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Diagnostic & Research Supplies

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### Top Picks

Ticker	Rating	Price	Target
GPRO	B	\$69.69	\$74.00
PPDI	B	\$38.90	\$42.00

### Least Favorites

Ticker	Rating	Price	Target
BEC	N	\$75.38	\$68.00
CRL	N	\$56.58	\$54.00

## Dental Products Manufacturer Update

### Talking Amalgam

- ▶ Revisiting a theme from our recent visit to the American Dental Association's 148<sup>th</sup> Annual Session in San Francisco, we have completed an extensive analysis of the controversial dental amalgam issue. This report includes a comprehensive picture of dental amalgam usage, thoughts on its potential reclassification, and implications of any regulatory changes on dental manufacturers.
- ▶ Dental amalgam is a stable alloy made by combining mercury, silver, tin, copper and other metal elements. Given that mercury comprises 50% of its content, consumer and environmental advocates have attempted for years (unsuccessfully) to persuade the FDA to re-classify dental amalgam as either a class II (restricted use) or class III (ban) device. Dentists use 34 million tons of amalgam per year for cavity fillings, largely owing to the long-term durability, low-cost advantage, and ease of placement relative to alternatives. However, recent rumblings from the ADA indicate the FDA may soon adopt changes to its long-standing policy. Given the products' longevity and limited direct health risk, we view an outright ban as unlikely.
- ▶ **Implications for XRAY/SIRO.** Whether restricted or banned, the ultimate eradication of amalgam would leave essentially only two solutions for restorations – composite materials and CAD/CAM procedures. For sizable restorations, there is no other alternative to replacing an existing amalgam filling except with a crown – the fastest, most effective method is achieved with *Sirona Dental's* (SIRO, \$35.75, Neutral, Target Price: \$40.00) chairside CAD/CAM offering. While the potential financial impact to SIRO is difficult to discern, the same-day convenience of chairside restorations is an appealing option for patients, particularly given the long-term durability of crowns relative to composites. As procedure volumes grow, the economic returns available to dentists adopting SIRO's CEREC platform become increasingly attractive. *DENTSPLY* (XRAY, \$41.92, Buy, Target Price: \$44.00), the second largest manufacturer of amalgam, could see a more immediate benefit as any lost amalgam material sales would be substituted for higher priced alternative materials. A restriction or ban of amalgam in the U.S. could boost XRAY's organic revenue growth by approximately 0.2% to 0.5% in year one.
- ▶ **Sector View:** An aging population, product innovation, broader payer coverage, and acquisitions are contributing to growth in earnings and cash flow ahead of the general market.
- ▶ **PORTFOLIO MANAGERS' SUMMARY: Page 2.**

## Portfolio Managers' Summary

- ▶ **Our 12-month thesis on the sector.** An aging population, product innovation, broader payer coverage, and acquisitions are contributing to growth in earnings and cash flow ahead of the general market.
- ▶ **Our call today in a nutshell.** Reviewing the dental amalgam issue.
- ▶ **Risks to our call.** Unforeseen industry and/or company-specific developments.

## Talking Amalgam: The Issue That Won't Go Away

### Background

Revisiting a theme from our recent visit to the American Dental Association's 148th Annual Session in San Francisco, we are taking a deeper look at the controversial dental amalgam issue. One of the most commonly used materials to treat dental cavities may soon be under some close examination of its own. Despite its longevity of use in direct restoration procedures, regulatory pressures, environmental concerns, and rising public awareness of the ingredients of amalgam are contributing to an escalating debate on the safety and suitability of the product.

For over 150 years, amalgam has been the most preferred solution of dentists for direct restorations of cavities where diseased tissue is removed and replaced with a filling. Unbeknownst to a surprising percentage of patients, the dominant material in amalgam fillings is mercury (50%) along with silver, tin, copper and other metal elements. Its long-term durability, low-cost advantage, and ease of placement are among the several advantages of using amalgam materials for these procedures.

Surprisingly, consumers are not aware amalgam fillings contain mercury. An early 2006 Zogby poll of more than 1,200 Americans indicated more than 50% do not know the primary metal in amalgam. Further, over 90% thought dentists should be required to inform patients of the various types of filling material alternatives, which is not current practice. Whether or not increasing FDA regulation of the product actually occurs, rising consumer awareness of the ingredients of dental amalgam may accelerate a mix shift away from the product, particularly amidst the widening availability of alternative restoration options.

Even though the FDA classified all other dental restoration materials in the late 1980s, the agency does not currently have a classification for encapsulated amalgam. Rather, it classified individual ingredients, including the bottle of mercury and the amalgam powder, which dentists historically used as a mix to make the final product. But that form of making dental amalgam is banned in several states, including New York, and is forbidden by the ADA.

