Generic Drug Industry
Healthcare – Pharmaceuticals

Investment Thesis
We are bullish in generic drug industry because of the following key drivers: global spending trend towards generics, continued patent cliff, healthcare reform in US and fast growth in emerging market.

Drivers of Thesis
- Ever-rising healthcare expenditures have forced governments and third-party payers to seek ways to control healthcare costs. This pressure creates an increasing demand for generic drugs versus branded counterparts.
- Continued patent cliff till 2018 provides pipeline opportunities for the industry. Biosimilar, first-to-file and branded generics are the high value pipelines that provide better margins for the companies.
- Global increase in both overall populations and aging demographics will continue to increase the drug utilization rate.
- The Affordable Care Act allows the industry to see benefits from nearly 30 million currently uninsured Americans coming into the market. The Act also encourages increasing the usage of generic drugs.
- Faster generic drug spending growth rate in emerging market provides opportunities for the industry.

Risks to Thesis
- A recently proposed Food and Drug Administration (FDA) regulation affecting generic drug labeling would introduce product liability, increasing the overall costs for generic manufacturers. Should the rule be finalized, it would increase spending on generic drugs by $4 billion per year.2
- Pricing and margins in the industry have a tendency to decline as a result of fierce competition in the generic drug industry and increased government pricing pressure.
- Less pipeline opportunities after the patent cliff ending in 2018.

Key Index Statistics

<table>
<thead>
<tr>
<th>Price Data15</th>
<th>Price/Earnings (ttm)</th>
<th>Yield (ttm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Price</td>
<td>$92.39</td>
<td>6.56%</td>
</tr>
<tr>
<td>52wk Range</td>
<td>$64.50 – 102.80</td>
<td>0.63</td>
</tr>
<tr>
<td>YTD Return(Mkt)</td>
<td>6.56%</td>
<td></td>
</tr>
</tbody>
</table>

Trailing Returns15
- 3-Month Return: 6.56%
- 1-Year Return: 51.47%
- 3-Year Return: 28.14%
- 5-Year Return: 29.88%

Key Players by Market Cap(B)22

<table>
<thead>
<tr>
<th>Company</th>
<th>Market Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novartis(Sandoz)</td>
<td>229.5</td>
</tr>
<tr>
<td>Abbott</td>
<td>59.7</td>
</tr>
<tr>
<td>Teva</td>
<td>47.3</td>
</tr>
<tr>
<td>Actavis</td>
<td>35.4</td>
</tr>
<tr>
<td>Mylan</td>
<td>18.0</td>
</tr>
</tbody>
</table>

Industry Description
Generic drug industry mainly develops, manufactures and sells generic products which are comparable to the branded counterparts in terms of dosage, intended use and efficacy. The industry generally spends less money on R&D and is able to produce products at a much lower cost.

XPH: S&P Pharmaceuticals

April 23, 2014

Important disclosures appear on the last page of this report.
EXECUTIVE SUMMARY

We have positive outlook for generic drug industry for the next 12 months. Although the industry continues to face squeezed margins due to increased competition and pricing pressure from the government, as well as the uncertainty about the FDA generic drug labeling rule, we think the investment positives will offset the negatives and we are estimating a faster growth rate in the generic industry till 2017. With patent cliff coming to an end in 2018, we are expecting a slower growth rate after that considering less pipeline opportunities for the industry.

Right now, we are bullish on the generic industry for the following drivers. The biggest driver is global medicine spending trend towards generics. With most governments in the world to seeking ways to control healthcare budgets, we are positive about generic drug’s growth rate compared with its branded counterparts. Also, the continued patent cliff creates growing pipelines opportunities for the generic firms. Growth in both overall population and aging demographics prove to be beneficial for the overall healthcare sector including generic drug makers. Healthcare reform in US and fast growth in emerging market are other important drivers for the industry.

In particular, we will closely monitor the companies with high-value medicines (branded generics, biosimilars etc.) in their portfolio. We will also pay attention to the company that is the first-to-market generic forms of blockbuster at the same time. We believe first-to-file generics, branded generics and biosimilars will provide greater profit margins and companies with a higher percentage of these products will benefit the most.

