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# Specialty Pharma 2016 Outlook

## Favorable set-up but remain selective - our best ideas for the year

There is clear debate heading into next year around whether or not the "specialty trade" is over following three years of meaningful outperformance. The headwinds that emerged in 2H2015 eclipsed much of the year-to-date upside and have weighed on sentiment, shifting focus back to fundamentals. While M&A will continue and for some be an important driver, there will be greater deal scrutiny in an environment with fewer targets. But the bottom line is this: fundamentals remain intact against valuations that are back to previous 2013 lows and we think the sector can "grind higher" in 2016. Performance varied widely within the group in 2015, and we want to be selective in 2016. Our top two long ideas in large cap are ENDP and TEVA, top binary small-cap longs are FLXN and AGRX, and favored out of consensus ideas are INSY and SGNT.

**Four themes for 2016:** We drilled into four primary themes that are going to be front and center this year: (1) M&A and capital deployment – deals will continue, but we expect more scrutiny and favor targets over accretive buyers, (2) Generic approvals ramping – price versus volume debate will pick up with potentially major implications, (3) Headline concerns are not done – but they have had little impact, and that is unlikely to change, and (4) Sector growth is again inexpensive – back to 2013 levels and we think PEG valuations can move higher.

**Our top large-cap ideas: ENDP (Top Pick) and TEVA (OP):** Both names have meaningful leverage to US generics ahead of an expected approvals pick-up next year, double-digit EPS growth, and are positioned well as value plays at 9–11x 2017E. With ENDP we also see (1) an oversold stock on headline concerns that we expect will reverse throughout 2016E and (2) low expectations on P&L outlook ahead of an expected stronger 4Q. While large scale M&A isn't part of the thesis here we see optionality from a management team that has shown a propensity to be opportunistic this year. TEVA is set to close the AGN generics acquisition, which is helping to improve the overall mix and diversify away from Copaxone while the new specialty pipeline is set to begin to convert, helping re-introduce a growth story following several years of relative stagnation.

**Our top data-driven catalyst ideas: FLXN (OP, Spec) and AGRX (OP, Spec):** Both names are presenting data that will be binary, but that we expect to be positive. For those willing to take on binary risk, we see potential for doubles in both with a decent likelihood of take-out on positive results. We expect FLXN to read-out Zilretta for osteoarthritis pain in 1Q2016E, and on positive FDA acceptance, we think the stock can trade toward 1x peak implying ~$50 per share. We expect AGRX to release data for its patch contraceptive Twirla in 4Q2016 with a product that can fit well in a number of women's health portfolios.

**Our top out of consensus-debated names: INSY (OP) and SGNT (OP):** Both names have high short interest levels (INSY at 82% of public float) and have been among the bigger selloffs around the sector headline with both off more than 35% since July 31. For INSY, the debate is around the ongoing investigations into its sales' practices that we think can be settled this year, thereby shifting focus back to the transformation from a one-product company to one that we expect to be selling five products by 2017. Sentiment around SGNT is near all-time lows, and we see the company well levered to a pick-up in generic approvals that can reverse the recent negative P&L revision with a lot of valuation support at 1.3x EV to 2016 revenue.

**Priced as of prior trading day's market close, EST (unless otherwise noted).**
**All values in USD unless otherwise noted.**
**For Required Conflicts Disclosures, see Page 29.**

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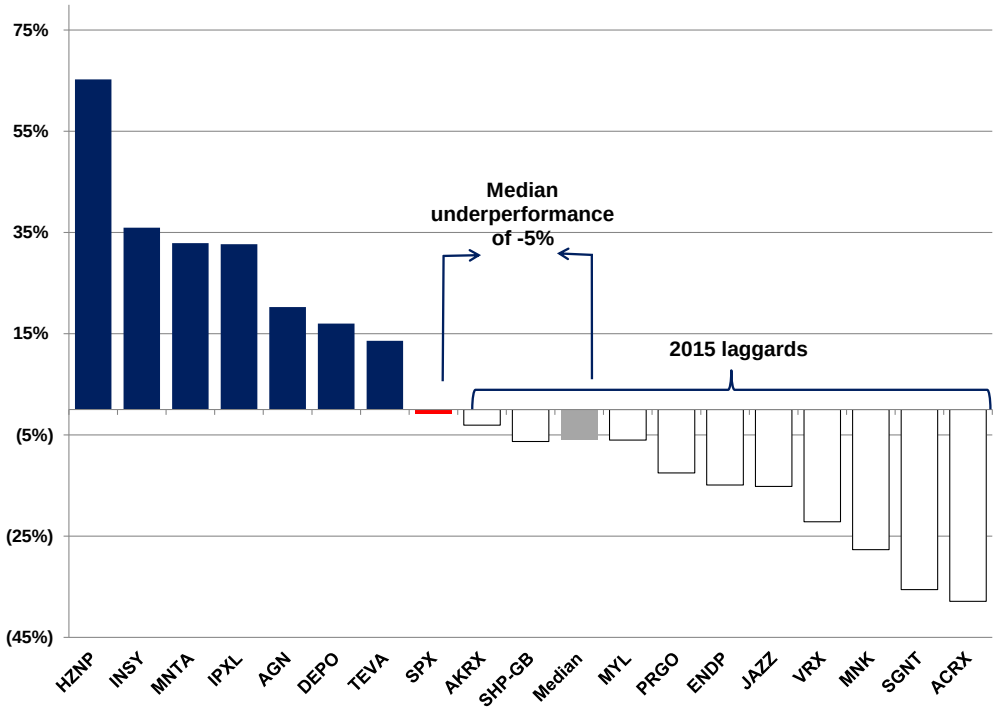
# Our outlook for specialty pharma in 2016 – Bullish but selective

**Our top stock ideas for 2016 are Endo, Teva, Flexion, Agile, Insys, and Sagent.**

**Our message on the sector for 2016 is that we remain favorable on specialty pharma given inexpensive valuations against still solid fundamentals, but we would be selective.** While we expect the negative headline that we saw in 2H2015 to continue, we think it will begin to fade and that a focus on sector fundamentals will again take center stage. Sector valuation has pulled back to 2013 levels and is at its five-year average with a deepening discount to biotech and big pharma. M&A will remain a core theme, but the pace of deal activity will slow as will investor enthusiasm around owning the consolidators for accretion potential. **As we approach 2016, we have six favored stocks across three buckets: (1) Top large cap – Endo (Top Pick) and Teva (Outperform), (2) Top data-driven catalyst ideas – Flexion and Agile (both Outperform, Speculative Risk), and (3) Top out of consensus ideas – Insys and Sagent (both Outperform).**

**Looking back at 2015 – we learned five things:** (1) While the second half selloff felt bad, the full-year underperformance was relatively limited at -5% versus -3% for the S&P500 and flattish DRG, (2) But the variability around performance was the most we have seen in years, which meant getting the stocks right was more important than ever (Exhibit 1), (3) The year was full of single-stock surprises with the top-four stocks that we highlighted at the beginning of the year up 16% (Allergan, Teva, Akorn, and Insys) but for reasons that we could not have foreseen (i.e., M&A, accounting updates, etc.), (4) Attractive M&A deals are becoming more difficult to get done, and investor enthusiasm around them is beginning to wane, and (5) Headlines matter and have the ability to weigh on the sector despite what is generally a consensus view that concerns around pricing and specialty distribution are unlikely to have any material impact.

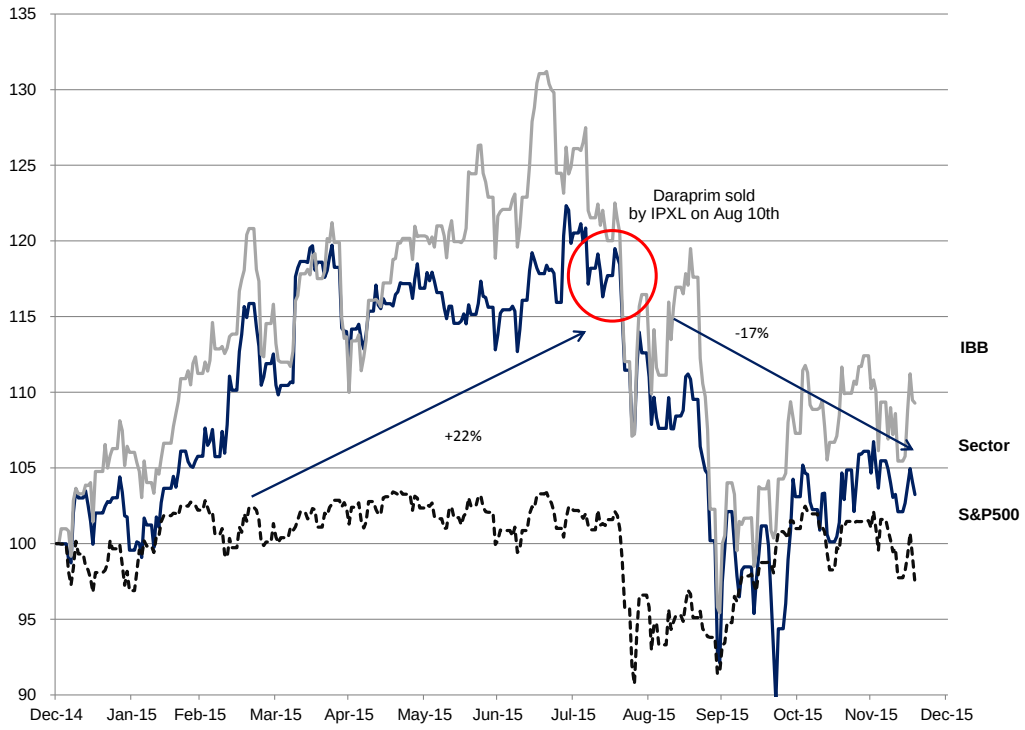
Exhibit 1: 2015 YTD saw a -6% median return in Specialty Pharma – that was below the median 37% return of the same stocks in 2014 and -5% below the S&P500




Source: FactSet, RBC Capital Markets (priced as of 12/18/15)

**The group is still well off mid-year levels following the broader market selloff.** Per Exhibit 2, while we have seen some improvement as more draconian views around potential fundamental impact have abated, the sector is still 17% off from July 31. There is better understanding around the three major headline issues at this point, which include pricing, specialty pharmacy, and tax inversions. Our view is this: (1) We do not expect any material changes to current pricing strategies outside of the acquire and re-price strategy employed by a minority of companies but we do see moderation in overall generic inflation ahead as new approval activity picks up, (2) Specialty distribution for the vast majority of companies is a limited but physically necessary tool, and (3) Near-term legislative tax changes are unlikely, and at this point, the vast majority of major consolidators has already inverted.