Today, manufacturers ship pre-capsulated amalgam in direct proportion to the size of the specific restoration in order to prevent spillage, lessen evaporation exposure and reduce excess material after each procedure, thereby reducing waste and the risk of mercury exposure to dental personnel. While the FDA has long expressed its intention to classify capsulated amalgam, the agency has yet to actually issue an official position; we think the odds of action are the greatest they've ever been. Below, we explore why the FDA may reclassify it, and opine on the benefits a policy change would hold for *Sirona Dental* and *DENTSPLY*.

### ADA and FDA Signaling Potential Policy Shift

In response to concerns raised by consumer groups, in September 2006 the FDA formed an advisory committee to review scientific literature on the safety of dental amalgam. By a 13-7 margin, the committee rejected its draft white paper claim that no changes to the FDA's risk estimates on the safety of dental amalgam were needed, citing inconclusive and contradictory evidence. The committee recommended, among other things, that it should consider labeling changes that restrict amalgam usage for pregnant woman and children, and adjourned to revisit its previous conclusions following a broader analysis, opening the door to a potential reclassification of dental amalgam.

The ADA's July 2007 update to its members signaled the FDA might begin taking another look at its dental amalgam policy. Its newsletter indicated the FDA could require a mandatory brochure containing limited warnings, and held out the potential for an eventual ban of the product, though its ultimate direction is clearly unknown.

Following its recent Annual Session in San Francisco, the ADA's House of Delegates called for the creation of a brochure to educate patients on the materials used in various dental fillings, the features of each type of filling, and the relative costs of each procedure. The ADA also revised its best management practices policy for disposing dental amalgam waste to advocate the adoption of separators and collection devices in dental office plumbing to protect mercury from entering downstream water supplies and wastewater treatment facilities. Amalgam separators remove amalgam particles from dental office wastewater using sedimentation, filtration, chemical removal by ion exchange, or some combination of those methods.

According to the Consumers for Dental Choice, up to 30% of U.S. dentists are already amalgam free. While the proportion of amalgam filling procedures has been falling for years, anecdotal conversations with several dentists indicate the mix is much less than 50%, as fewer dentists are using amalgam and an increasing number of dentists do not use amalgam at all. A recent report in the *Public Health Reports* journal compiled data from the ADA and Delta Dental Insurance and estimated amalgams make up 40% of direct restoration procedures while composites account for 60% of procedures. No data was readily available on less used, niche materials such as gold or porcelain restorations that take longer to complete and can require two appointments.

### Regulatory Momentum Building; Expect Increasing Headlines on Amalgam Issue

Consumer safety proponents and environmental activists have persistently lobbied the FDA to take a more aggressive approach to classifying amalgam under the Federal Food, Drug and Cosmetic Act. While the FDA has hesitated, Congressional members and several states are independently addressing the issue.

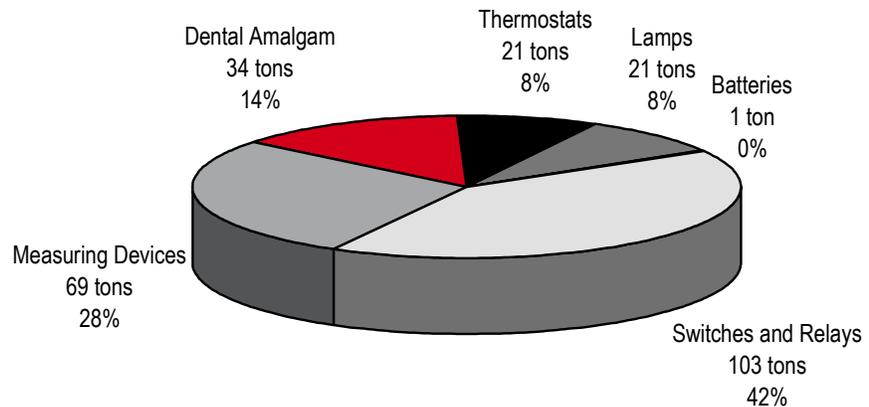
- **Congress.** We believe the US House Committee on Oversight and Government Reform's subcommittee on Domestic Policy will hold a hearing next month specifically on the risk of mercury in amalgam and the FDA's inaction on the issue to date. In May, Rep. Diane Watson (D-Calif.) introduced the Mercury in Dental Fillings Disclosure and Prohibition Act (H.R. 2101) that would prohibit dental amalgam and would require mandatory labeling for dental amalgam to highlight health risks. The bill is identical to several previously introduced bills that have not gained substantial traction.
- **States.** Several states have organized to form the "Great Lakes Regional Collaboration" to reduce mercury in products and waste. The group recently

issued a draft plan entitled the *Great Lakes Mercury in Products Phase-Down Strategy*, which recommends dental amalgam be reduced or eliminated, and the full phase-out of mercury-added products by 2015. The coalition is accepting public commentary through October 27.

