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Management

Mylan Laboratories Inc. (MYL)

Generic Pharmaceutical Industry

RECOMMENDATION: HOLD

October 15, 2001

Market Cap:

\$4.4 billion

Current Price:

\$34.97

52-week price range:

\$20.15-37.00

Dividend Yield:

.45%

Valuation Price:

\$38.44

6-month Price Objective:

\$42.62

Summary:

Mylan Laboratories Inc. is engaged in developing, licensing, manufacturing, marketing and distributing generic and brand pharmaceutical products. The Company conducts business through its generic (Generic Segment) and branded (Brand Segment) pharmaceutical operating segments. Mylan sells its products primarily to proprietary and ethical pharmaceutical wholesalers and distributors, drug store chains, drug manufacturers, institutions and governmental agencies within the United States. The Company's Generic Segment consists of two principal business units, Mylan Pharmaceuticals Inc. and UDL Laboratories Inc. Mylan's Brand Segment operates principally through its wholly owned subsidiary, Bertek Pharmaceuticals Inc.

Source: Market Guide

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Investment Summary

We are initiating a hold recommendation for Mylan Laboratories. The stock is currently trading at a 9.9% discount to fair value. We are cautiously optimistic on Mylan for the following reasons:

- Expected earnings (15.5%) to trail industry (20.8%) and overall market (17.0%).
- Intended 50/50 Generic and Branded revenue mix is not plausible in intermediate term.
- Market has already priced growth into the stock price:
 - Mostly due to beating 1Q02 earning estimates by 29%
 - \$.09 per share in 1Q01 came from investment income from a limited partnership. This partnership will not contribute future earnings after CY01.
- Near-term first to market launches may include generic forms of Glucophage and Accutane, with current sales of \$500Million and \$1.5 Billion, respectively.

	FY2001	2002E	2003E
EPS	\$1.28	\$1.56	\$1.68

Explanation of Ratings

Strong Buy: Valuation Price > 20% of current price
 Buy: Valuation Price > 10% -20% of current price
 Hold: Valuation Price +/- 10% of current price
 Sell: Valuation Price < 10% of current price

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Strategy

Mylan's goal is to become a well-balanced pharmaceutical manufacturer with 50% branded sales and 50% generic sales. Currently, branded sales account for only 17% of total revenues. Also, branded R&D only accounted for 30% of total R&D in FY2001. Mylan will have to significantly increase this percentage if it hopes to develop 50% of its sales from branded products.

Like all pharmaceutical companies, Mylan's long-term profitability is contingent on its ability to develop new products. Mylan currently has a modest pipeline relative to its peers, with only 24 pending new drug applications. Mylan is developing branded treatments for severe acne, epilepsy and insomnia.

Market Share

According to IMS Health estimates, Mylan held 11.8% of the global generics market in terms of sales in 2000.¹ Mylan drugs account for nearly 5% of all generic prescriptions written in the U.S. Mylan has a significant branded business which contributes approximately 17% of sales, a mix similar to Teva's but a far cry from Watson's 50% branded mix.

Growth Opportunities

In the near-term, management can exceed current Wall Street expectations by:

¹ Appendix B



1. *Avoiding distractions and Costs associated with ongoing litigation.* On Feb 02, 2001 Mylan settled with insurers and states' attorney generals for more than \$35 MM for allegedly violating various states' antitrust and consumer protection laws. It was alleged that the firm conspired with raw material suppliers to corner the market for the active pharmaceutical ingredients used to make generic lorazepam and generic clorazepate. The settlement stems from charges two years ago citing that states and insurers paid too much for the drugs which shot up in price more than 3,000% in 1998. The \$35 MM settlement comes on the heels of a \$147 MM suit brought on by the FTC last year. CEO Puskar acknowledged in a press statement that litigation was a distraction but assured the public that the company would not lose its focus. On Aug 20, 2001 the New York Patrolman's Benevolent Association sued alleging Mylan violated anti-trust laws by keeping much less expensive generic drugs off the prescription market at a multi-million dollar yearly cost to consumers. The suit alleges that Mylan settlement with Pfizer following the duos 1997 patent battle and ensuing counter-suit over Procardia, in which Mylan agreed to market Pfizer's licensed generic instead of its own, forced the NYPBA to pay inflated prices for the drug. Who knows what other back room deals will come to light? *Likelihood- Low*