INDUSTRY DESCRIPTION

The generic drug industry is mainly about developing, manufacturing and selling generic products which are comparable to the branded counterparts in terms of dosage, intended use and efficacy. The approval process is less time and cost consuming compared with branded drugs and therefore generic drug makers do not need to spend much in R&D. Generally, the generic drug makers are able to produce drugs 80% to 85% less than the comparable branded products.3

The following graph describes the products and service segmentation in the industry. The top products mainly come from metabolic drugs, cardiovascular drugs and central nervous system drugs.

Source: IBIS Industry Report22

There are two main competitive factors in this industry. In most cases, the generic products have no unique characteristics and cannot charge premium pricing. So the generic firms have to find ways to lower the cost and they usually compete based on manufacturing and economics of scale. Another important factor is the competence in litigating complex patent issues, as an important part of a generic manufacturer’s operation would be challenging and invalidating patents.

Generic drugs play an essential role in alleviating the high costs on the healthcare system. In US alone, $1.2 trillion spending was reduced because of generic drugs in the last decade.2 The following graph from the latest IMS health report reveals a global spending trend shift towards generics from 27% in 2012 to 36% of the in 2017. The global generic drugs market was valued at nearly $260 billion in 2012 and is estimated at nearly $432 billion in 2017, registering a compound annual growth rate (CAGR) of 11% from that period.

Looking closely at each segmented market we notice that generic drugs take a much bigger market share in pharmerging countries (China, Brazil, India, and Russia) than in developed countries. Also, the generic drug CAGR (14%) in the pharmerging countries is bigger than the CAGR (7%) in the developed nations. In addition, the manufacture costs in the pharmerging countries are generally less than in the developed nations. We think pharmerging market representing one of the best growth opportunities and we value those companies who expand their global presence.
In conclusion, we think firms that have good management of the manufacture cost and complex patent issues while actively engage in pharmerging market will perform the best in the industry.

RECENT DEVELOPMENTS

Continued Patent Cliff

2011 marked the beginning of the patent expirations of some of the major pharmaceutical blockbusters. Despite a projected lull in the patent cliff for the remainder of 2013 through 2015, key patents will continue to expire in through 2018. The total amount of branded drug sales jeopardized by patent expirations in 2014 is estimated to be $34 billion. A generic drug generally takes about 80% of the branded drug market share and prices at about 20% of the branded counterpart. This will translate to about 16% branded drug sales or $5.4 billion in revenue for the generics industry in 2014. The following chart describes the US major recent and potential patent expirations.

In particular, we notice that Teva’s loss of Copaxone will be the biggest event in 2014 considering its annual sales of nearly $2.9 billion. However, FDA recently approved a 40mg dose of Copaxone and this higher-dosage version is protected until 2030. The new drug is expected to offer patients 60% less frequent annual administration. The management predicts 30%~50% of current patients would be transferred to the new drug. This is one example illustrating how branded drug owner companies are seeking various ways to remain competitive in the face of generic competition. In general, however, we believe that the generic drug manufacturers are still and will continue to benefit from these patent cliff opportunities.

Affordable Care Act

The Obama Administration has estimated that about 7 million people will enroll in exchanges in 2014, of which about 5 million will represent newly insured persons. The total number of uninsured Americans is about 30 million. In addition, Medicare and Medicaid are expected to receive more federal funding which could be another opportunity for the industry. The following graph illustrates the year-to-year percentage of change for the number of people with private health insurance and the federal funding for Medicare and Medicaid. The Increasing demand provides a positive effect on the
pharmaceutical industry in general. We see the trend continue to increase in 2014.

At the same time, because of the pressure on the branded sector by government and third-party payers to reduce hyperinflationary pricing,¹ we believe there will be continued greater emphasis on generic drug usage in the long run, which will significantly improve the generic drug market share in the US.

**INDUSTRY TRENDS**

Despite an upward trend in the total spending of generic drugs, companies within the industry are facing tighter margins due to fierce competition and increased pricing pressure from governments around the globe. Also, companies may face a shortage of pipelines supply after the patent cliff. We have seen several strategies taken by the generic drug company to weather the storm.