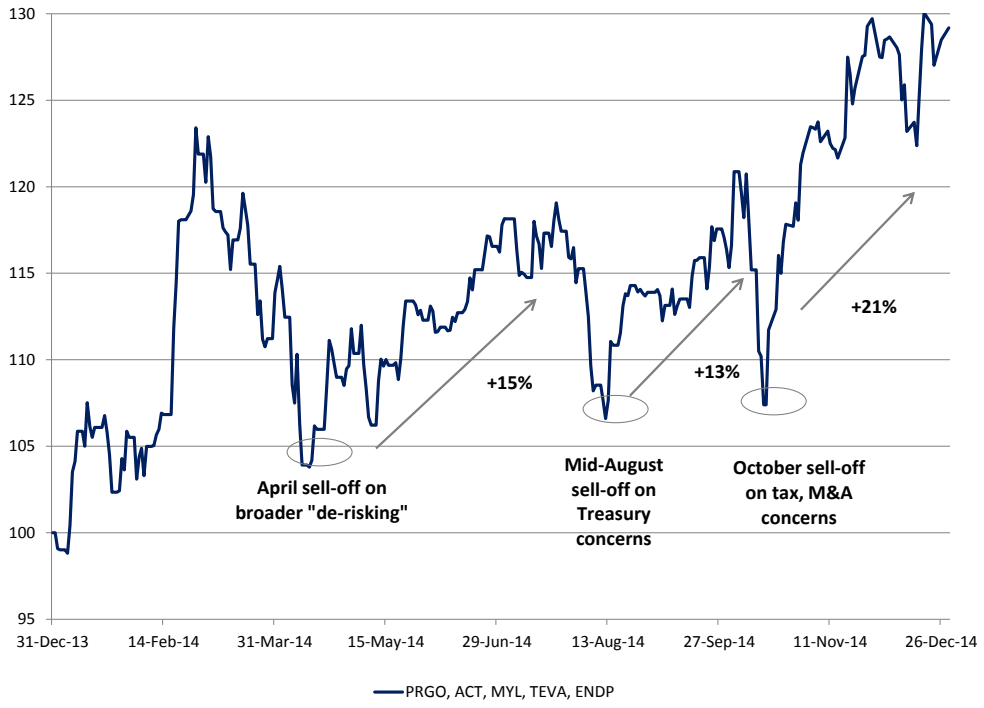
Exhibit 2: The group selloff in late summer erased sector gains for the year and introduced debate around the potential for a sector recovery




Source: FactSet, RBC Capital Markets

**We also saw negative headlines in 2014, but the group was up 37%, so what was different about this year?** Per Exhibit 3, we saw three "short lived" selloffs in 2014 on various headlines that drove short-term dips of anywhere from 10–20%. Those dips were temporary and were bought, taking the sector to new highs each time. It was different in 2015, we think, for several reasons, and a lot of it had to do with timing. The group was up 20% by mid-year with M&A enthusiasm high, and the sector was overweight by many. However, there were two important differences to call out (1) investor concerns around potential fundamental impact were much greater in 2015 and (2) there is a view that the headline is going to continue through the election, which is probably right. **The point we would make is that Valeant aside (which we would point to as a special situation), we have not seen any companies make meaningful changes to outlook based on any of the headline concerns and we don't expect them to.** In fact, we would argue that the broader EPS bias across our coverage is to the upside and that early year meetings combined with a solid 4Q earnings seasons can continue to push the group higher.

Exhibit 3: The market shrugged off previous "negative" headline that we saw in 2014




Source: FactSet, RBC Capital Markets

**How do we view the sector as we enter 2016?** We think there will be more stock debate this year, as it does not feel like there is any one consensus long in the sector like there was last year with Allergan. Our mid-/large-cap bias is to companies with low valuations, against P&Ls where EPS revision can go higher and M&A is not necessarily part of the thesis (Endo and Teva)—our complete stock views and catalysts are in Exhibit 4. There is more consensus around sector themes and specifically the following four for which we have taken a closer look.

**(1) M&A and capital deployment:** We expect deals to continue but at a slower pace and with more scrutiny. There is still significant free cash flow generation, and over the near term, we see more of that going toward debt reduction and share repurchases with less urgency on the part of most (but not all) corporate management teams to get transformational deals done.

**(2) General approvals inflection:** This was a major theme that we were focused on in 2015 and did not start to gain traction with it until 2H2015. Focus is clearly increasing with no current consensus as to how a pick-up in new approvals will affect the pricing and volume balance in the sector. We continue to favor companies with the largest pipeline relative to revenue base, with higher barrier portfolios and broad diversification.

**(3) Negative sector headline:** We think it continues but begins to wane. It is also not all bad. In fact, the recent Senate Aging Committee hearing on drug pricing of off-patent drugs centered on generics as a tool to address pricing on December 9. We also had a group of Congressional Republicans formally reach out to the FDA, requesting documents relating to the approval timing for generics. But we do expect pricing to remain in the spotlight through the Presidential election.

**(4) Valuation discount:** The selloff in the group has left the sector trading at 12.1x (excluding Allergan) on a forward P/E basis. This is well below the levels that we have seen over the last two years, putting PEG valuations at less than 1x, which is 20–40% lower the last several years.

## Exhibit 4: Our stock views and near-term catalysts to watch by company

| Company | Ticker | Rating | Price Target | Price 12/18/2015 | Implied Upside/ Downside | Our View |
|---|---|---|---|---|---|---|
| **Specialty Pharmaceuticals** | | | | | | |
| Endo | ENDP | Top Pick | $91 | $61 | 49% | We see potential upside to ENDP driven by the pipeline of the Par business, improving results in the branded specialty business, and optionality on bolt-on pipeline opportunities. Importantly, we see current valuation creating a floor in the stock adding favorably to the risk/reward. |
| Allergan | AGN | Outperform | $354 | $307 | 15% | With the pending PFE acquisition of AGN waiting to close, AGN shares currently imply a 18% spread (unadjusted for dividend) to deal price indicating some uncertainty. We believe the deal will ultimately get done despite potentially negative headlines into 2016 |
| Teva | TEVA | Outperform | $85 | $65 | 30% | TEVA is one of the best set-ups in heading into 2016 with headwinds on Copaxone competition largely baked in leaving room for upside, tailwinds from accelerated generic approvals and the close of the AGN generics deal, and a promising specialty pipeline. |
| Akorn | AKRX | Outperform | $52 | $36 | 44% | One of the best organic growth plays that we think can be supported by the strength of its pipeline. M&A adds significant optionality for AKRX as both a potential buyer and target particularly as the company moves through the completion of its restatement process. |
| Insys | INSY | Outperform | $49 | $28 | 73% | A conclusion to the ongoing DOJ investigation remains the biggest catalyst to the stock. Our Subsys NPV and cash covers current equity value at these levels which implies that the multiple pipeline assets (Syndros expected to launch in 2016) are effectively free. |
| Eagle | EGRX | Outperform | $100 | $97 | 3% | EGRX is well positioned to drive value from near-term launches of improved formulations of existing on-market products. We see a near-term transition from a pipeline story to a larger commercial hospital play with enhanced opportunities through M&A. |
| Sagent | SGNT | Outperform | $34 | $16 | 116% | 2016 could be an inflection year as potentially new sizable approvals are added to the established sales infrastructure at SGNT.Timing of new approvals and further business development remain near-term drivers. |
| Flexion | FLXN | Outperform | $44 | $19 | 131% | Lead product Zilretta is set to read out topline of its second pivotal study in Feb 2016 which we expect to be positive driving shares higher. We see a blockbuster product in Zilretta which targets the Osteoarthritis (OA) knee market with a differentiated, sustained release version of standard of care. |
| AcelRx | ACRX | Outperform | $6 | $4 | 34% | ACRX shares remain depressed as the near-term story continues to be about clinicals for US Zalviso and ARX-04 which could prove to be significant opportunities. |
| Neos | NEOS | Outperform | $33 | $12 | 166% | NEOS has a proprietary technology platform with three late stage ADHD products that we believe can take meaningful market share from leading treatments. The products can progress quickly and at a low cost via the 505(b)(2) approval pathway and the transition from a pipeline story to a commercial play can support the pipeline technology over time. |
| Agile | AGRX | Outperform | $13 | $8 | 68% | 2016 could be an inflection year as lead product Twirla reads out Phase III top-data in 4Q2016. We expect positive data to drive significant upside for investors . |
| Mylan | MYL | Sector Perform | $60 | $53 | 13% | MYL is positioned for sustainable growth given the breadth and diversification of its global generic platform. Near-term drivers include potential for M&A and what we expect to be a solid 4Q. However, equity owned by ABT and TEVA remain an overhang and sentiment following the PRGO process is negative. |
| Perrigo | PRGO | Sector Perform | $176 | $144 | 22% | Valuation is below trough levels which is alluring but we remain concerned about 4Q on what has been a light launch quarter. Debate is picking up around potential for a multiple re-rating downward and we remain concerned that a soft 4Q could increase that risk. |
| Impax | IPXL | Sector Perform | $48 | $42 | 15% | There is attractive optionality from potential for large M&A on a clean balance sheet and possible pipeline surprises on key products that include generic Renvela and Welchol. While we believe some of that is priced in our bias remains positive. |
| Depomed | DEPO | Sector Perform | $26 | $19 | 37% | DEPO is a commercial stage spec pharma with a long duration product portfolio in pain and CNS. We see a platform with a differentiated offering, high tax rate, and which could attract interest from a strategic acquirer over time. |