2. *Winning BuSpar federal appeals court case.* On Mar 03, 2001 Federal Judge Ricardo M Urbina in the US District Court for the District of Columbia (a lower court) ruled that Bristol Myers Squibb's defensive tactic, whereby it presented patents on BuSpar side effects, exploited a loophole. He ordered the BMS patents delisted and authorized the FDA to clear Mylan and Watson's generic versions of BuSpar for marketing approval. BMS appealed and a case is before a federal appeals court in Washington D.C. The appeals court could overturn the lower court's ruling allowing the two companies to sell generic BuSpar. According to legal commentary², because Judge Urbina opted to sidestep a time-consuming review process in delivering his verdict, the appeal looks to have a good chance of succeeding. According to the same source, few investors seem to be aware of the case, meaning they could be in for a nasty surprise when the verdict comes in. *Likelihood- Uncertain.*

² *WSJ Heard on the Street, Aug 20, 2001.*



In the intermediate term, management can exceed current Wall Street expectations by:

1. *Delivering on the Bertek promise.* Mylan's branded segment operates through its wholly owned subsidiary, Bertek Pharmaceuticals, Inc. Bertek was acquired on Feb 15, 1993. According to the firm, Bertek is a transitional pharmaceutical company that will enable to Mylan to grow from a traditional generic company to a proprietary based company; Bertek's goal is to expand the branded business to 50% of company revenues. However, in the quarter ending June 2001, branded revenues contributed to only 11.8% of quarterly \$237.9 MM revenues or \$28.1 MM³. In the same period, R&D spending was \$16.8 MM up from \$16.5 MM in the year ago period, though branded revenues decreased. Assuming even a 50% profit margin on branded sales of \$28.1 MM shows that Bertek is a cost center. The company has not disclosed research activities. A public clinical trials database does not reveal any drugs Bertek is testing.⁴ The company disclosed that it obtained U.S. and Canadian exclusivity for Nebivolol. Mylan plans to clinically test this beta blocker, currently marketed in 30 countries, and submit for NDA approval to the FDA in 2003. It is not clear what the company's motives are in backing a "me- too" drug nor were terms of any agreements disclosed. Physicians may already be prescribing the drug "off-label" for hypertension. *Likelihood- Low.*

2. *Beating U.S. ANDA approval expectations for the current fiscal year.* ANDA approvals for generic manufacturers vary greatly across firms and across years. In 2000, Mylan received approval and launched 15 drugs in the U.S. However in 1999 the figure was 22 and in 1997 it was 13. Generally, top tier companies can be expected to launch 8-12 drugs per year⁵. To date for the current year, Mylan has launched or gained tentative approval for well above the threshold⁶. *Likelihood- High.*

³ Chairman's 08-15-01 letter to investors

⁴ www.recap.com

⁵ Appendix C.

⁶ Press Releases



In the long term, management can exceed current Wall Street expectations by:

1. *Beating ANDA filing expectations going forward.* Mylan's pipeline is weak compared to its peers although they should meet launch expectations of 8- 12 drugs going forward.⁷ On March 29, 2001 Mylan's UDL subsidiary sold ANDA assets to Alpharma including 8 approved ANDAs, one tentatively approved ANDA, and four under development. Although Mylan's pipeline is weak relative to peers, it can afford to sell some assets as long as it is able to launch the threshold number. Other rivals may follow Mylan's divestiture strategy to generate funds and/ or focus. *Likelihood- High.*

2. *Obtaining Paragraph IV exclusivity on some of the high profile drugs coming off patent through to the end of 2005.* In 2005, drugs totaling \$16 billion in global sales will be coming off patent.⁸ Mylan has demonstrated its ability to go after top tier drugs and be first in line, obtaining approvals for BuSpar, Pepcid, Mevacor, Paclitaxel, and Stadol Nasal Spray all within the year to date. *Likelihood- High.*

3. *Re- engineering Mylan Technologies, Inc.* Mylan Technologies Inc. is responsible for value added generics mostly in cream dosage forms. This subsidiary was created from the acquisition of Penederm on Oct 02, 1998 and has not contributed any products thus far in 2001. On Oct. 02, 2001 Mylan announced Sharad Gavil as the units new President. As a company insider, it is not clear how effective Mr. Gavil will be in re-engineering Mylan Technologies, Inc. *Likelihood- Too early to tell.*

4. *Re- engineering the firm.* The company should consider whether it wants to stay in the value added generic and branded space. Its Mylan Technologies and Bertek subsidiaries are under- performing and are cost centers. Given current litigations and costly settlements, Mylan may find itself selling unprofitable units to pay suits. *Likelihood- Too early to tell.*

⁷ Appendix C.