**Innovation and M&A**

In the pharmaceutical industry, innovation and rich pipelines are generally the key to long-term success. Also, as the branded and specialty drugs generally have a higher margin than the generic drugs, companies have been seeking ways to add these high-value products, either through research and development or through mergers and acquisitions. In fact, for the key 5 players in the industry (Page 1), the generic drug business is not their solo business. In particular, the leading generic manufacturer in the world, Teva Pharmaceutical Industries, has a robust specialty medicines portfolio that takes about 41% of their annual sales in 2013. Copaxone, their leading innovative product, took 22% of total sales alone.¹⁰ Another important player in the industry, Mylan, has transformed itself with significant acquisitions from a US-only, generic-only company into a global, diversified, vertically-integrated company.¹¹ We believe this innovation and M&A trend will continue in the generics business as companies are seeking high-value medicines to make up for lower margin generics and revitalize their portfolios.

**Biosimilars**

Biologics are currently the star products in the pharmaceutical industry due to their high-value-added quality. The global biologics market is estimated to reach $176.4 billion by 2012 and is expected to grow at CAGR of more than 9.5%.¹² The signing of the Affordable Care Act has established an approval pathway for generic biologic drugs, or biosimilars, in the United States. With the anticipated biologic patent cliff over the two years to 2015, it will provide generic firms with more high-value pipelines in the future.

**First-To-File Generics**

In the US market, the 1984 Hatch-Waxman Act offers the generic drug maker the first-to-file exclusive right. The first-to-file generic maker is entitled to 180 days of “generic exclusivity” when its generic first enters the market.²⁴ The exclusivity allows the generic drug manufacturers to take the market share and enjoy a greater profit margin considering other generic makers are prohibited from entering the market during this period. The profit business has engaged many generic drug makers to focus on the first-to-file generics opportunity and Teva is one good example with about 50% generic submits come from first-to-file generics. We believe this will be another trend in the industry seeking high-value products.

**MARKETS AND COMPETITION**

The competition in the industry is high. As we discussed earlier, there is no unique characteristics in the generic drug and the players in the industry have to compete with each other on prices. The industry is also facing pressure by the governments to continue lower price in order to reduce healthcare costs. In the US, the industry faces another pressure: increasing purchasing power from the consolidation of retail drug chains and drug wholesalers.

The following graph illustrates major players by market share in the US (Actavis 10.7%, Teva 9.6%, Mylan 9.1%, Sandoz 4.1%). Abbott Laboratories is another important player with lots of its sales in emerging market. We will compare across operating and financial metrics of these 5 players (Sandoz is the generic division of Novartis, we will use the key statistics from Novartis to compare).
Teva’s higher P/E ratio suggests a higher earnings growth expected by the investors. Compared with others, Teva did a good job in rewarding shareholders; the dividend yield is much higher than the industry average, we think Teva will continue similar dividend strategies in the future in order to make its stock more attractive when it is losing sales on the blockbuster Copaxone.

### Relative Valuation Comparison

<table>
<thead>
<tr>
<th>Company Name</th>
<th>Price</th>
<th>Market Value(B)</th>
<th>P/E Actual</th>
<th>P/B Actual</th>
<th>Dividend Yield</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teva</td>
<td>49.85</td>
<td>47.3</td>
<td>33.46</td>
<td>1.87</td>
<td>3.36%</td>
</tr>
<tr>
<td>Actavis</td>
<td>202.91</td>
<td>35.4</td>
<td>NA</td>
<td>3.71</td>
<td>0.00%</td>
</tr>
<tr>
<td>Mylan</td>
<td>48.32</td>
<td>18.0</td>
<td>30.58</td>
<td>6.10</td>
<td>0.00%</td>
</tr>
<tr>
<td>Abbott</td>
<td>38.71</td>
<td>59.7</td>
<td>23.90</td>
<td>2.38</td>
<td>1.67%</td>
</tr>
<tr>
<td>Novartis</td>
<td>84.80</td>
<td>229.5</td>
<td>22.55</td>
<td>2.77</td>
<td>3.44%</td>
</tr>
<tr>
<td>Average</td>
<td>84.92</td>
<td>77.99</td>
<td>27.62</td>
<td>3.37</td>
<td>1.69%</td>
</tr>
</tbody>
</table>

Source: Factset

We also made a comparison in the operating results. Although Teva’s EBIT margin is higher than average, there is still room for improvement when compared with competitor Mylan. The Return on Assets and Return on Equity results for Teva are much less impressive and Teva could make more efficient use of its assets and equity in the future.

