

# Generic Drug Industry Overview

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## Key Investment Points

- The \$30 billion generic drug industry is expected to double industry revenues to \$60 billion by the year 2005
- Several high-growth generic firms are posting double digit revenue and gross margin increases, however remain undervalued and underfollowed
- The stock performance for the generic industry continues to show positive momentum with a 68% increase over the LTM and a 13.6% increase YTD (See Table 1)
- BRL and MYL show LTM increases of 68% and 63.5%, respectively, however YTD, they are not performing as strong
- ADRX, WPI and IVX have shown more consistent double-digit increases over both the LTM and YTD 2001

Table 1

Generic Firms' Stock Performance				
	Ticker	Current Price	% change	
			YTD	LTM
Industry	DRGEN	201	12.7	57.7
Watson	WPI	61	19.6	13.9
Barr Lab	BRL	70	-4.4	55.5
Andrx	ADRX	75	30.2	17.9
Ivax	IVX	38	22.4	13
Teva	TEVA	62	-15.3	11.9
Mylan	MYL	28	12.4	55.1

Source: Baseline

## Overview of Generic Drug Industry

Although generic drugs have been around since the early 1960s, it was only recently that changes in government regulations and demographic trends have fueled the industry's dynamic growth rate. A dramatic change occurred in 1984 as a new law allowed generic pharmaceutical manufacturers to file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA), which enabled them to manufacture generic equivalents of brand name drugs once patents expired. Future, and perhaps, accelerated growth can be expected from the following:

- Growing number of drugs coming off patent
- Aging baby boomers who will be demanding drugs "to stay young"
- Continued effort by Government to control medical costs

### Generic vs. Brand-Name Drugs

A brand name version of a drug is the original drug developed by an R&D-based "brand-name" pharmaceutical company. For generic manufacturers to obtain approval for a generic drug, they

have to demonstrate that the generic drug is: 1) bioequivalent to the brand-name drug (meaning the generic drug is absorbed and used by your body in the same way that brand-name drug is absorbed and used) and 2) pharmaceutically equivalent (meaning the generic drug must have the same active ingredients, the same dosage form, and the same strength as the brand name drug).

Generic drugs generally sell at discounts of 30-80% to the brand-name prices. The reason for this discount has nothing to do with quality but has a lot to do with patent laws and R&D expenses. For example, a brand-name company can spend anywhere between \$300 and \$500 million to develop a new drug. Once this drug is approved, the brand-name manufacturer enjoys a 20-year exclusive patent. By the time the patent expires, generic companies incur only a fraction of the development costs when manufacturing the generic product, and therefore can offer the drug at a lower price. In addition, because multiple manufacturers may produce generic products for the same brand-name drug, competition forces prices lower.

According to IMS Health, the world's leading provider of information solutions to the pharmaceutical and healthcare industries, the price gap between generic and brand-name drugs was \$16.97 in 1999 but by 2Q 2000, the gap had widened by nearly \$30 to \$46.76. A comparison between brand-name and generic drugs is shown in Table 2. Prices noted are for the same dosage form and equal quantities of brand-name and generic drugs.

**Table 2**

	<b>Brand-Name</b>	<b>Price</b>	<b>Generic</b>	<b>Price</b>	<b>Difference</b>
<i>Pain Relief</i>	<b>Lorcet</b>	\$ 40.83	<b>Hydrocodone</b>	\$ 14.39	\$ 26.44
<i>Blood Pressure</i>	<b>Tenormin</b>	\$ 32.66	<b>Atenolol</b>	\$ 4.29	\$ 28.37
<i>Blood Pressure</i>	<b>Lasix</b>	\$ 5.98	<b>Furosemide</b>	\$ 5.49	\$ 0.49
<i>Antibiotic</i>	<b>Amoxil</b>	\$ 6.73	<b>Amoxicillin</b>	\$ 6.40	\$ 0.33
<i>Asthma</i>	<b>Proventil</b>	\$ 32.66	<b>Albuterol</b>	\$ 11.24	\$ 21.42
<i>Pain Relief</i>	<b>Darvocet-N</b>	\$ 23.47	<b>Propoxyphene N-APAP</b>	\$ 8.21	\$ 15.26
<i>Antibiotic</i>	<b>Keflex</b>	\$ 49.71	<b>cephalexin monohydra</b>	\$ 7.46	\$ 42.25
<i>Anxiety/panic disorder</i>	<b>Xanax</b>	\$ 27.10	<b>Alprazolam</b>	\$ 5.49	\$ 21.61
<i>Pain Relief</i>	<b>Motrin</b>	\$ 7.13	<b>Ibuprofen</b>	\$ 5.49	\$ 1.64
<i>Pain Relief</i>	<b>Tylenol/Codeine</b>	\$ 6.33	<b>Acetaminophen-Codein</b>	\$ 6.33	\$ -
	<b>Totals</b>	\$ 232.60		\$ 74.79	\$ 157.81