### Environmental Impact Meaningful

According to a 2004 report by the EPA, dentists placed an estimated 34 tons of mercury into the mouths of patients in 2004, making the modality the third largest consumer of mercury. Mercury is also widely used in other products, such as switches, relays, measuring devices, thermostats, lamps, and batteries; many manufacturers and car makers have already adopted phase-out programs intended to remove mercury from product lines. Exhibit 1 depicts the annual mercury consumption by product.

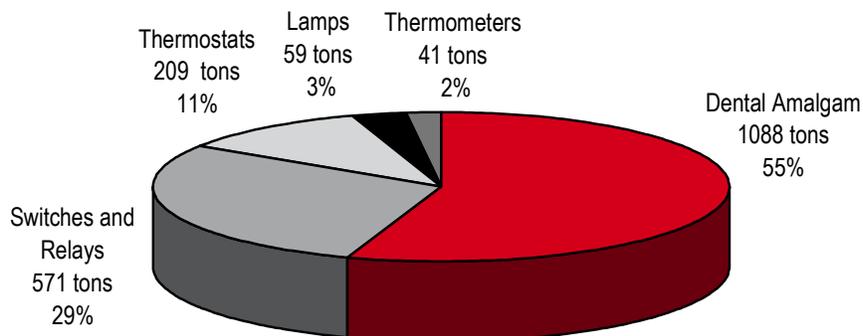
**Exhibit 1: Annual Consumption of Mercury by Product, 2004**



Source: EPA, Banc of America Securities LLC estimates.

Additionally, the EPA report also suggests more than 1,000 tons of mercury already lie in patients' mouths, accounting for more than half of all the mercury sitting in products (see exhibit 2). Given 60% to 70% of direct restoration procedures that are merely replacements of existing fillings, the amount of mercury amalgam being disposed on an annual basis is substantial. Several New England states as well as various other individual cities and counties already mandate amalgam separators in dental offices. Oregon recently passed a law requiring all dentists to install amalgam separators in new dental offices built beginning in 2008. Other dentists have until January 2011 to install separators.

**Exhibit 2: Estimated Existing Mercury Levels in Products, 2004**



Source: Company reports, Banc of America Securities LLC estimates.

Amalgam separator solutions can range from a few hundred dollars up to several thousand for larger systems; only a handful of (private) dental companies we are aware of provide these systems and include *R&D Services*, *Rebec LLC*, *Air Techniques*, *Maximum Separation Systems*, and *DentalEZ*. *Kerr*, owned by *Danaher*, is believed to be the largest manufacturer of dental amalgam and has partnered with *Dental Recycling North America* to offer a complete end-to-end recycling solution for all dental amalgam and capsule waste.

**What Happens Next?**

We believe the FDA could issue an advanced notice of proposed rulemaking (ANPR) as soon as the end of the year, indicating it has initiated a formal regulatory process on dental amalgam. Once the ANPR is issued, the FDA will take 60 days to gather public opinion of the matter prior to issuing a draft ruling, after which it will again accept public comments. The final step would be a final ruling which has no timeline, but could occur by the end of 2008.

Three possible conclusions exist; clearly, the FDA could stick to its long-standing position that dental amalgam is safe; the agency could reclassify amalgam as a class II product, similar to its status in several foreign countries, placing limited restrictions on who can receive amalgam or requiring educational brochures be distributed to patients highlighting the risks of amalgam; or the agency could ban the product altogether with a class III classification.

**Implications: Amalgam Regulation Should Benefit SIRO/XRAY**

A reclassification of dental amalgam as class II or III device would benefit *Sirona Dental's* CEREC franchise and *DENTSPLY's* composite products offering. With one of the three primary restoration methods no longer a competitive threat, these companies could realize substantially higher demand for their offerings.

**SIRONA DENTAL**

While direct financial benefit to Sirona's top-line from a reclassification of amalgam is somewhat difficult to quantify, such an event would provide dentists with several more compelling reasons to adopt a CEREC chairside CAD/CAM system, helping drive

penetration of the technology which currently stands at only 6% of U.S. dental offices. A reclassification of amalgam could provide another catalyst to drive increased adoption of high-technology restoration alternatives, such as those offered by SIRO.

According to a 2003 study in the *Journal of Dentistry*, crowns have the longest duration of any restoration material. The study indicated the median survival period of amalgam restorations is 12.8 years, while crowns lasted roughly 14.6 years. Composite restorations exhibited an average duration of 7.8 years. Given the extended longevity of crowns versus composites, we believe patients would be increasingly willing to consider crowns despite the higher cost, particularly if available with the convenience of a chairside, same-day solution.