⁸ Appendix D.



Ratio Analysis⁹

Mylan's sustainable growth rate for the year 2000 was below Teva and the Sector. Its plowback ratio is similar to Teva's, however Mylan is not as leveraged as Teva, Watson, or the Sector. This lack of leverage should concern management. Mylan's profitability and turnover were healthy. Mylan's earnings growth rate for the year 2000 was best in its class, yet its P/E was below Teva and Watson. Investors may be concerned that Mylan's earnings growth is not sustainable or that earnings have reached a plateau.

Idiosyncratic Risk Factors

High Litigation Costs

Mylan recently agreed to pay \$147 million in damages relating to alleged anti-trust violations related to the sale of raw materials for certain drugs. In the future, the company may face high costs associated with this pending settlement as well as other suits including an alleged anti-trust violation with Pfizer involving the heart drug Procardia.

Management Worries

Outspoken Chairman, CEO and founder, 66 year old Milan Puskar, may find it difficult to hand the reigns over to new management. Recently, both the COO and the CFO left after only a few months with the firm due to an inability to "fit with Mylan's culture". This lack of managerial continuity is a significant risk given Mylan's goal of dramatically altering its branded/generic mix over the coming years.

Industry Risk Factors

New Products

Future earnings are dependent on Teva's ability to successfully develop and commercialize additional generic and branded pharmaceutical products. Due to the intense competition in the generic drug industry, Teva's inability to be first to market with new products is the greatest risk for future earnings growth.

⁹ Appendix A



Brand-name Manufacturers

Brand-name manufacturers do not face significant barriers to entry into the generic market of their branded drug. Furthermore, these companies can extend brand-name exclusivity through years of litigation or by developing and marketing as over-the-counter products those branded products that are about to face generic competition.

Legislation

Interpretive changes in the Waxman-Hatch Act could affect the FDA's current policy of 180-day exclusivity for new generic drugs. A decrease in the exclusivity period will have a significant negative impact on future earnings. Furthermore, changes in the rules that govern health-care in the U.S., Europe and Israel could reduce Teva's profit margins and ability to sustain growth.

Power Buyers

Industry's principal customers include wholesale drug distributors, major drug store chains and large public and private healthcare providers. A continued trend toward consolidation in these distribution networks will likely result in downward pricing pressures on pharmaceutical manufacturers.

Stock Performance and Volatility (Source: Yahoo! Finance, Bloomberg)