### Relative Operating Comparison

<table>
<thead>
<tr>
<th>Company Name</th>
<th>EBIT Margin</th>
<th>Return on Assets</th>
<th>Return on Equity</th>
<th>Current Ratio</th>
<th>Total Debt/ EBITDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teva</td>
<td>19.4%</td>
<td>2.6%</td>
<td>5.6%</td>
<td>1.15</td>
<td>2.10</td>
</tr>
<tr>
<td>Actavis</td>
<td>8.9%</td>
<td>NA</td>
<td>NA</td>
<td>1.35</td>
<td>4.99</td>
</tr>
<tr>
<td>Mylan</td>
<td>20.4%</td>
<td>4.6%</td>
<td>19.9%</td>
<td>1.51</td>
<td>4.18</td>
</tr>
<tr>
<td>Abbott</td>
<td>12.2%</td>
<td>4.3%</td>
<td>9.2%</td>
<td>2.02</td>
<td>1.50</td>
</tr>
<tr>
<td>Novartis</td>
<td>16.9%</td>
<td>7.5%</td>
<td>13.2%</td>
<td>1.16</td>
<td>1.19</td>
</tr>
<tr>
<td>Average</td>
<td>15.6%</td>
<td>4.8%</td>
<td>12.0%</td>
<td>1.44</td>
<td>2.79</td>
</tr>
</tbody>
</table>

Source: Factset

Regarding liquidity, Teva’s current ratio is lower than the average of peers and there is room for improvement in the future. The good sign is Teva’s total Debt/ EBITDA is lower than the average which suggests the company is still able to continue pursuing big transactions in the future. This proves to be beneficial considering Teva’s CFO signals appetite for acquisition earlier this year.

Overall, we think Teva is a good choice in our portfolio, but Teva needs to do a better job improving its profitability and efficient use of the asset. We will also keep an eye on Mylan given its outstanding return on a relatively small market cap, but we also have concerns about its high Debt/ EBITDA ratio, we will keep on monitoring its future business development.

**Teva**

Teva is the leading generic maker in the world. Its generic sales accounts for 49% of 2013 sales revenue. As we mentioned earlier, Teva also has a rich portfolio of specialty drugs, which provides great sales revenue and gross margin for the company. In the future, Teva is going to continue diversify their products and expanding their global presence to business markets such as China and India. Regarding generics business, the company is planning to focus on high-value medicines (branded generics, first-to-file generics, biosimilars etc.) as a way to better position itself in the competitive generic industry.

**Actavis**

Actavis is a global pharmaceutical company focused on developing, manufacturing, and distributing generic, brand, and biosimilar products. They have operations in more than 60 countries and they are in leading market-share positions in more than 33 markets, including emerging market Russia. Actavis has aggressively expanded through M&A since 2009. By December 31, 2013, the company had more than 195 Abbreviated New Drug Applications (ANDAs) in its generic pipeline that are pending FDA approval.

**Mylan**

Mylan also operates in both generics and specialty. It acquired a controlling interest in top generic drug ingredient maker Matrix from India. It also acquired generic business Merck KGaA from Germany. These two acquisitions made Mylan grow into the third largest generic and specialty pharmaceutical company in the world. The company has been known for an active deal maker in the M&A, the acquisition of Agila make it possible for Mylan to be a global leader in generic injectables. Together with Actavis, Mylan has one of the
highest Debt/EBITDA ratio, we think that may have some negative impact on its M&A activities in the future.

**Abbott**

Abbott Laboratories mainly operates its generics business abroad and it has a strong position in some important emerging markets. Abbott is also facing pricing pressures in Europe which have undercut its growth. The company is working on improving commercial execution to boost those sales.  

**Novartis (Sandoz)**

Sandoz is the generic pharmaceuticals division of Novartis, representing 15% of the Group’s total net sales. Being as a part of large diversified brander drug company benefits Sandoz’s business development. Sandos had a variety of generic drugs and did a good job in biosimilars. Sandoz already markets 3 biosimilars and has another 8-10 biosimilar molecules in its pipelines, including one for Roche’s leukemia drug Rituxan with annual sale around $7 billion. 

**ECONOMIC OUTLOOK**

**Population Growth**

World population is projected to increase by about 1 billion in the next 12 years (CAGR 1%). Most of the growth will occur in developing regions (with more than half in Africa). As more people will result in more illness to combat, the increasing population will benefit the healthcare sector including generic drug industry in the long run.