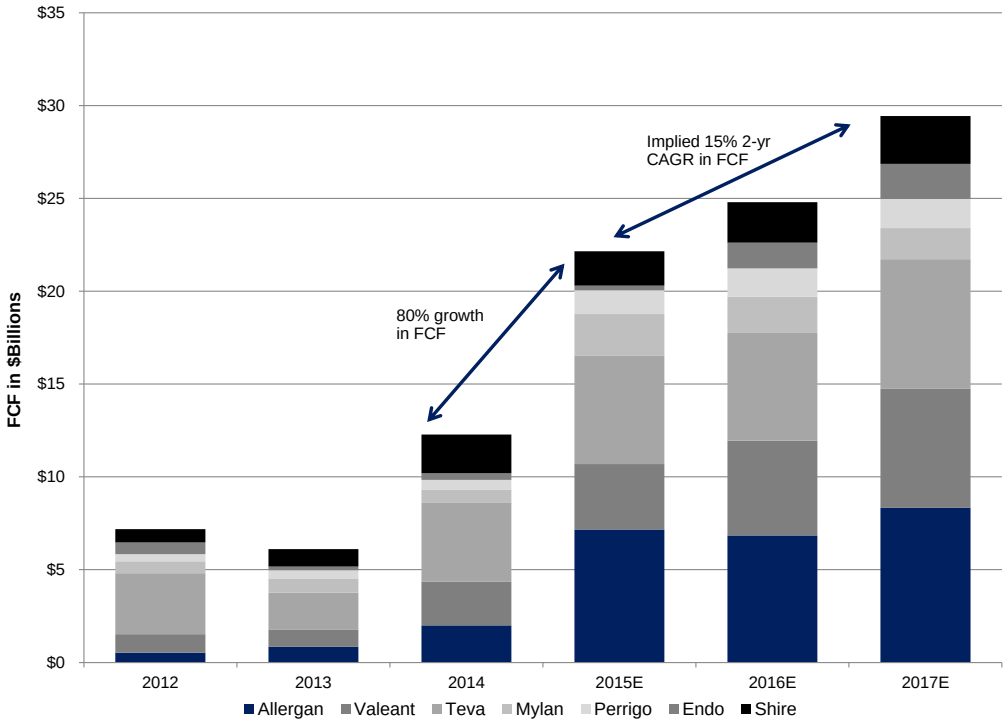
Note: AGRX, FLXN and NEOS have a Speculative Risk qualifier.
Source: Company reports, Factset, RBC Capital Markets estimates

# Theme #1: M&A and capital deployment – Fewer deals and more scrutiny

**M&A has been the single-most important sector theme over the last two years, and while it will remain one to watch, we expect a slowdown in the pace of transformational M&A in 2016.** There are several important considerations that factor into this including fewer attractive assets that are available, fewer consolidators with urgent transformational needs, higher financing costs particularly on the high-yield side, levered balance sheets, and more debate around take-out valuation. However, the sector consolidators are still generating significant cash flow, and that cash will need to be deployed. **In the near term, we think that it is more likely to go toward share repurchases, debt reduction, and bolt-on M&A activity.** However, we still think that 2016 will bring several large transformational deals in the sector but at a slower pace than we saw in 2015. **Mylan and Impax are most likely in our coverage to pursue a transformational deal; Teva, Perrigo, Sagent, Eagle, Depomed, and Endo are more likely to pursue bolt-on transactions; and Akorn is the most likely target. We also see Agile and Flexion as likely targets assuming favorable data readouts.**

**The level of free cash flow generation among the consolidators is significantly stepping up, and that capital will need to be deployed, in our opinion.** This is important to think about. The seven sector consolidators have moved from $6.1 billion in free cash flow in 2013 to $12.3 billion in 2014, which were big years for M&A. We expect that number to top $22 billion in 2016 and grow to $29 billion in 2017. We included Allergan despite the pending acquisition by Pfizer, as we expect part of the business potentially to be spun back out over the next several years.

Exhibit 5: The top specialty pharmaceutical consolidators are seeing free cash flow jump from $6.1 billion in 2013 to an estimated $29 billion in 2017E




Source: Company reports, Factset, RBC Capital Markets estimates

**It is becoming more difficult to be long the "acquirers" on the assumption that accretive M&A will be a positive catalyst.** Per Exhibit 6, reactions to deals announced in 2015 have been mixed despite what has been immediate accretion in most cases.

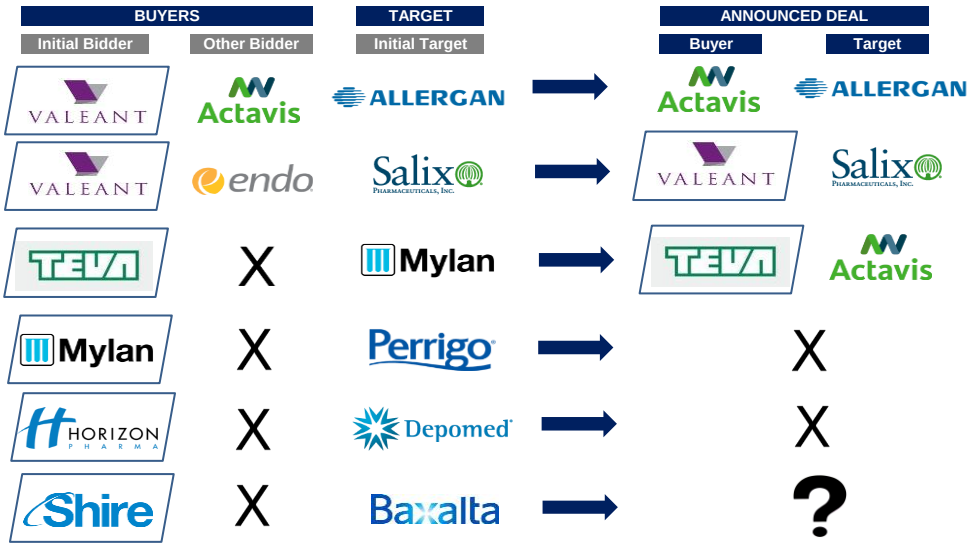
Exhibit 6: There are fewer remaining attractive assets, and investors are beginning to scrutinize announced M&A more closely, meaning that we may not see the same magnitude of moves on announced accretive deals as we have in the past

| | | | Acquirer reaction | | | S&P500 | | | |
|---|---|---|---|---|---|---|---|---|---|
| Acquirer | Target | Date announced | 1-day move | 5-day move | Move on announcement | 1-day move | 5-day move | Deal value ($billion) | Accretion commentary at announcement |
| MNK | Cadence | 2/11/14 | 12% | 13% | ↑ | 1% | 2% | $1.3 | Significantly accretive FY15 |
| ACT | Forest | 2/18/14 | 5% | 14% | ↑ | 0% | (0%) | $25.0 | Double digit accretion |
| **MNK** | **Questcor** | **4/7/14** | **(3%)** | **0%** | ↓ | **(1%)** | **(3%)** | **$5.6** | **Significantly accretive FY15** |
| MYL | ABT assets | 7/14/14 | 2% | 3% | ↑ | 0% | 1% | $5.3 | Significantly accretive (we had est. 6-11% year 1-2) |
| **PRGO** | **Omega** | **11/6/14** | **(4%)** | **(2%)** | ↓ | **0%** | **1%** | **$4.5** | **Double digit in "EPS" year 1** |
| ACT | AGN | 11/17/14 | 2% | 7% | ↑ | 0% | 1% | $66.0 | Double digit accretion |
| **SHPG** | **NPS Pharma** | **1/11/15** | **(4%)** | **(1%)** | ↓ | **(1%)** | **(1%)** | **$5.2** | **Mild initial dilution but accretive in 2016 onward** |
| PFE | Hospira | 2/5/15 | 3% | 6% | ↑ | 1% | 1% | $15.8 | Accretive |
| VRX | Salix | 2/22/15 | 15% | 14% | ↑ | 0% | (0%) | $15.8 | 20%+ in 2016 |
| HZNP | Hyperion | 3/30/15 | 18% | 19% | ↑ | 1% | 0% | $1.1 | Accretive |
| **ENDP** | **Par** | **5/18/15** | **(5%)** | **(1%)** | ↓ | **0%** | **0%** | **$8.1** | **~15% accretion in 2016, ~20% in 2017** |
| TEVA | AGN Generics | 7/27/15 | 16% | 12% | ↑ | (1%) | 1% | $40.5 | Double digit accretion and >20% by year 3 |
| **CXRX** | **Amdipharm Mercury** | **9/8/15** | **(11%)** | **(13%)** | ↓ | **3%** | **2%** | **$1.9** | **Immediately accretive, >35% in year 1** |
| **HZNP** | **Crealta Holdings** | **12/11/15** | **(7%)** | **4%** | ↓ | **(2%)** | **1%** | **$0.5** | **Immediately accretive to adj EBITDA in 2016** |

Source: Company reports, RBC Capital Markets

**The pick-up in unsolicited and "hostile" M&A over the last year is a clear signal that there are fewer attractive assets available and that new deals are becoming difficult to find.** Per Exhibit 7, there have been six unsolicited deal attempts in the last year, and none was successfully acquired by the unwanted buyer. The only exception to this could be Endo and Auxilium, which started out as unsolicited, turned friendly, and was completed.

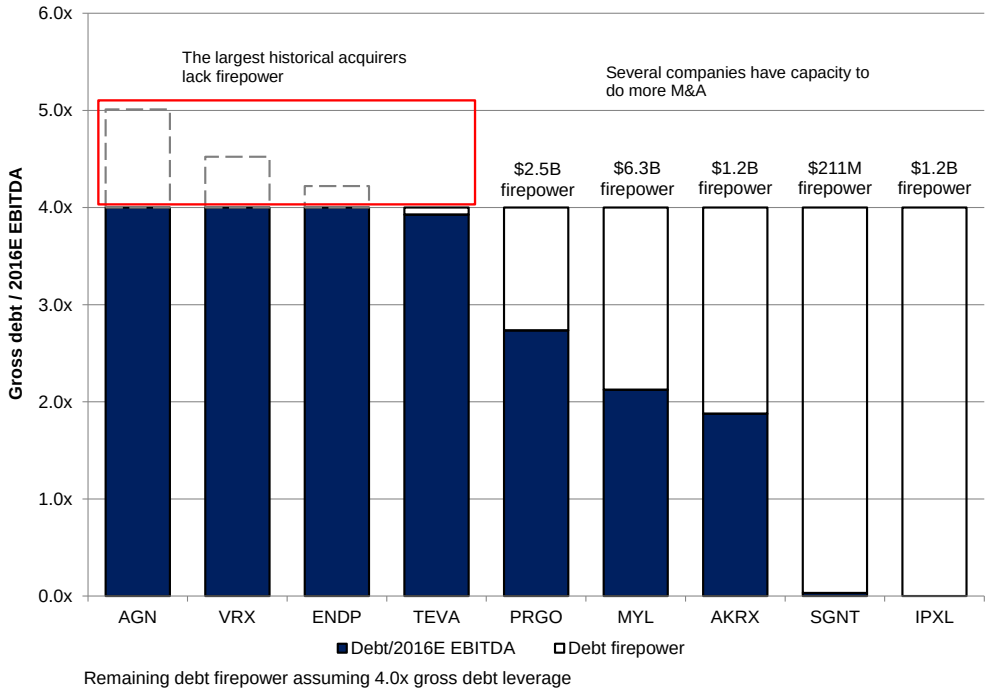
Exhibit 7: We have seen 6 hostile deal attempts over the last year with little success




Source: Company press releases

**Several of the traditional acquirers are currently levered at close to 4x and unlikely to pursue a sizable, near-term, equity-based deal.** Per Exhibit 8, the companies in our coverage with the most debt capacity are more likely to pursue smaller M&A, with the exception of Mylan and Impax. We believe Mylan is looking to pursue a large OTC or generic-based assets (we have previously highlighted Endo as a potential fit). For Impax, we believe the company is looking at potential divested assets from companies closing existing deals but could also see company or product deals in 2016.