While the vast majority of tooth restorations are completed in-mouth during a single-visit, the volume of indirect restorations is growing more rapidly owing to technology advancements, demographic shifts, growth in disposable income, and a desire for aesthetics, among other factors. Accelerating volume growth from a reclassification of amalgam is likely, in our view, particularly given increased consumer awareness of amalgam ingredients and the availability of convenient high-tech solutions.

Computer-aided design/computer-aided manufacturing (CAD/CAM) technology automates the indirect tooth restoration process. Most restorations are manufactured in dental laboratories based on impressions (or casts) created in the dental office; traditionally, the physical cast is sent to a nearby dental laboratory, which manually produces a custom restoration, and ships the finished product back to the dental office. This process takes approximately 7 days. As such, the restoration process requires multiple dentist visits. SIRO pioneered the use of CAD/CAM technology in the dentist office through the commercialization of the CEREC method in 1987. The equipment allows a dentist to manufacture a customized indirect restoration and complete the dental procedure in a single visit. It remains the only chairside CAD/CAM solution on the market today. Exhibit 3 depicts the various options available to dentists for indirect restorations, including the turn-around times and average costs per restoration.

**Exhibit 3: Indirect Restoration Options**

Application	Manual fabrication	Manual fabrication	Centralized CAD/CAM fabrication	On-Site CAD/CAM fabrication	In-Office CAD/CAM fabrication
Location	Offshore dental laboratory	Domestic dental laboratory	Centralized manufacturing facility	Domestic dental laboratory	In dental office
Average consumable cost / restoration*	\$30	\$60	\$60	\$25	\$25
Turn-around time	>7 days	<7 days	~ 7 days	5 days	<1 hour

\* Cost of single tooth restoration to dentist.

Source: Banc of America Securities LLC.

SIRO's CEREC system provides dentists the needed capacity and technology solutions to capture increased demand for amalgam removal for several reasons. For sizable restorations, where little remaining tooth structure exists after amalgam has been removed, a chairside restoration would offer patients and dentists the convenience of rapid turn-around times for replacements. Further, given that CAD/CAM restorations can generally last several years longer than composites and are created with high quality ceramic materials without the inevitable variations of manually produced restorations, many consumers and insurance policies may be willing to pay a premium for the increased durability, quality, and comfort.



sales. Despite the attractive financial economics often available to dentists adopting high-technology platforms that reduce inefficiencies and maximize patient counts through automation, the systems still require a sizable up-front investment which dentists are often hesitant to make. However, given that consumables costs account for about 5% of overall dental practice costs, dentists are insensitive to pricing adjustments and can simply pass on the higher costs to patients.

While a reclassification of amalgam would clearly impact XRAY's amalgam franchise, we believe lost sales would simply be substituted for higher priced composite alternatives. Our analysis indicates XRAY could realize a 0.2% to 0.5% boost to its 2009 organic growth rate if amalgam is reclassified. Exhibit 5 highlights our assumptions.

**Exhibit 5: XRAY Scenario Analysis of the Impact of a Reclassification of Dental Amalgam**

2009 (Current BofA estimate)		Restricted (50% decline in amalgam sales)		Banned
Current Sales est.	\$2,249,480,952	Amalgam sales	\$2,538,764	\$0
% US	44%	% change from current estimates	(50%)	(100%)
% Consumables mix	38%			
		Composite sales	\$33,944,218	\$41,560,510
U.S. Consumables	\$376,113,215	% change from current estimates	29%	58%
Amalgam sales	\$5,077,528			
% amalgam of consumables	1.4%			
Composites sales	\$26,327,925	Incremental Net Benefit	\$5,077,528	\$10,155,057
% composites of consumables	7.0%	% growth of product sales	16%	32%
Wholesale Price - Amalgam	\$1.25	<b>Total (amalgam + composite sales)</b>	<b>\$36,482,982</b>	<b>\$41,560,510</b>
Wholesale Price - Composite	\$3.75			
<b>Total (amalgam + composite sales)</b>	<b>\$31,405,453</b>	<b>Incremental contribution</b>	<b>0.2%</b>	<b>0.5%</b>
% of total consumables sales, U.S.	8%	<b>to organic revenue growth</b>		

Source: Company reports, Banc of America Securities LLC estimates.

