemia drug Neulasta last year by 9%, per Nielsen. Left: a point-of-care ad

the "high expectations" of payers and regulators will ultimately lead to better patient satisfaction (and, presumably, continued strong sales). "Patients," he says, "will not benefit from medicines they cannot access."

Hooper has quite an interesting professional history. Prior to his career in healthcare marketing, he received law and MBA degrees from the University of South Africa and worked as a criminal attorney. That may at least partly explain why he appears to approach his role with an uncommon degree of meticulousness.

Asked about Prolia's success in 2013, Hooper partly frames his response in the context of the category. "Post-menopausal osteoporosis is a competitive disease area, but in spite of that there is still a considerable unmet need," he explains, noting that the challenge was different from previous ones he and his team had encountered. "Adoption would take time, [so] our primary focus was to help physicians understand the clinical profile of this therapeutic option so that they could make informed choices for their patients."

It's making headway: Prolia's US value share of the osteoporosis market grew by 6 % in Q3.

Amgen's stewardship of Enbrel—during 2012, the company assumed US field sales of the 15-year-old RA brand from Pfizer, and locked up exclusivity for it until 2028—presented a different challenge: Namely, not to mess with a good thing.

"Ultimately," he says, "I think the transition was a success because we empowered our teams across the company to put the Enbrel patient first."

The acquisition of Onyx presented an opportunity more than it did a challenge. The deal brought under Amgen's purview multiple myeloma drug Kyprolis, plus royalty revenue from Nexavar, Stivarga and, possibly, palbociclib. Adding these to Amgen's existing portfolio—T-vec for melanoma, trebananib for ovarian cancer—positions the company as a potential leader in the oncology market, right alongside longtime cross-state rival Genentech. Still, Hooper doesn't view the Onyx deal as a sign that Amgen is doubling down on oncology.

"It makes sense to focus on continuing to expand our leadership in oncology therapeutics," he says, pointing to the company's "robust" oncology product pipeline. "Our acquisition of Onyx is entirely consistent with our strategy of advancing innovative medicines that address serious unmet medical needs."

Hooper doesn't directly address the False Claims Act settlements, layoffs or other 2013 headaches, instead noting that the company's overriding mission "cannot be fulfilled without a strong commitment at its core to compliance and ensuring that our research, operations, sales and marketing activities are done in full compliance with FDA regulations and other laws and rules." He chooses instead to focus on what looks like a promising immediate future.

Amgen's pipeline includes 10 late-stage programs, highlighted by AMG-145 for cholesterol and AMG-827 for psoriasis. Combined with six biosimilars set to launch starting in 2017, it's not hard to understand Hooper's "confidence" and "conviction" about the months and years ahead.

"We have the determination to stay out front and continue to unlock the potential of biology for patients with serious illness," he says. "All companies will face challenges, but Amgen has a clear strategy in place to grow, innovate and bring vital medicines that provide real value to more patients—and we're delivering on this strategy." —*Larry Dobrow*

2013 Media spend by brand

12 months ending Sept. 30, 2013

Brand	DTC spend	Journal spend	%Total media spend**
Enbrel	$164.6M	$1.6M†	67.3%
Prolia	$74.0M	—	30.0%
Xgeva	$0.1M	$1.7M	0.7%
Aranesp	*	$1.5M	0.6%
Neulasta	$0.8M	$0.5M	0.5%
Nplate	—	$0.1M	0.4%
Procoralan	—	$0.02M	0.0%
Sensipar	*	—	0.0%
Vectibix	*	—	0.0%
All others	$0.4M	$1.5M	0.8%

*Less than $5K;
**DTC and journal only;
†Amgen and Pfizer

Sources: DTC spend, Nielsen; journal spend, Kantar Media