Exhibit 8: Sector leverage has picked up, but free cash flow yields are generally high, supporting a quick de-lever and balance sheet firepower still remains – debt to 2016E (normalized) EBITDA by company ($ billions)




*Note that AGN will receive $29 billion in 1Q2016 from proceeds from sale of Generics to TEVA

Source: Company reports, Factset, RBC Capital Markets estimates

**There is a more balanced capital deployment message going into 2016 than we have heard the last two years.** Specifically, we are hearing a greater focus in paying down debt and buying back stock rather than a focus on M&A solely, per Exhibit 9. Following the mid-year sector selloff, several companies opportunistically announced share buyback programs, which we think is prudent. We are also seeing several companies looking to de-lever from recently announced deals. The use of equity as currency has been an active tool in the space over the last couple of years as a way to do larger deals and in some cases de-lever at the same time; however, given depressed valuations, we are unlikely to see that continue at the same pace.

Exhibit 9: There is a much more balanced approach to capital deployment this year following the sector pullback

| Company | Buyback | Debt paydown | M&A | Announced share buybacks | Debt repayment message | Total net debt in 2016E | M&A message |
|---|---|---|---|---|---|---|---|
| MYL | ✓ | X | ✓ | $1 billion authorized - expires 8/27/16 but not obligated to acquire | Unlikely - recently raised debt partly to finance repurchase | We estimate ~1.7x 2016E net leverage | Following the failed PRGO tender, could pivot to another accretive deal. The share repurchase announced shortly after the failed tender allows management to be flexible in capital allocation in the interim |
| ENDP | ✓ | ✓ | ✓ | $250 million buyback (expected by YE2015) under previously authorized $2.5 billion plan | Committed to delevering | Targeting 3.0x to 4.0x by mid-2016, "probably closer to four". By YE2016: low to mid 3.0x | At scale for US Generics. Interest in tuck-ins: injectables, topicals, patches, thin films, "more unusual formulations". Continue to build branded, esp pipeline. "Will likely not pursue" $1 to $5 billion deals in 2016 unless "truly transformational" with a share exchange |
| PRGO | ✓ | ✓ | ✓ | $500 million buyback (expected by YE2015) and $1.5 billion in subsequent 24-36 months | Would be willing to lever up to 4.0-4.5x for the right asset | We estimate ~2.5x 2016E net leverage | If attractive M&A available, will suspend share repurchase. Opportunities in: opthalmics, adult nutrition, diabetes, pet care, Rx, extended topicals or dermatology, respiratory, nasal. "Full range of opportunities" in terms of size - could be several billion and could be bigger than Elan ($8.6 billion) |
| INSY | ✓ | X | ✓ | $50 million buyback with no termination date | N/A - no debt | No debt with ~$187 million in cash/ST investments as of 3Q2015 | Most likely will pursue the existing share repurchase program and allow cash balance to grow. Management has suggested it could be opportunistic in looking at deals if valuations come down. |
| MNK | ✓ | ✓ | ✓ | $500 million buyback + previously authorized $200 million buyback with no termination date | Open-ended debt reduction program authorized; amount is discretionary | Guided 4.0x net leverage; has stated willingness to go to >5.0x. Consensus implies 2016E 3.2x | M&A can be commercial or developmental assets. Generics deals make sense long-term but would be "very happy to use that cash to buy other businesses" of all sizes in branded ARD (esp neurology/rheumatology, nephrology and pulmonology) and hospital assets |
| VRX | X | ✓ | X | "Largely off the table in the short-term" - in favour of debt pay down | Expects to pay down ~$2.25 billion by YE2016 | Targeting ~4.0x p/f adj EBITDA by YE2016 | Large M&A unlikely - "lion's share of cash flow generated next year will go towards debt reduction" |
| SHPG | ? | X | ✓ | 59 million shares repurchased annually for 2 years: only under BXLT deal otherwise no buyback | Fund buyback with combination of free cash flow and net debt | ~2.9x 2016E net leverage off of consensus estimates assuming deal gets done incl. buyback | Ongoing all-stock hostile offer for BXLT. Even if offer is accepted, can "continue to leverage the balance sheet to do more deals". Rare diseases continue to be the focus but some specialty deals may be considered. Interest in HAE, GI, opthalmology |
| IPXL | X | X | ✓ | None announced - focus is on M&A | No debt. Willing to lever to 4.5x if can de-lever quickly | We estimate ~0.3x 2016E net leverage | Focus is on generics: oral solid dose or alternative dosage forms where they do not have current capability. Also interested in branded: women's health or CNS |

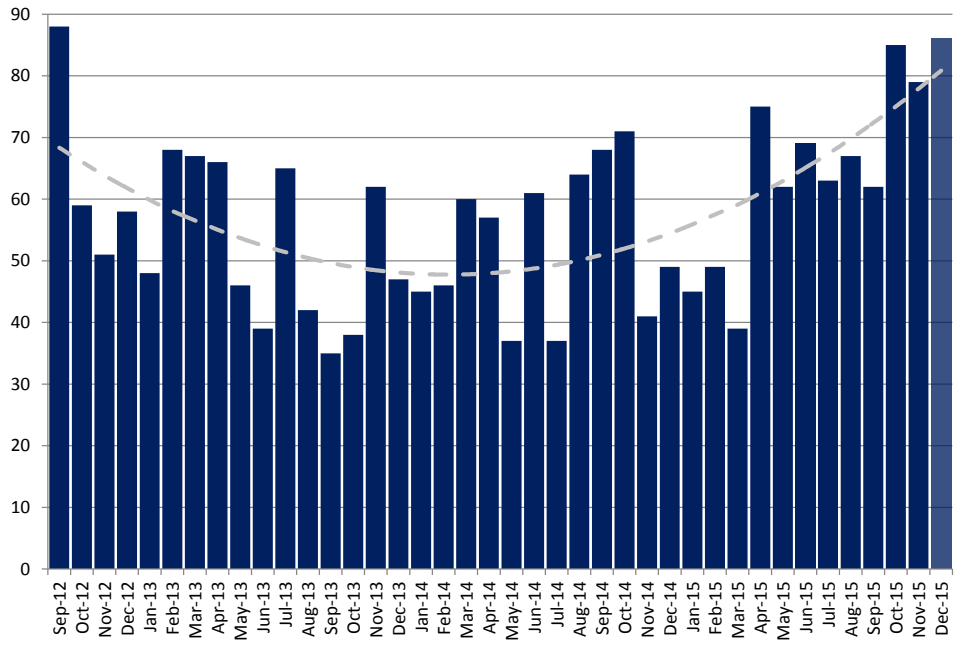
Source: Company reports, RBC Capital Markets estimates

# Theme #2: Generic approvals inflection – Expect price versus volume debate

This is a theme that we have been focused on in 2015 and should become much more important as we move into 2016. We have seen a clear up-tick in FDA approval activity since April, as we move through Generic Drug User Fee Amendments (GDUFA) II negotiations with six meetings now having taken place. The FDA has also been handing out target action dates (TADs) at a much more meaningful pace, and we believe about half of the current backlog now has TADs attached to it. Finally, as we are now in fiscal 2016, the FDA approval targets again step up with 2017 representing the most material move and only one year away. We are starting to get more incoming calls from investors trying better to understand what the impact of a ramp in approvals could be to both pricing and individual companies. **Overall, we think a ramp in approval activity is going to weigh on generic price inflation with the most diversified companies with the largest alternative dosage portfolios best positioned.**

**Approval activity has clearly picked up since April but it is still not at the levels needed to clear the existing backlog.** Approvals in the ~70 per month range are a big improvement but not meaningfully enough to work through roughly 4,000 Abbreviated New Drug Application (ANDAs) that are pending at the FDA. We suspect the number of approvals will ramp further as we get into 2016 and see target action date activity pick-up.

Exhibit 10: We have seen a meaningful pick-up in monthly ANDA approval activity by the FDA




*Dec 2015 is an estimate based on MTD approvals

Source: FDA

**Our checks suggest that the issuance of TADs by the FDA has spiked from June to October, and that was effectively endorsed by several manufacturers on the most recent earnings calls.** While TADs do not imply a definitive approval, they give us an indication as to the volume of ANDA files the FDA plans to address over the next 12 months via straight approval, tentative approval, or Complete Response Letter (CRL). The potential for an inflection in generic approval activity has been an important theme that we have continued to revisit, which would have far-reaching implications across the supply chain.

Exhibit 11: Several companies have provided TAD updates

| Company | % revenue from US Generics (2016E) | Total ANDAs outstanding | % TADs | Date |
|---|---|---|---|---|
| SGNT | 90% | 68 | ~33% | As of 3Q15 call |
| AKRX | 89% | 78 | 40% | As of 10/31/15 |
| IPXL | 79% | 28 | ~35% to 50% | As of 3Q15 call |
| ENDP | 65% | 165 including Par | N/A | As of 05/18/15 |
| MYL | 40% | 272 | N/A | 11/24/15 PR |
| TEVA | 35% | 320 including AGN Gx | Management stated "probably close" to the 30% to 60% range | As of 07/27/15 |
| PRGO | 20% | 37 | N/A | As of 12/17/15 |

Source: Company reports

**FDA approval timing per GDUFA continues to improve in 2016.** Importantly, we see another big pick-up in fiscal 2017 (less than a year away), and the FDA is committed to address the most of the pre-October 1, 2012 backlog. To put the backlog clearing into perspective, there

are currently about 4,000 ANDAs pending, and we currently see new monthly approvals in the ~70 range. If we assumed that the current backlog cleared over two years, ignoring new submissions, that would imply 167 approvals every month.