XRAY generates 44% of sales domestically, 38% of which are categorized as consumables, under which it sells restoration materials such as amalgam and composites, among other products. We believe amalgam and composite materials account for roughly 8% of XRAY's U.S. consumables sales mix; our estimate conservatively assumes amalgam is about a \$5 million product line (1.4% of its U.S. consumables sales) and composites are roughly five times the size of amalgams, or a \$26 million product line (7.0% of sales). According to the company, encapsulated amalgam sells for an average wholesale price of around \$1.25, depending on the size. Composites also sell for three to four times more than amalgam; our analysis conservatively assumes \$3.75. Analyzing the impact of a potential mix shift under two scenarios, we believe a reclassification of amalgam could drive an impressive and meaningful boost to XRAY's organic growth rate from merely swapping amalgam for higher priced (and arguably higher margin) composites.

Our scenario analysis initially contemplates a 50% decrease in amalgam sales if a class II restriction on the product is determined by the FDA. For reference, we note amalgam's share of the overall mix of direct restoration materials used (weight) fell to less than 6% in Sweden after restrictions were implemented. Assuming the 50% decrease in restoration cases simply swap materials from amalgam to composites, we estimate the shift would add 0.2% to incremental organic revenue growth. Banning the

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product altogether and swapping all implied case volume from amalgam to composites could add 0.5% percent to XRAY's organic revenue growth.

Our analysis does carry some inherent limitations based on the limited availability of information. For example, while approximately 50% of the U.S. population has dental insurance that would provide coverage for a slightly higher priced composite filling, we do not assume any of those patients without dental insurance opt out of getting the procedure due to the slightly higher cost. From our point of view, the potential cost of a root canal procedure from leaving tooth decay untreated outweighs the slightly higher incremental cost of a composite filling. Second, our analysis does not incorporate any benefit XRAY should realize over a longer-term period for composites having a higher failure rate and replacement rate than amalgams. That said, we believe a reclassification of amalgam would clearly benefit both SIRO and XRAY, and we plan to continue to monitor developments with alacrity.

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		Buy	Neutral	Sell
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Medium	25%-35%	15%+	14.9%-(2.9)%	(3)% or worse
High	35%-55%	20%+	19.9%-(6.9)%	(7)% or worse
Extreme	55%+	32%+	31.9%-(14.9)%	(15)% or worse

Source for volatility: Bloomberg.

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Hold	490	52	Hold	361	74
Sell	33	3	Sell	26	79

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**Beckman Coulter, Inc. (BEC)**

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**Target Price, Valuation Method, Risk Factors****Target Price:** \$68.00**Valuation Method Used To Reach Target Price:** Our target price of \$68 represents a 10-year discount horizon in our DCF model.**Risk Factors:**

- 1 Continuing slow-down in funding for the research market.
- 2 Abbott Laboratories re-entering immunodiagnostic market.
- 3 Sysmex's new marketing strategy in U.S. hematology.
- 4 Potential for dilution to return on invested capital through its operating lease conversion strategy.

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**Charles River Laboratories International, Inc. (CRL)**

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**Target Price, Valuation Method, Risk Factors****Target Price:** \$54.00**Valuation Method Used To Reach Target Price:** Our price target of \$54 implies a nine-year discount horizon in our DCF model.**Risk Factors:**

- 1 Potential for increased animal rights activism.
- 2 Potential pharmaceutical company mergers could slow R&D spending.

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**Gen-Probe Incorporated (GPRO)**

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**Target Price, Valuation Method, Risk Factors****Target Price:** \$74.00**Valuation Method Used To Reach Target Price:** Our \$74 price target is based on a DCF model targeting 15% sales growth and incremental returns of 50%.**Risk Factors:**

- 1 Collaboration Agreements
- 2 Distributor Agreements
- 3 Single Product Sourcing
- 4 Litigation
- 5 Third Party Reimbursement

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**Pharmaceutical Product Development (PPDI)**

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**Target Price, Valuation Method, Risk Factors****Target Price:** \$42.00**Valuation Method Used To Reach Target Price:** Our \$42 target represents a 10-year discount horizon in our DCF model.**Risk Factors:**

- 1 Increased spending increasing as internal development accelerates.
  - 2 Pharmaceutical manufacturer spending patterns
  - 3 Moving into new corporate headquarters
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**DENTSPLY International Inc. (XRAY)**

**Target Price, Valuation Method, Risk Factors**

**Target Price:** \$44.00

**Valuation Method Used To Reach Target Price:** Our \$44 target assumes a discount horizon of 12 years in our cash flow model.

**Risk Factors:**

- 1 Increasing Japanese market share may be dilutive to ROIC.
- 2 Size could preclude certain acquisitions in specific markets.
- 3 Converting intellectual property agreements into products.