Summary

Price (October 12 2001): \$34.97

52-week range: \$20.15-37.00

1-Year Total Return: 29.7%, S&P 400 Midcap: -8.2%

Dividend: \$.16 per share

Current P/E: 27.32

Recent Insider Trades (6-month): None

Short Interest: 3.3%

Shares held by institutions: 62.3%

Beta

Vs. S&P 500 = .64

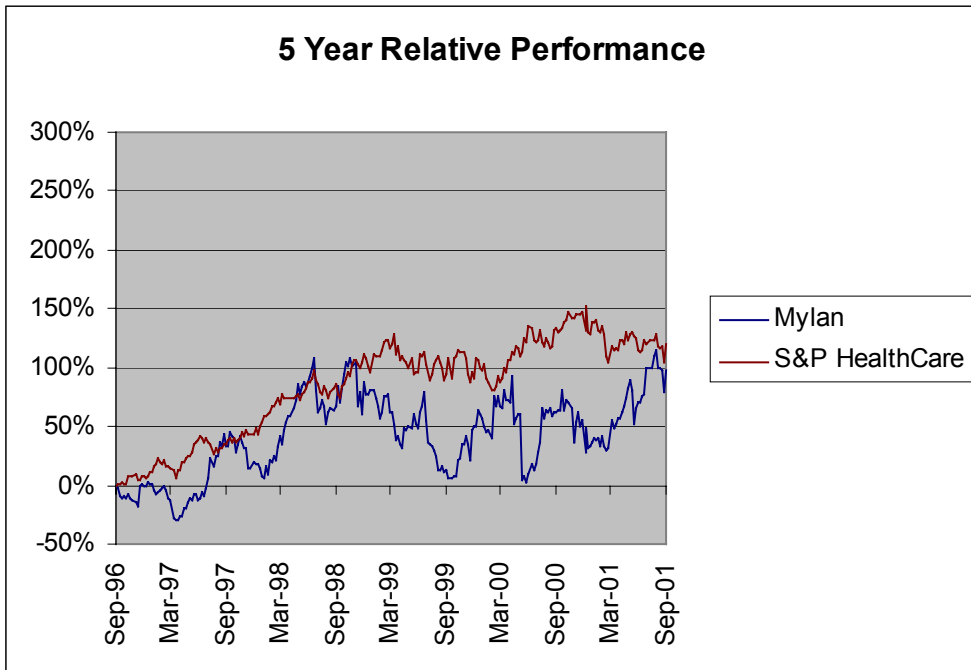
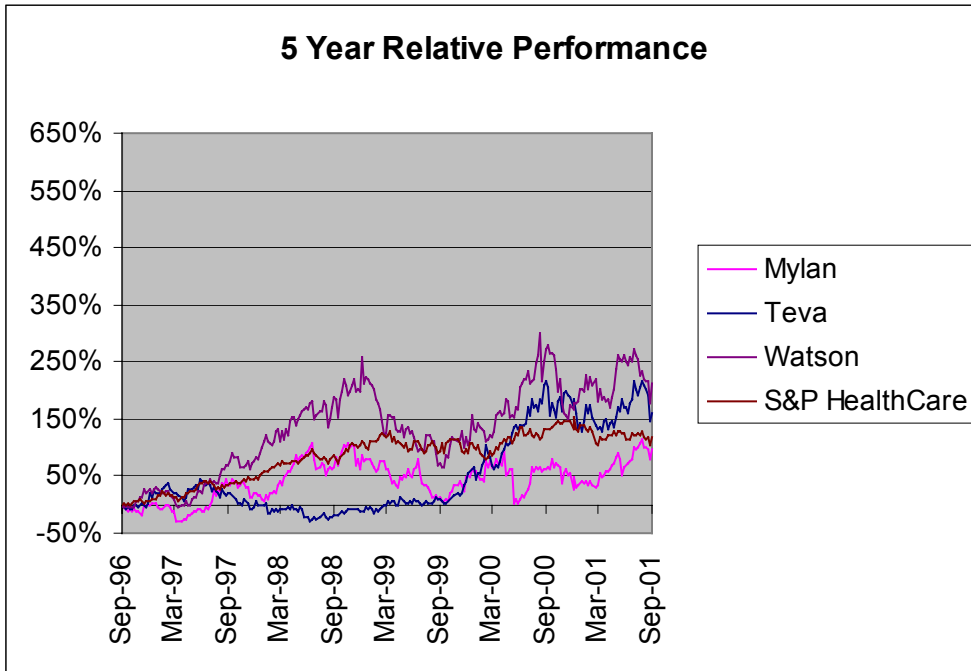
Vs. S&P Drug = .33

Vs. S&P Healthcare = .37



Volatility

100 Day Historical Standard Deviation: Mylan = 40.9%, S&P 500 = 20.7%





Mylan Laboratories Inc
as of 11-Oct-2001



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**Valuation Model****DCF Analysis****Assumptions**

Risk-free rate (10-year T-bond yield)	4.66%	(Yahoo! Finance)
Average historical risk premium	6.50%	(Ibbotson Associates)
Company beta	0.64	(S & P's Stock Report, 10/6/01)
Tax rate	36.00%	(Calculated from company data)
WACC	8.30%	
Long-term growth rate	3.00%	(Assumed)
Average number of outstanding shares	126MM	(Assumed)