*Sources: Prices from Drugstore.com; drug rankings from Drug Topics*

However, despite significant price increases, consumers continue to prefer brand-name drugs, according to the Generic Pharmaceutical Association "GPhA". In fact, the use of generic drugs has remained between 40-42% since 1993, even though 70% of prescription drugs have a generic substitute. A recent study released by pharmacist Tim R. Covington of Samford University found that a 10% increase in generic drug use in the United States would cut drug costs by more than \$11 billion annually. Coupled with the continued pressure to reduce medical costs, consumer preference for brand-name drugs becomes even more baffling. That is, until you consider that consumers may be swayed to brand-names because:

- Physicians are less likely to discuss generic alternatives
- A perception that generics are inferior to brand-names
- Brand-name drugs are more advertised and consumers often recognize them by name

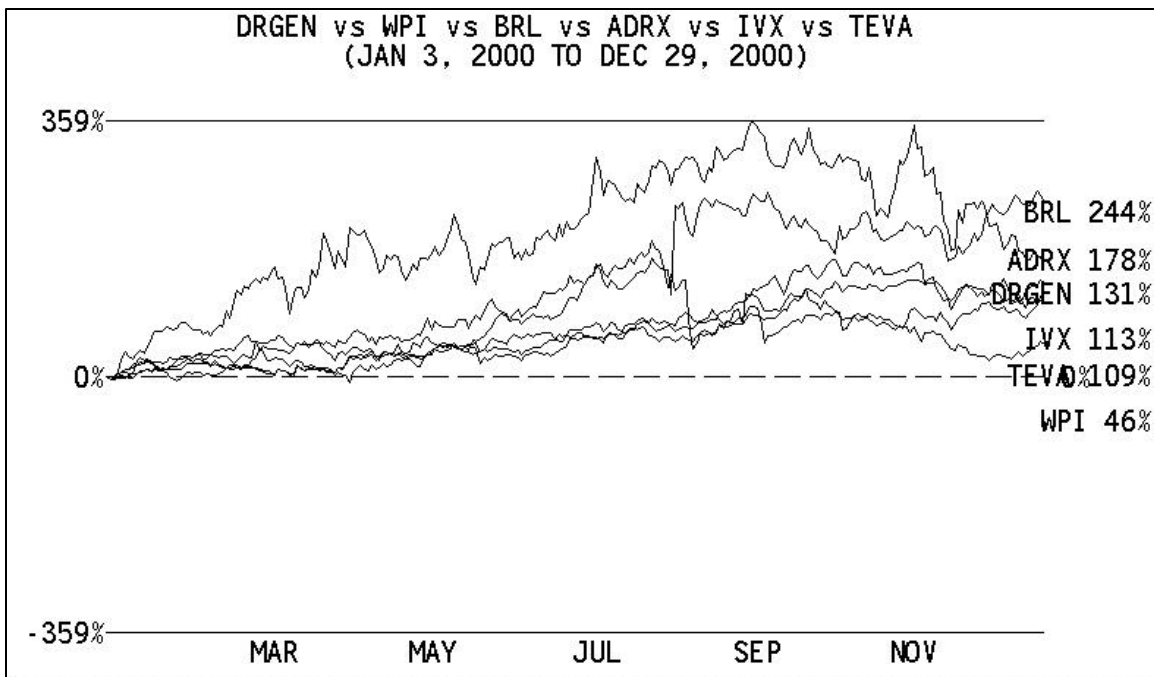
## Legislation

Although originally established to increase competition, loopholes in the Waxman-Hatch Act enabled anti-competitive agreements to be formed between brand-name and generic manufacturers. These agreements are gaining a lot of attention in the courts today as they allow for additional delay in the introduction of generic drugs. This delay occurs as brand-name manufacturers gain additional market exclusivity after a patent expires by forming an agreement with the generic manufacturer with first-to-file status to delay the introduction of the generic product. (The generic firm with first-to-file status is the first generic firm that can introduce a generic form of the brand-name drug to market.) This purchased “patent extension” prevents other generic manufacturers with ANDAs from launching their product until the “first-to-file” maker introduces its version and forces consumers to continue paying for the higher-priced brand-name drug until the generic products are introduced.

This scenario could all drastically change if the McCain-Schumer 2001 bill (aka the Greater Access to Affordable Pharmaceuticals Act) is passed. The bill is designed to establish a rollover system whereby the first-to-file status will be passed to another generic manufacturer if the first-to-file firm engages in any anti-competitive behavior or fails to meet certain guidelines, including launching its generic product within 90 days of FDA approval. The bill will also discourage litigation by eliminating the automatic 30-month patent extension provided to the brand-name producers when suit is brought against a generic patent challenge.