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**Sirona Dental Systems, Inc. (SIRO)**

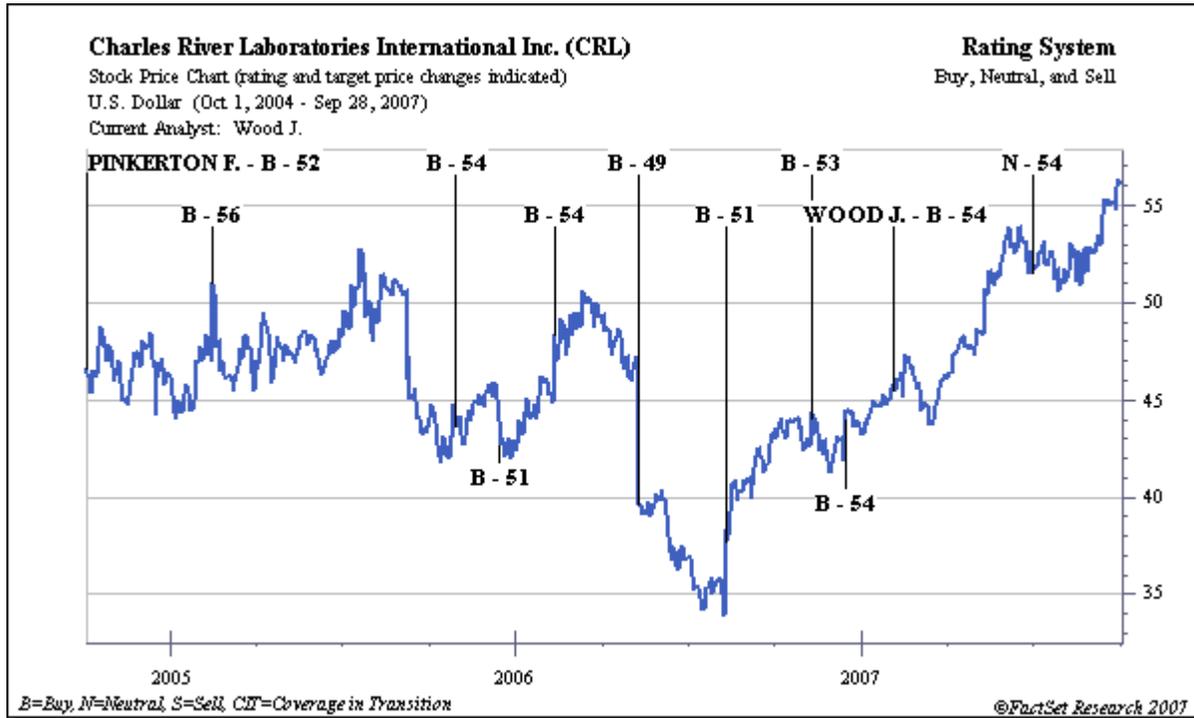
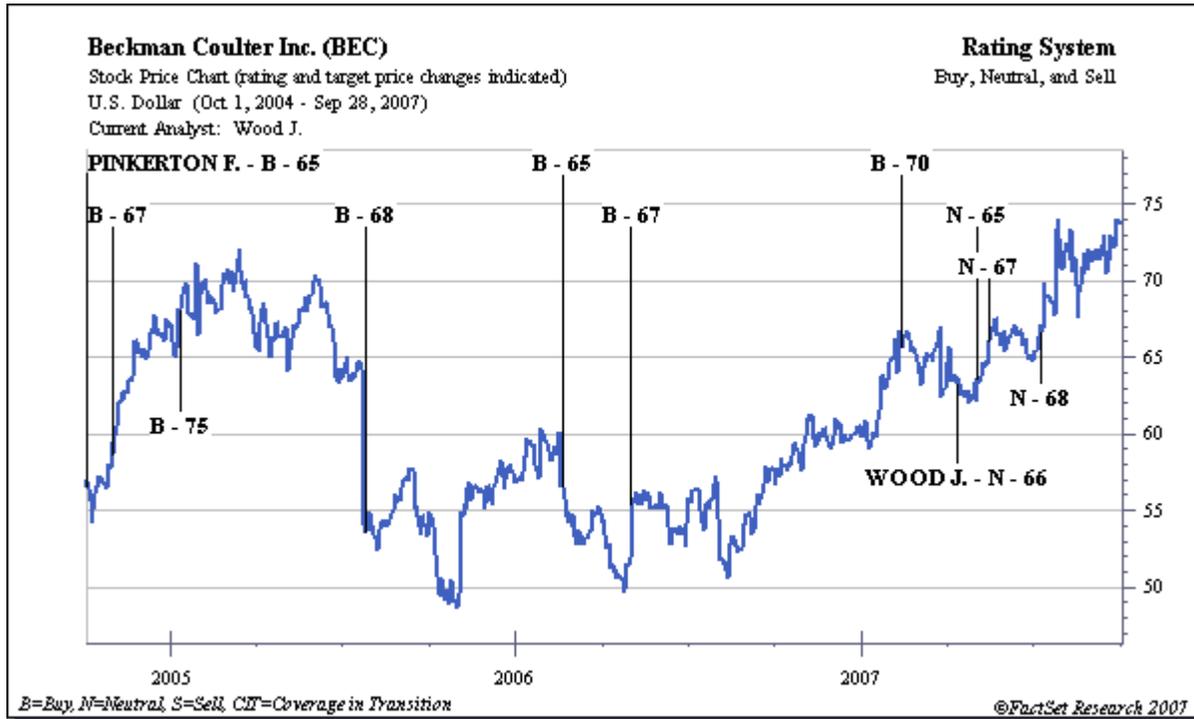
**Target Price, Valuation Method, Risk Factors**