	2002E	2003E	2004E	2005E	2006E	2007E
Strong Growth Model						
Growth Rate	18.00%	17.00%	15.00%	12.00%	7.00%	3.00%
Enterprise Value	\$8,299.12 MM					
Market Value of debt at September 2001	\$333.40 MM	(Assume market value = book value)				
Value of Equity	\$7,965.72 MM					
Value per share	\$63.22					
Moderate Growth Model						
Growth Rate	15.00%	14.00%	12.00%	9.00%	6.00%	3.00%
Enterprise Value	\$5,626.66 MM					
Market Value of debt at September 2001	\$333.40 MM	(Assume market value = book value)				
Value of Equity	\$5,293.26 MM					
Value per share	\$42.01					
Slow Growth Model						
Growth Rate	12.00%	11.00%	9.00%	7.00%	5.00%	3.00%
Enterprise Value	\$3,146.98 MM					
Market Value of debt at September 2001	\$333.40 MM	(Assume market value = book value)				
Value of Equity	\$2,813.58 MM					
Value per share	\$22.33					
Fair value per share	\$38.44					



Comparable Companies Analysis

Selected Comparable Companies	Mkt cap. (\$ billion)	Price/sales	Price/book
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Teva Pharmaceuticals	8.56	4.34	7.29
Watson Pharmaceuticals	5.63	5.42	3.33
Average of comparable companies		4.88	5.31

Mylan Laboratories	Sales/Share	Book/Share
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LTM	15.42	9.18
Value per share	\$75.25	\$48.75
2002E	7.80	10.42
Value per share	\$38.06	\$55.33

Value Range
\$38.06 ---- \$75.25

Source: www.hoovers.com

Definition:

Price/Sales Ratio - Equals the last closing stock price divided by the LTM revenue per share.

Price/Book Ratio - Equals the last closing stock price divided by common stock equity per share from the most recent balance sheet.



Appendix

Appendix A

Company Ratios

	Teva		Watson		Mylan		Industry		Sector	
	One Yr	5 Yr Av	One Yr	5Yr Av	One Yr	5 Yr Av	One Yr	5Yr Av	One Yr	5 Yr Av
Profit Margin (Net Income/ Sales)	11%	8%	6%	25%	18%	14%	N/A	1%	14%	12%
X Sales Turnover (Sales/ Assets)	75%	83%	42%	57%	65%	65%	N/A	21%	95%	92%
Return on Assets	9%	7%	2%	14%	12%	9%	4%	0%	13%	11%
X Leverage (Assets/ SE)	228%	226%	157%	130%	128%	115%	225%	1637%	183%	228%
Return on Equity	20%	15%	4%	18%	15%	11%	8%	5%	24%	25%
X Plowback Ratio	87%	87%	100%	100%	88%	88%	99%	99%	73%	73%
Sustainable Growth Rate	17%	13%	4%	18%	13%	9%	8%	5%	18%	18%
Sales Growth Rate	33%	17%	40%	33%	18%	17%	22%	32%	13%	16%
Earnings Growth Rate	97%	14%	-85%	24%	273%	-19%	21%	22%	27%	14%
Return on Investment	12%	11%	3%	16%	14%	10%	5%	3%	17%	17%
EPS	1.15		1.68		0.3					
P/E	37.45		107.7		25.05					
P/S	4.24		5.59		4.48					
P/B MRQ	6.39		3.44		3.45					

Source: TTM FY00 Business Browser

Appendix B

Leading Global Generic Manufacturers	Generic Market Share		Overall Prescription	
	1999	2000E	1999	2000E
Mylan	11.2%	11.8%	4.8%	5.0%
Teva	10.8%	11.9%	4.6%	5.1%
Geneva	6.7%	7.2%	2.9%	3.1%
Watson	6.4%	6.9%	2.7%	2.9%
Schein	5.9%	6.1%	2.5%	2.6%
Apothecon	6.1%	5.4%	2.6%	2.3%
Zenith	4.8%	5.1%	2.0%	2.2%
Abbott	3.4%	3.6%	1.4%	1.5%
Prods	2.9%	2.9%	1.2%	1.2%
Greenstone	2.8%	2.6%	1.2%	1.1%
Others	39.0%	36.5%	74.1%	73.0%
	100.0%	100.0%	100.0%	100.0%

Source: IMS and UBS Warburg LLC estimates



Appendix C

ANDA Approvals By Manufacturer 1997-2001

	1997	1998	1999	2000	YTD (2) 2001
Teva	14	7	6	18	1
IVAX	8	4	7	11	2
Watson (3)	8	8	2	8	5
Mylan	13	16	22	15	3
Schein	4	8	6	0	0
Barr Labs	4	6	1	6	3
Taro	3	5	4	7	0
Alpharma	5	6	4	3	0
Abbott Laboratories	7	6	3	8	0
Geneva	5	3	2	2	1
Subtotal	71	69	57	78	14

