# Cutting Edge Information

www.cuttingedgeinfo.com

### Contact Information

1000 Park Forty Plaza Suite 440 Durham, NC 27713

P: (919) 403-6583 F: (919) 433-0220

### info@cuttingedgeinfo.com

### Product Commercialization

For more information on this topic, please contact Eric Bolesh, our market segmentation specialist, at (919) 433-02109 or email him at eric\_bolesh@cuttingedgeinfo. com

### Consulting

For more information on pharmaceutical consulting, please contact Jason Richardson at (919) 403-6583.

### **Related Studies**

PH61 \$6,995 Pre-Clinical to Phase III Resource Allocation

PH62 \$6,995 Phase III to Post-Launch Resource Allocation

# Pharmaceutical Product Commercialization

### By Eric Bolesh and Shannon Litalien

Increasing R&D costs, generic competition and fragile pipelines make the successful launch of new drugs critically important for pharmaceutical and biotechnology companies. Optimal resource allocation for the commercial development of emerging brands, however, continues to challenge companies across both sectors. This paper profiles one brand's marketing expenditures and team headcounts throughout commercialization.

To uncover the resource levels that best support brand commercialization, Cutting Edge Information (CEI) investigated 16 brands and their marketing budgets and headcounts from the pre-clinical period through the first year on market. CEI divided the results into "early-stage" and "launch" periods and published profiles of these brands in two reports:

• Pharmaceutical Product Commercialization: Pre-Clinical to Phase III Resource Allocation

• Pharmaceutical Product Commercialization: Phase III to Post-Launch Resource Allocation

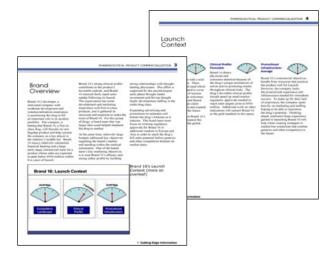
This white paper contains a complete brand profile combined from both reports. "Brand 16," the blinded product examined here, is a niche product that expects peak annual sales of less than \$500 million. Brand 16 illustrates how companies balance their resources to pursue critical marketing objectives. The drug's brand team recognized its key commercial challenges – promoting the drug's efficacy among key physicians, for example, and overcoming an organizational lack of launch expertise – and allocated marketing dollars and staff to address these points.

The data and resource allocation discussions below show how specific marketing investments and staffing decisions boosted Brand 16's ability to meet its unique commercialization demands.

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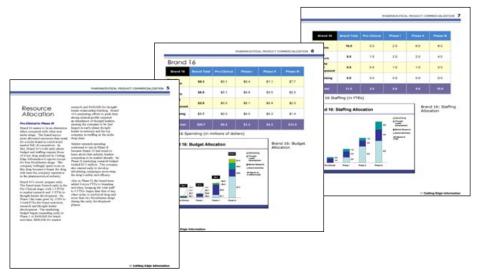
# Brand Profile Contents

# Page 3: Brand Overview Page 4: Launch Context



## **Pre-Clinical to Phase III**

Page 5: Resource Notes Page 6: Spending Data Page 7: Staffing Data



## Phase III to Post-Launch

Page 8: Resource Notes Page 9: Spending Data Page 10: Staffing Data



## Brand Overview

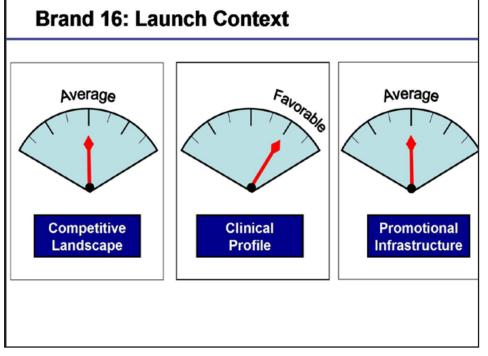
Brand 16's developer, а mid-sized company with moderate development and commercialization experience, is positioning the drug to fill an important role in its product The company is portfolio. betting that Brand 16, a firstin-class drug, will become its new flagship product and help cement the company as a key player in the industry's middle tier.

Brand 16 enjoys relatively substantial financial backing and a large early-stage

commercial team for a product whose sales are expected to peak below \$500 million within five years of launch.

Brand 16's strong clinical profile contributes to the product's favorable outlook, and the drug enjoyed fairly rapid sales uptake following its launch. The organization has some development and marketing experience with first-in-class products, and it gathered its resources and expertise to make the most of Brand 16. Among niche and specialty drugs, a brand team that was larger than usual helped shepherd Brand 16 to market.

At the same time, relatively large budgets addressed key objectives concerning the brand's market and standing within the medical community. One of the brand team's key marketing objectives was to tout Brand 16's efficacy and strong safety profile by building



Brand 16 enjoys relatively Brand 16's Launch Context

relationships with thought-leading physicians. This effort is supported by a strong early-phase thought leader investment, especially for a niche drug.