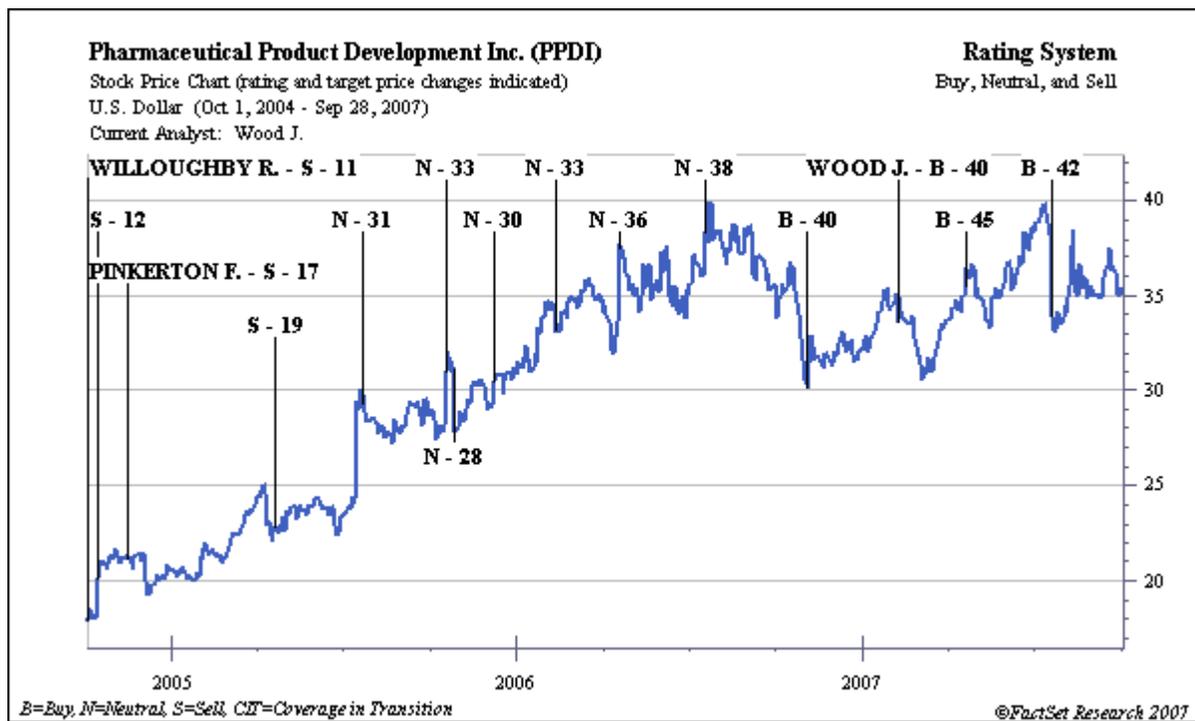
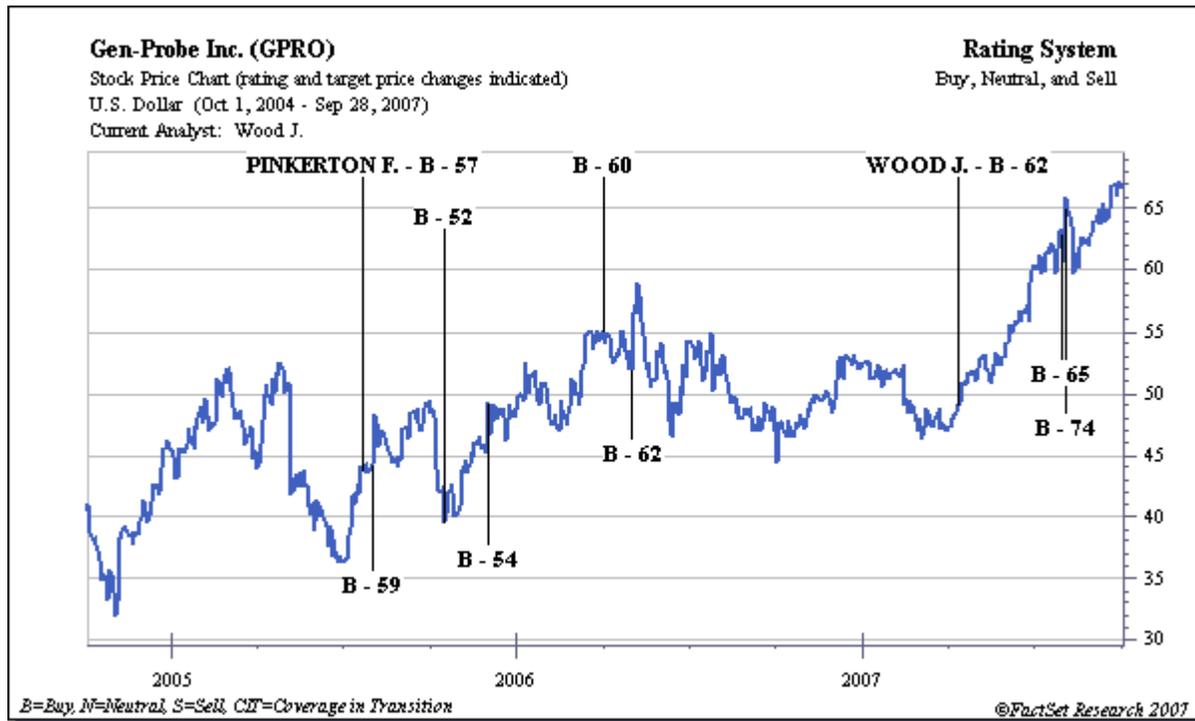
**Target Price:** \$40.00