Exhibit 12: ANDA approval targets are continuing to improve in 2016

| | FY 2013 | FY 2014 | FY 2015 | FY 2016 | FY 2017 |
|---|---|---|---|---|---|
| **Original ANDA** | Expedite review of paragraph IV and maintain pre-GDUFA productivity | | 60% in 15 months | 75% in 15 months | 90% in 10 months |
| **Tier 1 first major amendment** | Maintain pre-GDUFA productivity | | 60% in 10 months | 75% in 10 months | 90% in 10 months |
| **Tier 1 minor amendments (1st-3rd)** | Maintain pre-GDUFA productivity | | 60% in 3 months | 75% in 3 months | 90% in 3 months |
| **Tier 1 minor amendments (4th-5th)** | Maintain pre-GDUFA productivity | | 60% in 6 months | 75% in 6 months | 90% in 6 months |
| **Tier 2 amendment** | Maintain pre-GDUFA productivity | | 60% in 12 months | 75% in 12 months | 90% in 12 months |
| **Prior approval supplements** | Maintain pre-GDUFA productivity | | 60% in 6 months | 75% in 6 months | 90% in 6 months |
| **ANDA, amendment, and PAS in backlog on Oct 1st, 2012** | Act on 90% by end of FY 2017 | | | | |
| **Controlled correspondences** | Maintain pre-GDUFA productivity | | 70% in 4 months | 70% in 2 months | 90% in 2 months |

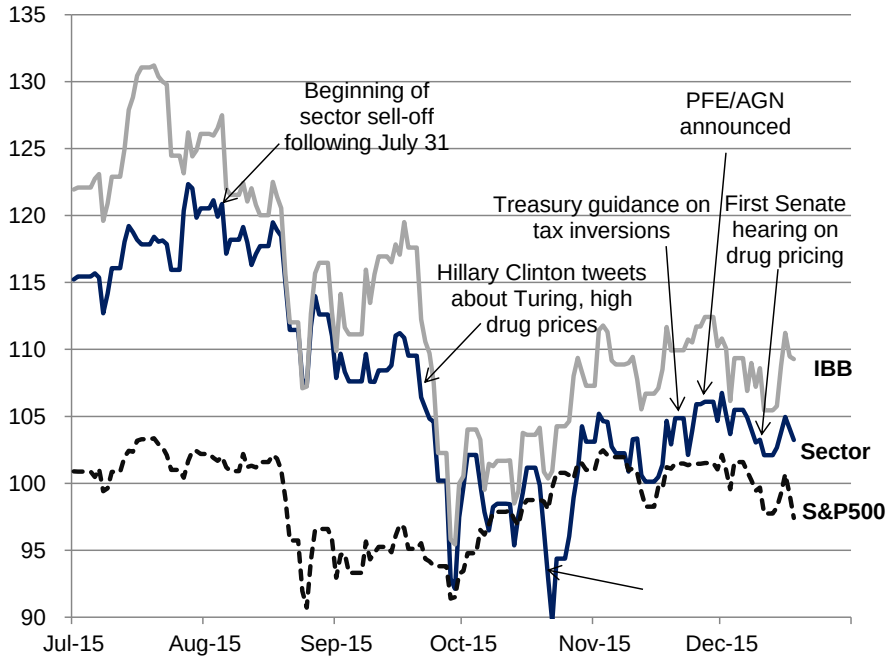
Source: FDA

## Theme #3: Negative sector headline – Expect more in 2016, but it is not all bad

The sector has been punished in 2H2015 on the back of concerns around pricing, specialty distribution, and to a lesser degree tax-inversion structures. The reality is that none of this is expected to have any real fundamental impact, and the sector is still down 17% since July 31 when many of the concerns began. **While we do expect sector headline to continue in 2016, it is not all bad, as generics are being highlighted regularly as a tool to rein in pricing, and there appears to be bipartisan support for the FDA to approve generics more quickly.**

**Much of the concern began in August around the price hike on Daraprim, which was followed quickly by political attention.** Per Exhibit 13, concerns around pricing began in August and picked up significant attention with calls for legislators to rein in what has been viewed as unfair and aggressive pricing strategies. That was followed by concerns around the use of specialty pharmacies, which came about from concerns around Valeant's relationship Philidor. We expect focus on pricing to remain through the election, and there should be several hearings with more political outreach that should keep pricing in the headlines. While the acquire and re-price strategy pursued by a minority of companies is likely more challenging going forward, we do not see any real change in strategy or pricing expectation among our covered companies.

Exhibit 13: There has been significant focus on the sector following some high-profile examples of egregious pricing




**Upcoming potential headline**:

1) Further Senate hearings should continue to drive some headline around pricing: dates unknown

2) Further presidential candidate debates in 2016 should continue to drive focus around drug pricing and accessibility

Source: Company reports, RBC Capital Markets estimates

**Specialty pharmacy concerns have died down and are unlikely to be an issue going forward.** None of our covered companies has financial relationships per Exhibit 14, with specialty pharmacies and exposure in general small and for the most part necessary given distribution and handling needs for certain specialty-drug types.

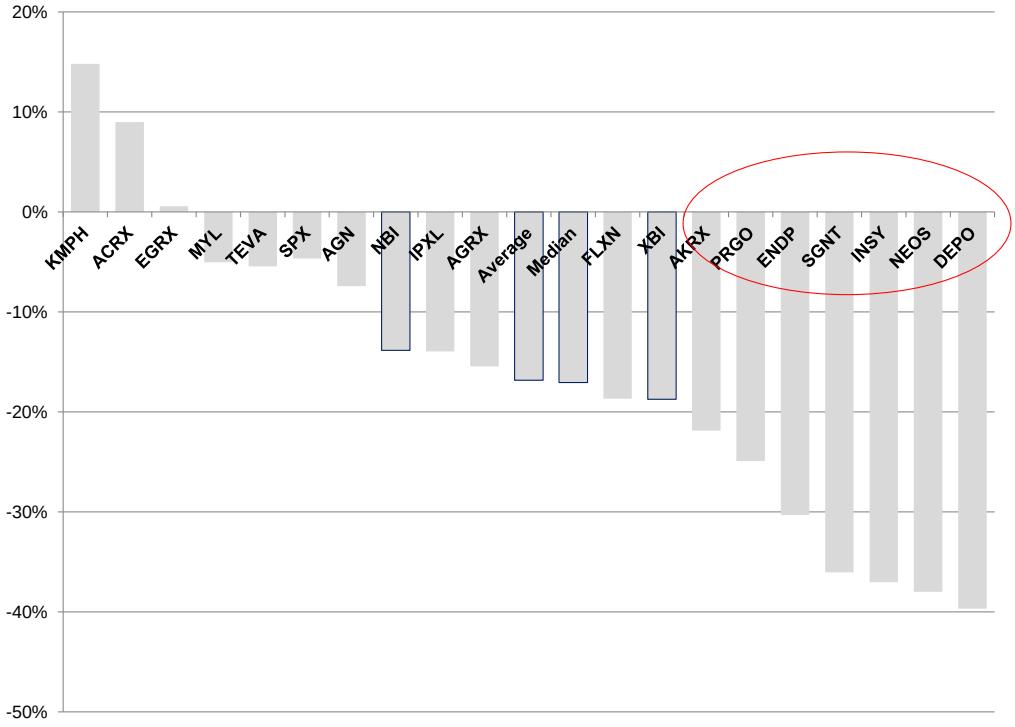
Exhibit 14: There is a much more balanced approach to capital deployment this year following the sector pullback

| Company | Ticker | PR released (Y/N) | % of rev (est.) | Comments |
|---|---|---|---|---|
| Allergan | AGN | Y | <3% | AGN put out an intra-day release 10/21 to state that 3% of US brand products (largely unique specialty products - BOTOX and ZENPEP) are distributed through unaffiliated specialty pharmacies. It also noted that its Anda distribution business is a traditional wholesaler with no specialty pharmacy capability. |
| Endo | ENDP | Y | ~3% | Per our outreach to ENDP and its intra-day 10/21 release, it utilizes specialty pharmacy services primarily for certain physician-administered brand products including XIAFLEX, AVEED, TESTOPEL, Supprelin LA, Vantas and Valstar (<10% of brand revenue and ~3% of 2015E revenue). |
| Teva | TEVA | N | Insignificant ex-Copaxone | Per our conversation with TEVA, ex-Copaxone use here is insignificant. Close to 80% of US Copaxone goes through third party specialty pharmacies (including CVS, WAG etc.) with only about 1% going through TEVA's internal specialty pharmacy the use of which is not inconsistent with MS drugs. |
| Perrigo | PRGO | N | 0% | Per our back and forth with PRGO there is no specialty pharmacy exposure. The company's business is driven by generic, OTC and royalty driven as opposed to brands and specialty products. |
| Insys | INSY | N | NA | Per conversation with management there are no specialty pharmacy financial relationships. Recent filings show 88% of revenue through the big three wholesalers and Rochester Drug Cooperative (RDC - 8th largest distributor) which is 38% of that. Specialty distribution is used in the TIRF class and must go through REMS. |
| Akorn | AKRX | Y | 0% | AKRX provided a press release intra-day 10/21 to clarify that it does not use alternative fulfillment systems or specialty pharmacies for distribution of its products. |
| Depomed | DEPO | N | ~3% | Per our discussion with management, it has exposure to third party specialty pharmacy via its "Simple Script" program confined to Cambia and Gralise (not NUCYNTA). It also utilizes specialty services for a portion of LAZANDA sales (small product at $12M in total sales or 6% of consolidated), consistent with the rest of the TIRF class. |

Source: Company reports, RBC Capital Markets estimates

**While we have seen some recovery from the initial selloff, the sector is still down 17% (ex-Valeant) from mid-year.** Per Exhibit 15, there are only three names that are up from July 31, with most of the sector down at least 10%. This is still a long way from the 33% selloff at the peak, but we have yet to see a full recovery.