Expanding advertising and promotion investments will bolster the drug's fortunes as it matures. The brand team must focus on winning regulatory approvals for Brand 16 in additional markets in Europe and Asia in order to reach the drug's full sales potential before generics and other competitors threaten its market share.

## Launch Context

#### Competitive Landscape: Average



Brand 16 launched into a subdued market with a midsized patient population. There were pockets of unmet need which existing market leaders attempted to cover with varying degrees of success. The patient population welcomes innovative therapies, and Brand 16's strong safety profile helps the product claim increased market share and expand its international sales.

Team members believe Brand 16's efficacy will help to expand this market, especially at the global level. Brand 16 draws physician and consumer attention because of the drug's unique mechanism of action and its promising throughout clinical results The drug's favorable trials. clinical profile should speed up small-market regulatory approvals needed to reach sales targets close to \$500 million. Additional work on other indications will cement Brand 16 as the gold standard in this space.

**Clinical Profile:** 

Favorable

Promotional Infrastructure: Average

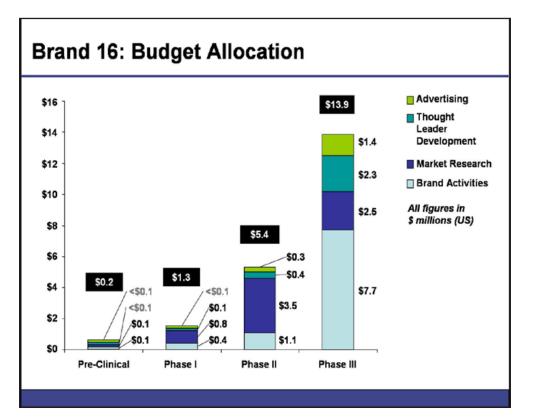


16's Brand commercial objectives benefit from resources that position the product well for launch. However, the company lacks the promotional experience and infrastructure needed for immediate success. To make up for its lack of experience, the company spent heavily on marketing and staffing to maximize the drug's potential. Thinking ahead, marketers hope experience gained in launching Brand 16 will help when creating strategies for market line extensions that combat generics and other competitors.

| Brand | 1 | 6 |
|-------|---|---|
|-------|---|---|

| Brand 16                         | Brand Total | Pre-Clinical | Phase I | Phase II | Phase III |
|----------------------------------|-------------|--------------|---------|----------|-----------|
| Brand<br>Activities              | \$9.3       | \$0.1        | \$0.4   | \$1.1    | \$7.7     |
| Market<br>Research               | \$6.9       | \$0.1        | \$0.8   | \$3.5    | \$2.5     |
| Thought<br>Leader<br>Development | \$2.8       | \$0.0        | \$0.1   | \$0.4    | \$2.3     |
| Advertising                      | \$1.7       | \$0.0        | \$0.0   | \$0.3    | \$1.4     |
| Brand Total:                     | \$20.7      | \$0.2        | \$1.3   | \$5.3    | \$13.9    |

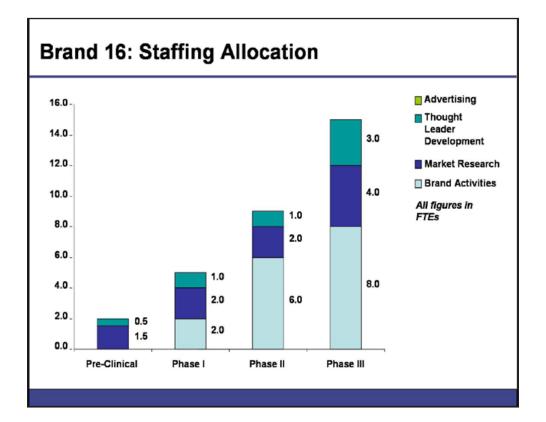
Brand 16 Spending (in millions of dollars)



### Brand 16: Budget Allocation

| Brand 16                         | Brand Total | Pre-Clinical | Phase I | Phase II | Phase III |
|----------------------------------|-------------|--------------|---------|----------|-----------|
| Brand<br>Activities              | 16.0        | 0.0          | 2.0     | 6.0      | 8.0       |
| Market<br>Research               | 9.5         | 1.5          | 2.0     | 2.0      | 4.0       |
| Thought<br>Leader<br>Development | 5.5         | 0.5          | 1.0     | 1.0      | 3.0       |
| Advertising                      | 0.0         | 0.0          | 0.0     | 0.0      | 0.0       |
| FTE Total:                       | 31.0        | 2.0          | 5.0     | 9.0      | 15.0      |

Brand 16 Staffing (in FTEs)



Brand 16: Staffing Allocation (in FTEs)

## **Resource Notes**

#### Phase III to Post Launch

During the critical Registration and Launch period, Brand 16 invested more in brand activities, market research and thought leader development than any other niche drug, and the brand's headcounts would not make it out of place among the studied mid-level brands. Nonetheless, a sign of the brand team's ambitions is one manager's conviction that the product is "under-funded."