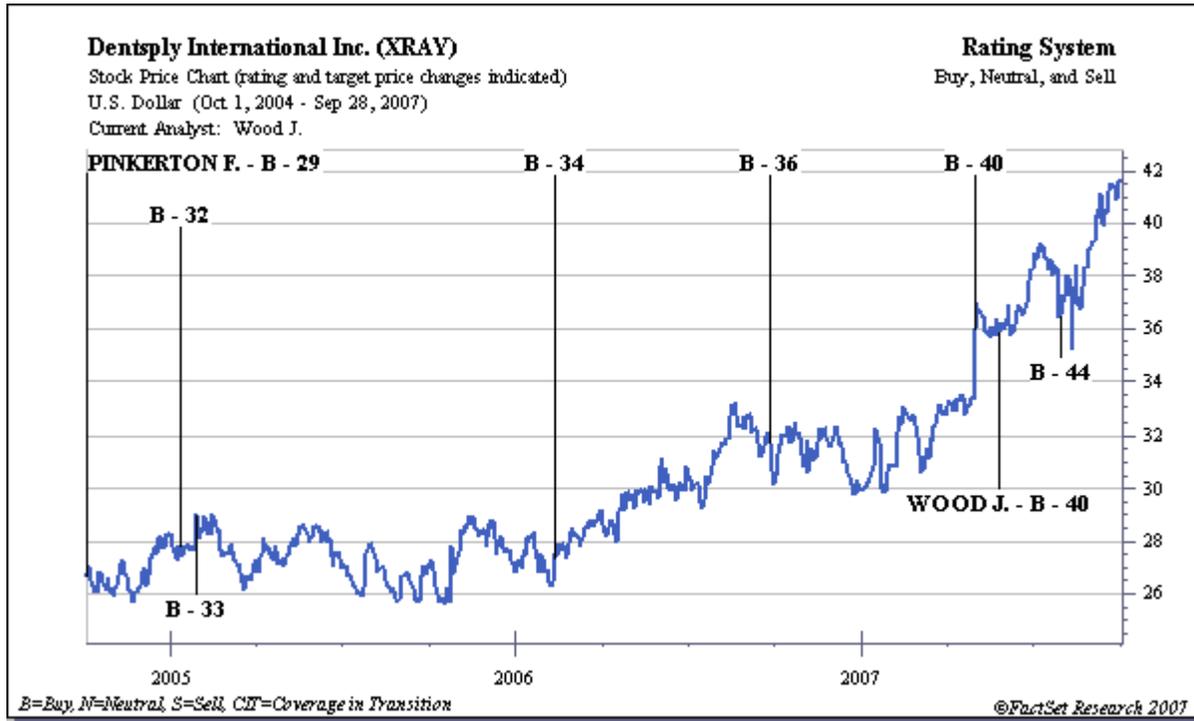
**Valuation Method Used To Reach Target Price:** Our \$40 price target implies a 10-year discount horizon in our discounted cash flow model.

**Risk Factors:**

- 1 Lower than anticipated near term uptake of its new CEREC MC XL milling unit.
- 2 Slower than expected roll-out of its GALILEOS instrument.







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