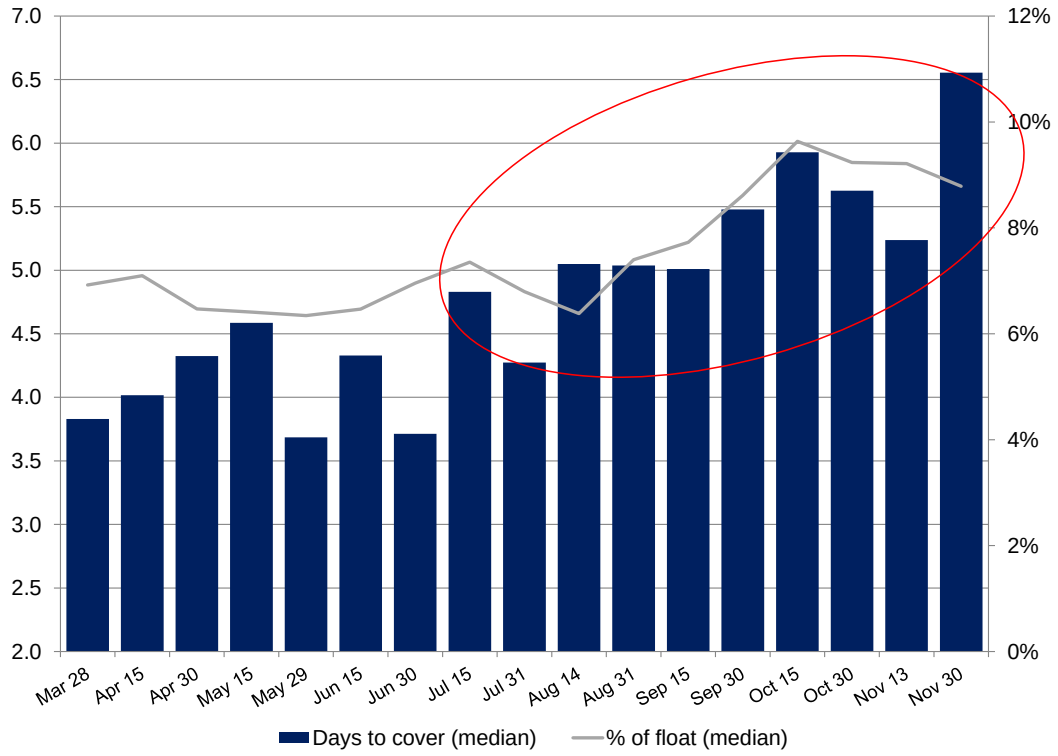
Exhibit 15: Stock move since 7/31/15 – several stocks still off more than 20% despite having limited to no fundamental P&L exposure to negative headlines




Source: Company reports, Factset, RBC Capital Markets

**We are also yet to see the pullback in short interest that came following the introduction of the headline concerns.** Per Exhibit 16, across the broader sector, median days to cover are at 6.5 days from under 4.0 earlier in the year. Median shares short as a percent of overall float is also now at over 10% for the first time this year.

Exhibit 16: Short interest is still elevated on both median days to cover and median shares short as a % of float – across all of specialty pharma including non-covered companies

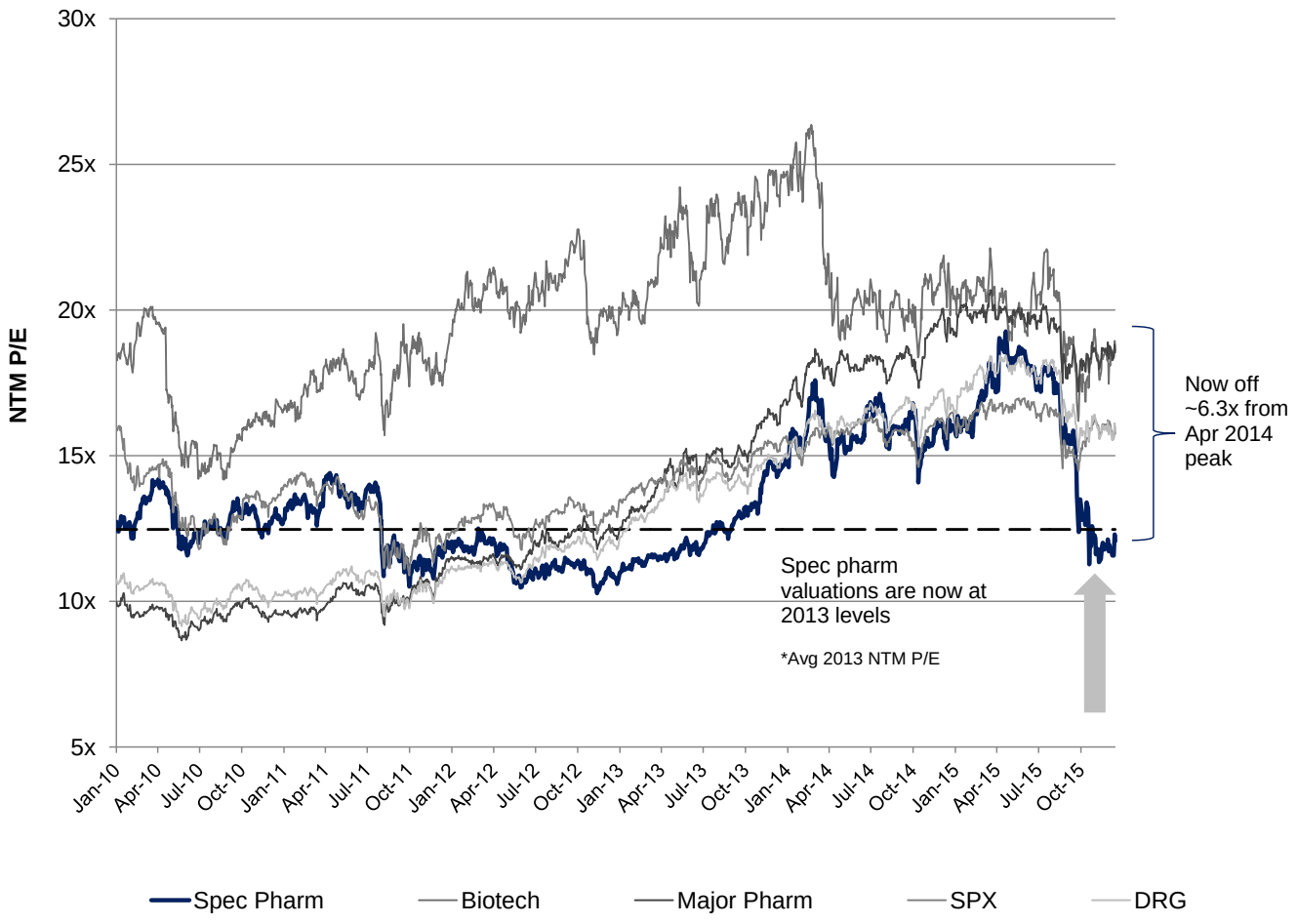



Source: Company reports, Factset, RBC Capital Markets

## Theme #4: Sector valuation – Growth is real and at a discount to recent levels

The specialty pharmaceutical sector is now trading at 12.1x on a forward P/E basis against a low to mid-teens EPS growth rate. This is a 37% discount to its earlier year high of 19.3x and puts valuation back to 2013 levels. It also puts it at a 35% discount to big pharma and biotech. While we do not expect an M&A premium to enter the sector in the near term, we believe that this valuation sets this group up well heading into 2016.

Exhibit 17: The sector is now trading at 12.1x, which is well below the 19.3x peak in early 2015 and a widening discount to both biotech and major pharma (excluding Allergan, which is being acquired by Pfizer)




*Median values used

Source: FactSet, RBC Capital Markets estimates

**Specialty pharma now offers growth at a meaningful discount to other sectors outside of financials and energy.** The debate that we expect to see in 2016 should be around the quality of that growth and whether or not there is risk associated with the headline. That is why 4Q earnings will be important, because not only will we get a look at near-term performance, but also they will come with first-time 2016 outlooks for many.

Exhibit 18: Specialty pharma growth is at a large discount to most other sectors outside of financials and energy

| Sector - Top 10 Largest Mkt Cap | Median P/E 2016E | EPS CAGR '16-'18 | Median PEG |
|---|---|---|---|
| Utilities | 15.4x | 6% | 2.6x |
| Consumer Staples | 19.5x | 10% | 1.9x |
| HC Major Pharma | 15.9x | 12% | 1.8x |
| Materials | 17.6x | 13% | 1.6x |
| Consumer Discretionary | 20.1x | 15% | 1.6x |
| Info Tech | 16.9x | 14% | 1.4x |
| Telecomm | 11.5x | 2% | 1.5x |
| Industrials | 16.2x | 11% | 1.5x |
| Health Care | 15.8x | 11% | 1.4x |
| HC Biotech | 17.4x | 18% | 1.4x |
| **HC Spec Pharma** | **12.1x** | **13%** | **0.9x** |
| Financials | 10.7x | 11% | 0.9x |
| Energy | 22.1x | 30% | 0.8x |

*Median values used

Source: FactSet, RBC Capital Markets estimates

# Endo (ENDP) – Fundamentals will be the focus for 2016

**Bottom line – Inexpensive valuation against improving P&L outlook set Endo up well as we enter 2016**. This has been a challenging stock call for us given 2H2015 underperformance. However, we like three things about the setup here (1) an improving P&L outlook particularly as we head into 4Q, (2) the leverage to generics into what we think is going to be approvals acceleration, and (3) valuation that at 8.7x should provide a floor to the stock. We also see unique optionality in Endo given management's previous attempts at transformational moves in 2015 by bidding on Salix and entering discussions to combine with Perrigo, according to various unconfirmed media reports (i.e., Reuters).

**1. Generics business could deliver upside from an improving trend of FDA approvals.** We like Endo's relative positioning, given its generic diversification, the size of its pipeline, and the higher barrier, alternative dosage bend to it into a year when the FDA should begin to approve more ANDAs. Moreover, there are 47 potential first-to-file or first-to-market opportunities with several of those expected to hit in the next one to two years, which bring unique but important visibility. If Endo delivers upside here, then that would provide a boost to sentiment.

**2. Sentiment around the branded business has turned negative but that could change in 2016.** Expectations are low, but there are several things in early 2016 that could help change that (1) the Belbuca (recently approved) launch will shift focus to new product cycles, (2) we anticipate stronger Xiaflex results in 4Q with low expectations following a weak seasonal quarter (sales were flat 2Q to 3Q), and (3) there is real upside optionality around OPANA and a potential removal of generics from the market that is getting little attention and is not factored into Street numbers or expectations.

**3. M&A is no longer part of the thesis, which once again, adds unique optionality.** With valuation at these levels, transformational deals using equity are unlikely, but late-stage pipeline or bolt-on branded and specialty deals that could leverage the existing sales infrastructure could still make sense and could be digestible.

**Rating and risks:** Our price target of $91 is based equally on P/E and EV/EBITDA on pro forma forecasts using multiples of 14x and 11x, respectively. Our lower target to its peers also reflects reduced M&A optionality, given leverage and reduced equity value as currency for deals, which is an integral part of Endo's model. Risks include (1) integration of Par, (2) performance of base business below expectations, (3) Increased competition to key franchise products, (4) delay or inability to launch key products in generics and specialty.

