

Cerulean Publishes Tips on Competing with Generics
for Biopharmaceuticals

Cerulean Associates LLC
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FOR IMMEDIATE RELEASE

August 4, 2008 – Williamsburg, Va. – Follow-on biologics are a foregone conclusion in the US. Too much money is at stake. The more difficult discussion starts with how to prepare your company to compete.

Science Succumbs to Dollars

The financial pull on reimbursement organizations and the constituent push on Congress for less expensive biotechnology treatments will inevitably lead to a regulatory approval pathway for so-called follow-on or generic biologics.

Traditionally, biologics could count on long marketplace exclusivity to make up for the high cost of development, a cost that typically took 10-13 years to recoup. That is all about to change.

Generic biologics will force investors and executives alike to reassess return on investment. The most conservative analysts estimate that follow-on biologics will cut biopharmaceutical revenue by 25%. Many biologics will not be able to sell enough to justify the cost of their creation.

Rather than looking to cut margins in manufacturing, biopharmaceutical executives will gain more marketplace leadership by taking a page from other industries and differentiating themselves in the eyes of patients, healthcare providers and reimbursement agencies. This starts in product development by figuring out what the customer wants, not just what the patient needs.

Tip #1: Focus on the Customer

To incorporate the voice of their customer, focus on gathering and analyzing the medical needs and desires of prospective patients.

Assign sales and marketing personnel to learn the desires of healthcare providers and patients through interviews and surveys.

With this information in hand, product development teams can incorporate these as differential characteristics. Customer information can lead to a redesign of packaging, a preferential set of dosing parameters to target, or even a list of drugs typically taken by the proposed patient population—and thus a list of drug interactions to avoid.

This information is powerful on two fronts:

1. Customer information like this has historically been seen as proprietary by the courts, and thus not open to review by a generic competitor; and
2. This information can let the company accentuate patient lifestyle improvements or healthcare provider margins, providing an edge over generics.

Tip #2: Changing the Role of Sales

Sales and marketing executives need to learn how to ask the right questions to diagnose what the provider and the patient would prefer in terms of lifestyle, ideal dosing, labeling and so on. This requires building trust with providers and not simply pitching product or samples.

This also requires a cross-functional team. Regulatory affairs needs to review the survey material and anticipated questions to ensure no promotion of products in development. Legal needs to ensure that intellectual property and trade secret information are not accidentally shared in conversation.

Tip #3: Observation as a Technique

Harvard Business School's Dorothy Leonard has cited the example of a medical device firm whose representatives watched a surgical operation to get new ideas to bring back to product development.

During the operation, the medical device representatives noticed that the surgeon's ability to see the micro tools inside the patient was interrupted every time a nurse walked between the surgeon and the video screen display. This information was taken back to product development engineers who developed a small screen that could be worn by the surgeon.

Once the sales force has added information gathering to its repertoire, it's time to examine all the other functions within the company for their contribution to product development and competitive capabilities.

Are you ready?

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