Other small teams would argue that point. A total investment of \$62.3 million between Phase III and 12-18 Months post-launch, as well as a headcount of 21.5 FTEs at Registration and Launch, is illustrative of a mid-sized company's ability to put strong resources into a product that will decide the firm's fortunes in coming years.

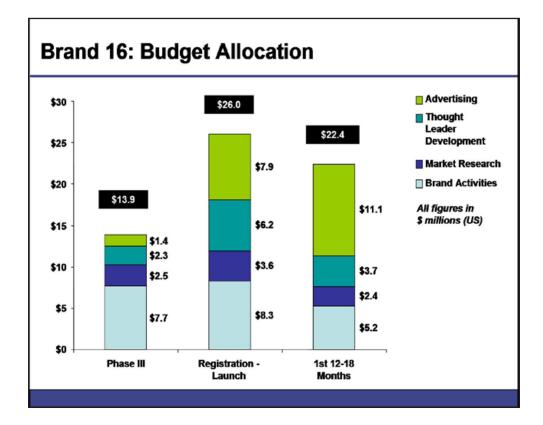
In fact, the large core team for brand activities – 8 FTEs in Phase III and 12 FTEs for Registration and Launch – represents the company's brain trust of product managers. Since the organization's fate goes hand in hand with Brand 12's success, the drug's developer brought in as many marketing veterans as it could to guide the product to market.

To spread the news about its niche product, the brand team focused on thought leader activities. During Registration and Launch, the team drew on \$6.2 million for its thought leader development. The focus continues after launch, when the thought leader development team expands from 4 FTEs to 8.5 FTEs.

An emphasis on advertising accompanies these thought leader investments. The team started preparing its promotional activity in Phase III, when it had the flexibility to dedicate \$1.4 million to advertising. This total increased to \$7.9 million during Registration and Launch, when advertising comprised more than 30% of all spending in that period. In the drug's First 12-18 Months, an advertising budget of \$11.1 million helped drive Brand 16 toward its goals.

| Brand 16                         | Brand Total | Phase III | Registration<br>- Launch | 1st 12-18<br>Months |  |
|----------------------------------|-------------|-----------|--------------------------|---------------------|--|
| Brand<br>Activities              | \$21.2      | \$7.7     | \$8.3                    | \$5.2               |  |
| Market<br>Research               | \$8.5       | \$2.5     | \$3.6                    | \$2.4               |  |
| Thought<br>Leader<br>Development | \$12.2      | \$2.3     | \$6.2                    | \$3.7               |  |
| Advertising                      | \$20.4      | \$1.4     | \$7.9                    | \$11.1              |  |
| Brand Total:                     | \$62.3      | \$13.9    | \$26.0                   | \$22.4              |  |

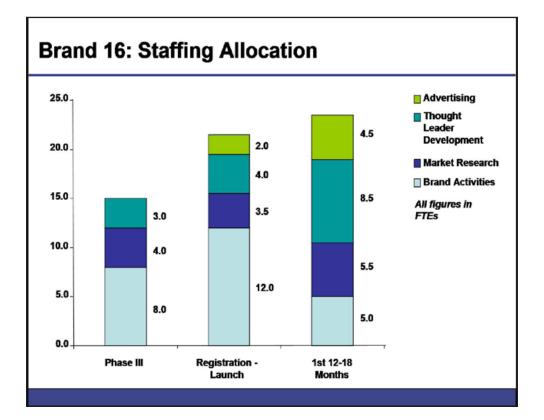
Brand 16 Spending (in millions of dollars)



## Brand 16 Budget Allocation

| Brand 16                         | Brand Total | Phase III | Registration<br>- Launch | 1st 12-18<br>Months |  |
|----------------------------------|-------------|-----------|--------------------------|---------------------|--|
| Brand<br>Activities              | 25.0        | 8.0       | 12.0                     | 5.0                 |  |
| Market<br>Research               | 13.0        | 4.0       | 3.5                      | 5.5                 |  |
| Thought<br>Leader<br>Development | 15.5        | 3.0       | 4.0                      | 8.5                 |  |
| Advertising                      | 6.5         | 0.0       | 2.0                      | 4.5                 |  |
| FTE Total:                       | 60.0        | 15.0      | 21.5                     | 23.5                |  |

Brand 16 Staffing (in FTEs)



Brand 16 Staffing Allocation (in FTEs)