## 2000 Industry Review

Up, up and away was the theme for the generic drug industry (DRGEN) performance in 2000, increasing 131% for the year. As shown in the graph below, Barr Laboratories (BRL), Andrx (ADRX), Ivax (IVX) and Teva Pharmaceutical Industries Ltd. (TEVA), all enjoyed watching their stock prices rise with greater than 100% gains for the year. The stock for Watson Pharmaceutical (WPI) also performed well in 2000, increasing 46% for the year.



Source: Baseline

This performance was largely due to the introduction of new generic products and also from acquisition activity:

- BRL's generic drug for breast cancer treatment, Tamoxifen, was a big earner contributing to their 244% increase for the year
- The 113% stock price increase for IVX was a result of their market exclusivity for Onxol, a generic version of cancer drug Taxol, which launched in October 2000
- TEVA introduced several new generic products and also acquired Novopharm in April of 2000
- WPI's stock price increase 46% as generic sales benefited from its acquisition of Schein Pharmaceutical Inc. in 2000

## Industry Outlook

### Growth Drivers

As the patent protection expires for many popular prescription drugs, brand-name market monopolies will be lost as competitors bring their generic twin to market. (See Table 3) This presents tremendous growth opportunity for the generic manufacturers, which could potentially double industry revenues to \$60 billion by the year 2005.

Patent expiration is only one of the drivers expected to continue positive industry momentum. Others include:

- The value of products facing patent expiry by 2005 is estimated at \$100 billion, of which \$37 billion represents "blockbuster" drugs
- The McCain-Schumer 2001 bill has been proposed which is designed to facilitate the generic drug approval process and eliminate the loopholes in current legislation
- Ongoing pressure to control medical costs
- Some health care plans are offering financial incentives to encourage the use of generics, such as higher co-pays for brand-name drugs
- Awareness of generic drugs is increasing as consumer groups launch campaigns to educate the public and the spotlight is on the industry as litigation continues
- The Federal Trade Commission is investigating allegations of conspiracy between brand-name and generic drug makers to delay the introduction of generic products into market
- In April 2001, the generic drug industry formed the Generic Pharmaceutical Association (GPhA), which will provide a stronger voice in public policy and enable industry resources to be better utilized

Table 3

<b>Upcoming Patent Expiration</b>		
<b>Brand Name</b>	<b>Generic Name</b>	<b>Patent Expiration</b>
Prozac	Fluoxetine	8/2/01
Prilosec	Omeprazole	6/1/01
Mevacor	Lovastatin	6/15/01
Zestril	Lisinopril	12/30/01
Axid	Nizatidine	6/12/02
Relafen	Nabumetone	12/13/02
Blazin	Clarithromycin	5/23/03
Diflucan	Fluconazole	1/28/04
Claritin	Loratadine	4/21/04

*Source: Generic Pharmaceutical Association*

## Competition

### Top Industry Performers

The earnings for generic firms in the first quarter 2001 provide a glimpse of what is to come as some generic manufacturers realize the rewards of launching new generic drugs and as others continue to be tangled in patent litigation. (See Table 4) For the purpose of this section, we will focus on top performing generic firms, highlighting key investment points.

**Andrx (ADRX)** 1Q01 sales increased 35% due to the continuing success of Cartia XT and Diltia XT, but net income decreased by 9% as ADRX continued to

feel the impact of patent litigation revolving around its generic for Biovail's Tiazac. Assuming litigation proceeds in their favor, ANRX has great potential to profit from generic versions of products that are about to lose patent protection. (The company currently has 10 ANDAs filed with the FDA and expects to have first-to-file exclusivity on five of the 10, which represents an estimated \$4.7 billion in innovator sales.) In addition, Andrx expects to enjoy six months as the only seller of the generic for Prilosec, the world's top-selling drug for heartburn and ulcers.

**Barr Laboratories (BRL)** launched Fluvoxamine in 1Q01, the firm's generic version of Luvox tablets, which are used to treat obsessions and compulsions. This introduction led to their double-digit gains in revenues and earnings in 1Q01. In addition, five new generic drug approvals were granted in the 1Q01 that are expected to continue to drive sales in future months. Barr's challenges revolve around litigation as several suits have been filed against them, alleging collusion to keep their generic versions of branded drugs off the market, specifically targeting Tamoxifen, their breast cancer big earner.

**Ivax (IVX)** continued to realize the rewards for its drug Onxol, a generic of cancer drug Taxol, which fueled the company's 126% earnings increase. In 1Q01, revenues for Onxol were \$50 million (19% of total revenues). Market exclusivity expired in April 2001 for Onxol, however no new generic product is expected to be introduced until 3Q01, keeping IVX poised for continued growth in sales of this product.