Exhibit 19: Endo upcoming 2016 catalysts

| Event | Impact | Timing | P&L impact | Comments |
|---|---|---|---|---|
| **BELBUCA launch** | ++ | Early 2016 | ++ | We forecast peak sales of $300 million with ENDP paying mid to high teens royalties to BDSI for US Belbuca (in addition to other milestones). BDSI has previously pointed to $500 million or better in sales. |
| **2016 Business Outlook and Strategy Update** | +++ | Early 2016 | ++ | The outlook call should give 2016 guidance and while a 2016 EPS range was already given ($5.85 to $6.15), further color around outlook could boost sentiment. |
| **Potential for small M&A or BD** | Yes | Anytime | Yes | While large transformational deals are no longer likely near-term, bolt-on deals that leverage existing sales infrastructure could continue to make sense. |

Source: Company reports, FactSet, RBC Capital Markets estimates

# Teva (TEVA) – One of the better setups in specialty heading into 2016

**Bottom line – An improving mix and accelerating growth outlook set Teva up well for a valuation re-rating in 2016.** With the early 2016 closing of the Allergan generics deal and Street forecasts that largely have Copaxone becoming a smaller component of earnings, Teva's mix is improving, but we also expect to see P&L benefit from new specialty launches in 2016. At this point, we see a $6.00 EPS floor in the stock, a 12% EPS CAGR off that floor, and several levers of upside that set Teva up well fundamentally. M&A could add further upside but does not need to be part of the bull thesis.

**1. Copaxone 40mg generic impact framed, but entry far from clear, leaving upside potential in our model.** Our forecasts conservatively build in a 40% generic share in 2017E, removing $0.80 (before costs) in after-tax gross profit. However, there are real legal hurdles to generics that set our model up for potential upward revision. The other takeaway consistent with our survey is the strong patient-physician demand for the 40mg 3TW in the US.

**2. Specialty pipeline not assigned much value in the stock but could yield meaningful contributions going forward.** Our survey on SD-809 ahead of next year's launch for Huntington's (HD) and phase 2 topline results for TEV-48125 in migraine indicate blockbuster opportunities for both, which we think will get more focus.

**3. Teva represents a solid play on increasing ANDA approvals.** Teva has the largest generic pipeline in the US, and if we see 2016 emerge as the inflection year for generic approvals, Teva would not only benefit both fundamentally but also from a sentiment perspective. The company confirmed that it received target action dates across 30–60% of backlog, and while we do not know the "approval hit rate" versus complete response letter rate, we think this is a positive underlying trend in that there is potential to see a meaningful ramp in approval activity, and as of 1Q2016, Teva will have the largest US pipeline.

**Rating and risks:** Our $85 price target is based equally on P/E and EV/EBITDA, which reflects Teva's moderately lower tax rate and current leverage. Our price target reflects multiples of 14.5x and 11.0x, respectively, above where the stock has been valued over the last two years. Risks include: (1) deterioration in the base generics business, (2) stronger than expected impact from Copaxone generic entry, and (3) inability to launch new products to market.

## Exhibit 20: Teva upcoming 2016 catalysts

| Event | Impact | Timing | P&L impact | Comments |
|---|---|---|---|---|
| **Rapid Bendamustine (50 ml) launch - partnered with EGRX** | ++ | Early 2016 | We have modeled ~6% in 2016E EPS | We have modeled Treanda going from $775 million in 2014 to $590 million (net of double digit royalties to EGRX) in 2016 and remaining ~flat for the next several years. The product has 7 years of orphan exclusivity. An update on the J-code is expected in April. |
| **Close of Rimsa acquisition** | + | Early 1Q2016 | ++ | Neutral to 2016E adjusted EPS and accretive starting 1Q 2017E. The acquisition furthers TEVA's reach into EM by expanding its presence in Mexico and Latin America. |
| **Close of AGN Generics acquisition** | ++ | 1Q2016 | +++ | We model ~29% of 2016E generic revenue as AGN-acquired which is ~45% of 2016E generic gross profit. |
| **2016 Business Outlook and Strategy Update** | +++ | 1Q2016; after close of AGN Gx | ++ | The outlook call should give 2016 guidance and in particular, more guidance around Generics following the close of the acquisition. |
| **Initiate Phase III in anti-CGRP (TEV-48125) for chronic and episodic migraine** | ++ | 1Q 2016 | Each $1 billion in revenue drives ~$0.70 to EPS in 2023 | Targeting BLA submission for 2018 and launch by 2019. This could be TEVA's biggest pipeline opportunity - we forecast peak sales of $1.2 billion which we believe remains conservative. TEVA has guided to $2-3 billion in peak sales. |
| **PDUFA for SD-809 for Huntington Disease** | | May 2016 | Every 100 bps of penetration drives $0.03 to EPS in 2021 | Orphan drug designation Nov 2014 (7 years exclusivity). We forecast peak sales at $469 million with a modest 13% peak share. Management guided to $2 billion peak sales for SD-809 in all indications (combined). |
| **Expected launch on generic EPIPEN** | + | 2H2016 | 25% share at generic pricing would give ~$0.08 or 1% to 2016E EPS - minimal P&L impact | TEVA expects a CRL by YE2015 and the expected launch has been pushed back to 2H2016. |
| **Launch of SD-809 for tardive dyskinesia** | ++ | 2H2016 | Every 100 bps of penetration drives $0.40 to EPS in 2022 | Expect $2 billion in sales from SD-809 between TD and HD. Phase III results expected in 2016 and we anticipate a 2017E launch with peak sales at $612 million which assumes a ~1% peak share. |
| **Copaxone 40mg IPR challenge timeline** | ++ | Various, in 2016 | Guided to $0.65 2017E EPS hit after cost offset given Gx entry | February 17: MYL reply to TEVA's response due. May 12: Oral arguments, if requested. September: Trial for 3TW begins. August: IPR final decision. In addition, we could see a potential IPR on the new '776 method of use patent come at any time. |

Source: Company reports, FactSet, RBC Capital Markets estimates

# Flexion (FLXN) – We are buyers into key pivotal data in Feb 2016

**Bottom line – Flexion is our top near-term clinical data-driven idea with a major upcoming catalyst, which we believe will drive shares higher.** We are buyers into data from the second pivotal study for lead product Zilretta expected in February 2016. Shares have been under pressure since data from the first pivotal introduced uncertainty in the name, but we expect upcoming data to be positive and largely put those prior concerns to rest. We see a differentiated offering in Zilretta and see a substantial market opportunity that should ultimately attract strategic interest from an acquirer.

**1. We believe setup into upcoming data as favorable and see shares moving higher.** Our confidence into the second pivotal comes from (1) a substantially larger patient count in the second pivotal, which should benefit separation against both the placebo and TCA IR arms, (2) potential separation against TCA IR up to 12 weeks (prior phase 2b showed only 10 weeks) given better formulation, which should prolong Zilretta's therapeutic effect and demonstrate an even more compelling opportunity to the market, and (3) the overall pain relief that patients will likely experience over the length of the study compared to marketed treatments.

**2. Zilretta has the potential to capture significant market share given its compelling and straightforward value proposition.** Combining the same TCA IR 40mg strength, safety profile, and injection procedure, which doctors are familiar with an extended duration technology that already exists, is a straightforward sell. We see upside to our base case $1.05 billion peak sales that include (1) faster ramp to peak of 26%, which is arguably conservative (2) higher peak market share, (3) expansion of use beyond knee (+$13 per share on 20% market share expansion), and (4) increased injections per year (none baked into assumptions).

**3. We see Flexion ultimately being acquired by a strategic buyer post-phase 3 data**. We see a stock that can ultimately trade up to 0.9–1.0x peak implying close to a $50 level (which we could see on positive data assuming they are statistically significant against the comparator). The company is well funded, ending 3Q with ~$132 million in cash, which can take Zilretta through approval. Timelines remain on track for a 2H2016 NDA submission.

**Rating and risks:** Our $44 price target is a blend of: (1) 40% M&A reflecting a 40% premium to fundamental price, (2) 30% net present value (NPV) for lead product FX006 of $32 combined with cash of $3, which get us to $35, and (3) 30% discounted cash flow analysis of $38. We arrive at ~$32 per share in NPV for FX006 based on a peak sales forecast of $1.05 billion, which reflects 26% TRx market share penetration of the IR steroid and HA market combined. Risks include: (1) unexpected FDA delays and adverse results from the second pivotal study currently running, (2) commercialization and uptake risk exists, (3) we anticipate another funding raise prior to commercialization efforts in the US, (4) market acceptance and uptake for FX006, and (5) no takeout by an acquirer, which would affect our base-case price target.

Exhibit 21: FLXN upcoming 2016 catalysts

| Event | Impact | Timing | P&L impact | Comments |
|---|---|---|---|---|
| **Zilretta (FX006) top-line Phase III data** | +++ | 1Q2016 | N/A | Management believes the strength of the data overall should suffice for FDA acceptance however should be affirmed following Phase III results and the FDA meeting. |
| **Zilretta NDA filing** | ++ | 2H2016 | N/A | If FLXN is required to run another trial we expect it would add ~6 months to timing but would still allow for a 2H2016 NDA submission. The supplementary trial would be 300-400 patients at <$10 million. |
| **Zilretta approval** | +++ | 2017 | FX006 is worth $42 per share in our NPV analysis | We anticipate a mid-2017 launch with peak sales of over $1 billion, with further upside potential from label expansion opportunities. |

Source: Company reports, FactSet, RBC Capital Markets estimates

# Agile (AGRX) – 2016 set to be an inflection year following phase 3 data in 4Q16

**Bottom line – Agile is now within a 12-month investment horizon with phase 3 pivotal data in 4Q2016 for lead product Twirla, which we believe will be positive and drive shares higher**. Twirla is a low-dose weekly combination contraceptive patch that we believe fills an established unmet need in the market, offering both convenience and compliance benefits that we think would appeal to a core patient base. We believe Agile will attract strategic interest among the multiple players in women's health with established sales infrastructure.

**1. We expect positive phase 3 data in 4Q16 to drive shares higher.** As poor patient recruitment and loss of data were significant factors to the prior phase 3 failure, we believe that the rigorous patient selection process in place for this study will improve patient compliance and data, which should show Twirla to be an effective and safe combination contraceptive patch with an acceptable Pearl score.

**2. Market opportunity is key to the story, and we see a substantial market opportunity for Twirla that is under appreciated.** Our $340 million peak sales estimate reflects only 3% TRx market penetration and 4% annual pricing increases—both of these are arguably conservative, thereby creating what we think is a very favorable upside scenario. For each 100 basis points in TRx penetration, we see roughly $114 million in additional peak sales, and that translates into close to $3 in NPV per share.

**3. Twirla is a unique offering in the combination contraceptive market that should be attractive to many strategic acquirers.** With potentially a longer-duration potential for Twirla (latest patent expiry through 2028), manufacturing know-how, and additional pipeline opportunities, Agile is a logical takeout for an established women's health sales force. At 1.5x peak sales, that implies potentially a takeout around ~$20 per share.