**Aging Demographic**

Globally, one of the fastest growing demographics includes people over 60 years of age. The growth rate of the older population (1.9%) is significantly higher than that of the total population (1.2%). With more than 90.0% of seniors rely on prescription medication on a regular basis, we believe the aging demographic will be a long-term driver for the healthcare sector including generic drug industry.

**Consumer Confidence and Real GDP Growth**

Generally, healthcare sector has been known as a defense sector for people even in bad economy are to spend money on healthcare products and services, but still, lower consumer confidence and real GDP growth will negatively impact the industry. We have seen steady slow improvement in both indicators and we believe this trend will continue. Stronger consumer confidence in a slowly recovery economic environment has led to a continued increase in consumer spending, as shown in the following graph. We believe this increase consumer spending trend will benefit the industry as well.
CATALYSTS FOR GROWTH

As we mentioned earlier, there are many catalysts for the healthcare sector as well as the generic manufacturer industry.

In short term, ongoing patent cliff provides continued benefits to the generic drug industry. The passage of the Affordable Care Act also allows the industry to benefit from significant market expansion. Faster growth opportunities in the emerging markets are also in favor of generic industry.

In long term, global increase in both overall populations (especially developing countries) and aging demographics paint a rosy picture for the healthcare sector.

In addition, global governments and third-party payers shift their focus to generic drugs in order to control healthcare costs also drive the growth in the generic drug industry.

INVESTMENT POSITIVES

- The ongoing patent cliff provides valuable opportunities for generic drug manufacturers to increase the products in their portfolios. In 2014 alone, it is estimated that the total amount of branded drug sales jeopardized by patent expirations is $34 billion. As generic drug generally takes 80% of branded drug market share at about 20% of their price, this translates to over $5.4 billion market share for generic drugs.

- The overall increase in the population and the aging demographics in the world provide a long term growth opportunity for the healthcare industry, including generic drug manufactures.

- The passage of the Affordable Care Act provides a significant inflow of newly insurance people into the market. Also, the greater emphasis on generic-drug usage will also create a positive impact.

- The global regulatory pressures to control healthcare costs will increase the utilization of generic drugs in the long term. This is a growth opportunity for the generic drug manufacturers.

INVESTMENT NEGATIVES

- On November 13, 2013, the Food and Drug Administration (FDA) released a Proposed Rule that would permit generic drug manufacturers to make changes to their products’ labels. Should the rule be finalized, it would eliminate preemption and introduce product liability for generic manufacturers, which in turn will increase the manufacturer costs; The Proposed Rule could be expected to increase spending on generic drugs by $4 billion per year.

- Generic drug pricing and margins in the industry may have a tendency to decline as a result from both the fierce competition and increased government pricing pressure. For example, a number of significant markets such as Germany and Russia are using “tender systems” for manufacturers to submit bids that establish prices for generic products, in an effort to low price.

VALUATION

When evaluating specific companies within the industry, we will pay special attention to those with a rich and diversified portfolio of pipelines, especially the high-value medicines, including branded generics, biosimilars, first-to-market generics and even high-value specialty drugs.

We will also focus on companies that already have global expansion in important emerging markets.

We favor big companies in the industry considering with their economies of scale it would be relatively easier for them to lower the manufacturer cost and better compete in price compared with competitors.

KEYS TO MONITOR

1. The FDA proposal on generic drug manufacturers to make changes to their products’ labels. Should it be finalized, negative about the generic drug industry.
2. The eventual passage of a new FDA pathway for the approval of biosimilars. Should it be finalized, positive about the generic drug industry.
3. First-to-market company: The generic company who is the first-to-file after the brand drug expires, positive about this company.
4. Global government healthcare policies and budgets, will continue monitor the net effect of increasing generic drug usage and decreasing pricing at different countries.
5. Any possible legislative changes or different strategies took by the branded drug owner companies that would lengthen the patent life should be monitored closely.

REFERENCES

2. FDA’s Proposed Generic Drug Labeling Rule: An Economic Assessment By Alex Brill February 5, 2014
3. Generic Drug Industry: Market Research Reports, Statistics and Analysis
4. Fisher Investments on Health Care
5. Generics Outlook: Turning to Innovation After the Patent Cliff
10. Teva Annual Report
14. Global Market for generic drugs, BCC research Report
15. Yahoo Finance
17. http://en.wikipedia.org/wiki/Mylan

22. IBIS US Industry Report Generic Pharmaceutical Manufacturing
25. Factset
27. www.tradingeconomics.com

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