**Mylan (MYL)** was significantly impacted in 1Q01 by patent litigation. The company reported a 9% fall in net income in 1Q, due to the litigation battle over the late introduction of anti-anxiety drug generic BuSpar. The company is expected to realize additional benefits from generic BuSpar in upcoming months.

Table 4

<b>Generic Firms' First Quarter 2001 Earnings</b>					
<b>Company</b>	<b>1Q Revenues</b>		<b>1Q Net Income</b>		
	<b>(in mils)</b>	<b>% Change</b>	<b>(in mils)</b>	<b>% Change</b>	
Andrx	\$ 156	35%	\$ 19.2	-9%	
Barr	\$ 137	13%	\$ 15.8	18%	
Ivax	\$ 260	42%	\$ 60.1	126%	
Mylan*	\$ 249	16%	\$ 42.1	-6%	
Teva	\$ 491	46%	\$ 54.8	46%	
Watson	\$ 297	67%	\$ 43.0	15.6%	

\* Mylan reports 4Q fiscal  
Source: Company reports

## Underfollowed, High Growth Firms

**Pharmaceutical Resources (PRX), Hi-Tech Pharmacal (HITK) and Bradley Pharma (BPRX)** are generic firms that have been performing well but they are not gaining the attention you might expect. (See Table 5) These high growth firms have posted double-digit revenue and gross margin increases over the LTM (some have outperformed the peer, industry and top performing group averages), however Wall Street does not follow them. With minimal attention given to these companies, we feel they have less downside risk than some of their peers and have a great upside potential.

**Duramed Pharmaceuticals (DRMD)** was one of our top picks in this underfollowed, high-growth group as we began compiling this report, trading at \$12.07 on June 13, 2001. On Friday, June 29, 2001, Barr Laboratories (BRL) announced their plans to acquire DRMD in a stock swap. (1 share of Barr for every 3.9032 shares of Duramed) DRMD's stock price gained 99 cents on the news, closing Friday at \$17.89. This transaction further supports our opinion of the attractiveness of this group.

Table 5

<i>Company</i>	<i>Symbol</i>	<i>Sales</i>	<i>Growth</i>	<i>Margin</i>	<i>Margin</i>	<i>/Share</i>	<i>Total Cap</i>	<i>ROE</i>
Peer Group Average*		\$ 61.2	42%	66.8%	19.0	\$ 0.09	15.9	16.3
Industry Average		\$ 344.8	37%	62.6%	27.8	\$ 0.75	15.9	15.5
Top Performers Average		\$ 954.0	20%	50.0%	27.2	\$ 1.60	19.8	19.4
<b>Selected Comps</b>								
Teva	TEVA	\$1,900.0	43%	45.0%	21.4	\$ 2.28	41.0	20.1
Duramed Pharma**	DRMD	\$ 94.0	76%	48.6%	13.8	\$ 0.30	69.0	-
Pharmaceutical Res	PRX	\$ 93.0	19%	32.4%	6.5	\$ 0.17	0.0	4.5
Hi-Tech Pharmacal	HITK	\$ 29.0	16%	49.3%	16.9	\$ 0.80	1.0	11.6
Bradley Pharma	BPRX	\$ 21.0	27%	78.7%	22.4	\$ 0.49	6.0	29.7
<b>Valuation Data</b>								
		<i>Price</i>	<i>2000</i>	<i>2001</i>	<i>2002</i>	<i>Price/ \$ Flow</i>	<i>Pri/Sales</i>	<i>Price/Bk</i>
Peer Group Average*		\$ 26.89	49.3	72.0	34.5	56.3	9.5	14.8
Industry Average		\$ 33.42	42.0	40.0	25.4	41.5	16.2	10.3
Top Performers Average		\$ 60.40	52.9	34.6	25.3	39.1	6.6	8.2
<b>Selected Comps</b>								
Teva	TEVA	\$ 62.01	43.7	34.3	28.6	27.2	4.1	6.6
Duramed Pharma**	DRMD	\$ 17.42	-	-	-	57.8	4.9	57.5
Hi-Tech Pharmacal	HITK	\$ 11.39	23.2	-	-	14.2	1.8	2.5
Pharmaceutical Res	PRX	\$ 5.5	-	105.0	28.1	181.5	9.8	14.6
Bradley Pharma	BPRX	\$ 5.5	23.7	-	-	11.2	2.2	3.5

Source: Baseline \*Peer group avg. includes firms with LTM sales between \$110-20 million. Top performers avg includes BRL, ADRX, IVX, TEVA, WPI, Industry average includes AZA, KG, WPI, MYL, ICN, SEPR, BRL, MRX, ALO, TARO, ADLR, NOVN, PRX, IPXL, MOGN, INKP, ELI, BPRX, HITK & NXXI. \*\*On 6/29/01, Barr Laboratories agreed to acquire DRMD.

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