ANDA Pending

	ANDAs Pending	Est. No. Of '01 Filings	Est. No. Of '01 Launches
Teva	49	15	8-12
Ivax	38	30	8-10
Watson	20	31	8-10
Mylan	24	18	8-12
Barr	18	15	8-12

Source: US FDA and SG Cowen Estimates

Appendix D

Generics Exposure Branded Drugs Off or Coming Off Patent					
Patent Expiration	Brand	Generic	Function	Patent Holder	1999 Global Sales (US\$MM)
1999					
Dec-99	Humulin	human insulin	diabetes	Eli Lilly	1,087
2000					
Feb-00	Hytin	terazosin	hypertension	Abbott	570
Feb-00	Vasotec	entapril	hypertension	Merck	2,805
Mar-00	Glucophage	metformin	diabetes	BMS	1,317
May-00	Ceftin	cefuroxime	infection	Glaxo	680
May-00	Buspar	buspirone	anxiety	BMS	605
Jul-00	Neurotin	gabapantin	epilepsy	Pfizer	918
Feb-00	Taxol	paclitaxel	cancer	BMS	1,481
Oct-00	Pepcid	famotidine	gastrointestinal	Merck	910
Oct-00	Cardura	doxazosin	cancer	Pfizer	794
Nov-00	ProcardiaXt	plfedpine	hypertension	Pfizer	521
				Subtotal	10,601
2001					
Feb-01	Prozac	fluoxetine	depression	Eli Lilly	2,613
Mar-01	Prilosec	bmeprazole		AstraZenecagastrointestina9	
Jun-01	Mevacor	lovastatin	hypercholestrolemia	Merck	600
Aug-01	Accutane	isotretinoin	acne	Rache	705
Dec-01	Prinivil	lisinopril	hypertension	Merck	815
Dec-01	Zestril	lisinopril	hypertension	AstraZenecathypertension	1,220
				Subtotal	5,953
2002					
Dec-02	Augmentin	amoxicillin	infection	Glaxo	1,819
Dec-02	Infron A alpha	interferon Plougn	hepatitis-C	Scnering	850
April-02	Axid	nizatidine	gastrointestinal	Eli Lilly	350
Dec-02	Relaten	nabumetone	arthritis	Glaxo	267
				Subtotal	3,286
2003					
Feb-03	Singulair	montelukast	asthma	Merck	500
Nov-03	Flovent	fluticasone	asthma	Glaxo	1,079
Nov-03	Flonase	fluticasone	allergy	Glaxo	593
Nov-03	Cipro	ciprofloxacin	infection	Bayer	1,625
Dec-03	Engerix-B	hepatitis B vaccine	Glaxohepatitis B	SmithKline	540
				Subtotal	4,337
2004					
Jan-04	Diflucan	fluconazole	infection	Pfizer	1,002
April-04	Paraplatin	carboplatin	cancer	BMS	500
April-04	Claritin	loratadine		Schering Plough	
June-04	Xencial	orlistat	obesity	Roche	499
July-04	Lamisil	terbinafine	tinea pedis	Novartis	700
Aug-04	Welbutn	bupropion		Glaxo	
Oct-04	Lupron	leuprolide	cancer	Tap	730
Dec-04	Lovenox	epoxapatin	deepveinthromposis	Aventis	760
				Subtotal	4,191
2005					
May-05	Biaxin	clarithromycin	infection	Abbott	1,275
June-05	Zotran	ondansetron	nausea	Glaxo	674
July-05	Prevacid	lansoprazole	ulcer	Tap	1,900
Aug-05	Aredia	pamidronate	hypercalcemism	Novartis	588
Sept-05	Zoladex	gosereline	endometriosis	AstraZeneca	686
Oct-05	Combivl	lamidudine	HIV	Glaxo	736
Oct-05	Zithromax	azithromycin	infection	Pfizer	1,333
Dec-05	Pravachol	pravastatin	hypercholesterolemia	BMS	704
Dec-05	Zocor	simvastatin	hypercholesterolemia	Merck	4,495
Dec-05	Zoloft	sertraline	depression	Pfizer	2,034
Dec-06	Paxil	paroxetine	depression	Glaxo	2,109
				Subtotal	16,534
				Grand Total	45,989

Source: Orange Book and UBS Warburg LLC estimates

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