**Rating and risks:** Our $13 price target is based on: (1) 30% M&A likelihood reflecting a 40% premium to fundamental price target, (2) 35% DCF, and (3) 35% NPV valuation. Given that the primary value of Agile comes from its lead product candidate, Twirla, we think that taking a blended approach is warranted. Our DCF valuation of $11 per share reflects our risk-adjusted forecasts in the US for Twirla. Risks include: (1) New phase 3 data for Twirla are insufficient for an NDA filing, (2) additional regulatory or execution delays to launch, (3) potential for greater than expected financing needs, and (4) lack of commercial uptake or adoption below expectations.

Exhibit 22: Agile upcoming 2016 catalysts

| Event | Impact | Timing | P&L impact | Comments |
|---|---|---|---|---|
| **Phase III data for Twirla** | +++ | 4Q2016 | N/A | We expect positive Phase III data and management has reiterated that the required target patient demographics have been hit in enrollment. |
| **Twirla resubmission** | + | 1H2017 | N/A | AGRX can also draw on another $8.5 million from Hercules upon positive Ph III data which could add to their cash balance into re-submission. It is likely they will require additional funding for the commercial launch though the commercial strategy remains unclear. |
| **Twirla approval and launch** | +++ | 2H2017 - following 6 mth review post-CRL | Every 100 bps in penetration gives ~$3 in NPV per share | We forecast $340 million in peak sales for Twirla at 3% penetration with conservative pricing assumptions. |

Source: Company reports, FactSet, RBC Capital Markets estimates

# Insys (INSY) – DOJ investigation overhang is key to unlocking value

**Bottom line: The conclusion to the ongoing DOJ investigation remains the key catalyst of the stock, which we believe could conclude over the next year.** With Subsys worth ~$25 per share and $2 per share in cash, Insys shares are not reflecting much for what we think is a growing and increasingly late-stage pipeline, which could bring Insys to a five-product company in 2017. Management continues to have confidence in its controls and believes worst-case scenarios are unrealistic, which could setup a sharp short squeeze over the coming year.

**1. Management is confident in its ability to move past the DOJ investigation.** Insys is spending ~$6–8 million/quarter on litigation costs and sees potential DOJ resolution at the shorter end of the typical three to five years (it has been nearly two years now since original subpoena). We believe a settlement is possible and note that the amount of sales in question is relatively small, and prescribing remains diversified with the top Subsys physician less than 1% of total scripts.

**2. Subsys remains the other focus of the story, and we believe there is room to grow from here.** While script growth in past few weeks has been tepid, management expects growth will come from a combination of improved pricing and better gross and/or net improvements in 2016. We see Subsys as a differentiated offering providing real benefit against existing treatments that can grow in sales with potential upside from indication expansion opportunities.

**3. Late-stage pipeline and multiple phase 3 studies starting this year should start to get more focus.** The most important near-term pipeline update will be the Syndros Prescription Drug User Fee Act (PDUFA) April 1, 2016, which will likely launch in early 2H2016 (we estimate NPV ~$10 per share). There will be a host of other updates from other 2017 "launch opportunities" including Subsys (label expansion studies), buprenorphine, buprenorphine, with naloxone and naloxone as well as progress on CBD, which may read out data in 1H2016.

**Rating and risks:** Our price target is based equally on our sum-of-the-parts (SOTP) valuation and discounted cash flow analysis, driving a $49 price target. Our SOTP analysis derives $50 per share on NPV of $25 for Subsys, $7 for Dronabinol OS, $16 for additional pipeline, and $2 for cash on hand. Our DCF gets us $48 per share and reflects explicit forecasts through 2023E with a 12% WACC and -5% terminal growth rate beyond. Downside risks arise from: (1) commercialization risk with Subsys, (2) regulatory risk for Dronabinol OS and CBD, (3) manufacturing and API sourcing, and (4) headline and government investigation risks.

## Exhibit 23: Insys upcoming 2016 catalysts

| Event | Impact | Timing | P&L impact | Comments |
|---|---|---|---|---|
| **Potential resolution of DOJ/State investigations** | +++ | Any time - could be in a year | ~$6-8 million/quarter currently spent on litigation costs | The ongoing investigations are the largest overhang on the stock and other cases have been resolved in 3-5 years. The original subpoena was received around 2 years ago which suggests we may see a resolution in the next year. |
| **Capital deployment** | +++ | Any time | +++ | INSY has ~$187 million in cash/investments with no debt (as of 3Q2015) which is worth ~$2.50 per share. Management announced a $50 million buy back which allows them to continue to fund R&D while remaining opportunistic around accretive M&A. |
| **Naloxone Sublingual Spray bioavailability study results** | ++ | January 2016 | N/A | FDA fast track designation received; we anticipate launch may occur in 2017. Will hold discussions with FDA in 1H2016 to determine a potential pathway for the NDA. |
| **Syndros (Dronabinol OS) PDUFA** | +++ | April 1, 2016 | Management guided to peak sales >$200M annually; we estimate ~$5 per share. | Launch expected in 2H2016. Syndros treats chemotherapy-induced nausea/vomiting and weight loss in AIDS patients and we model an opportunity worth ~$5 per share. |
| **Initiate pivotal Ph III trials for Buprenorphine sublingual spray** | N/A | 2H2016 | We model ramping R&D for increasing development of pipeline products | Trials will be run for both opioid naïve chronic lower back pain and opioid experienced patients in 2H2016. Management believes it will be a Schedule II product. |
| **Initiate Ph II studies for Subsys - expanded indications** | N/A | 2H2016 | We model ramping R&D for increasing development of pipeline products | Both a bone marrow biopsy study and a burn study will be conducted in 2H2016. |
| **NDA submission for Buprenorphine (acute) sublingual spray** | ++ | End of 2016 | N/A | We anticipate launch may occur in 2H2017. Management believes it will be Schedule II. |
| **NDA submission for Buprenorphine/Naloxone sublingual spray for opioid dependence** | ++ | End of 2016 | N/A | We anticipate launch may occur in 2H2017. The bioavailability results will be released in January 2016. Next steps include an additional PK dose proportionality study and a 12-week safety study. |

Source: Company reports, FactSet, RBC Capital Markets estimates

# Eagle (EGRX) – Catalyst path ahead could bring further upside

**Bottom line – Eagle is in the midst of an important transition to a platform capable of quickly scaling with at least four products expected by 1H2016E with potentially more M&A to come.** We model a meaningful EPS ramp ahead, given a number of near-term catalysts from recently approved BENDEKA (bendamustine rapid) expected to launch 1Q2016 and the acquisition of docetaxel. Management expectations for Ryanodex (positive EHS data recently announced) are substantially higher than the street and could prove to be a source of upside over time.

**1. Bendamustine royalties from Rapid and RTD should provide substantial cash flow, which we think is generally derisked.** We believe Teva will be successful in switching bendamustine products on the market to BENDEKA (20% royalty to EGRX), and we believe the "big bag" bendamustine RTD sold by Eagle can capture up to ~20% share (royalties back to Teva), generating substantial cash flow (we model more than $400 million by 2018E with no debt), which we think could be redeployed to M&A.

**2. Ryanodex could be a source of upside as EHS indication is added and launched in 2017.** We modeled $100 million peak sales for EHS, which is relatively conservative given the potential size of the market at more than $400 million with no approved therapy. Investor expectations are relatively limited, and each $100 million in additional sales equates to roughly $20 in NPV.

**3. Upcoming important catalysts should drive a meaningful EPS ramp**. We currently model 2016E–2018E EPS at $6.81, $6.90, $7.74, respectively, which are largely driven by bendamustine products (BENDEKA launch in 1Q2016, and RTD launch in 3Q2016). We see the opportunity for management to continue to pursue strategic business development with pre-existing capacity in its co-promote with SPPI.

**Rating and risks:** Our $100 price target is an equal blend of: (1) SOTP analysis, and (2) DCF valuation. Our DCF gets us to $98 while our SOTP brings us to $103, which blended get us to our $100 target. Our SOTP is driven by the bendamustine franchise ($51), Ryanodex ($25), bivalirudin ($3), remaining pipeline ($8), and cash ($11). Our DCF reflects an 11% WACC and 0% terminal growth rate.

Exhibit 24: Eagle upcoming 2016 catalysts

| Event | Impact | Timing | P&L impact | Comments |
|---|---|---|---|---|
| **Bendamustine EP-3102 Launch (with TEVA)** | ++ | Early 2016 | Yes | Treanda had 2014 sales of $767 million. Upon approval we expect TEVA to pursue an aggressive switch strategy from its 500ml bag to EP-3102. It has an incentive to do so ahead of EGRX's planned May 1, 2016 launch of EP-3101. |
| **Docetaxel Injection Concentrate Launch** | + | Early 2016 | Yes | Potentially first alcohol-free Docetaxel approved in the US following its Dec 26 2015 PDUFA. Exclusive US licensing agreement with Teikoku Pharma to market, sell and distribute Docetaxel. Per IMS, TTM sales of Docetaxel were $158 million. |
| **Bivalirudin (EP-6101) approval and launch** | +++ | Mar 16, 2016 | We model Bivalirudin at $8 per share in NPV | Litigation between Hospira and MDCO will likely formally complete in late 2015. Hospira launched July 2015. We expect approval in March 2016 with launch to follow. The primary swing factor is how many generics will ultimately enter - we have modeled EGRX capturing 20% share in 2016. |
| **J-code process** | ++ | ~April 2016 | Only if generics enter | EGRX will file in Dec and likely find out a decision in ~Apr/May. This matters if generics ultimately come to market as it will provide some added protection. |
| **Bendamustine 500 mL liquid (EP-3101) launch** | ++ | May 1, 2016 | We model EP-3101 at $13 per share in NPV | EGRX will be moving forward on EP-3101 and will target 20-25% of the market. The 500mL product will have a higher overall net margin relative to Rapid, where EGRX is partnered with TEVA and will receive a 20% royalty. |
| **Lyophilized Treanda (bendamustine) trial** | ++ | Fall 2016 | Yes | Litigation on TEVA's lyophilized bendamustine will determine the timing of generic entry. A 10-day bench trial began Nov 30 with a decision expected by the Fall of 2016. We currently model 2021 generic entry. |
| **Potential M&A or in-licensing** | +++ | Anytime | Yes | As of 3Q15, EGRX had $96 million in cash/equivalents with $30 million in milestones for Rapid from TEVA Dec 2015 (and royalties) and no debt. We think a company with hospital-based S&M company or hospital based products are the most strategically appealing for EGRX. |

Source: Company reports, FactSet, RBC Capital Markets estimates

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