

## MORNING ROUNDS

**TODAY'S HIGHLIGHTS / JANUARY 6,  
2015**

**TODAY'S RESEARCH:**  
CVS, BCR, ISRG, TFX

**INITIATIONS:** NONE / **RATING CHANGES:** NONE / **PRICE TARGET  
CHANGES:** BCR, ISRG, TFX / **ESTIMATE CHANGES:** BCR, ISRG, TFX  
/ **MEDACORP:** NONE / **PREVIOUS RESEARCH:** ZFGN, BDX, COV, SYK, ZMH

### REFERENCE TOOLS:

[Catalyst Tracker](#)

[Earnings Rundown](#)

[Abbreviations & Acronyms](#)

[Calendar of Events](#)

[HC Conferences](#)

[Leerink Events](#)

### MORNING PRIMER:

**Futures (as of 6:30am):** DJIA: -273.00 (17,723); S&P500: +0.75 (2,016); NASD  
-1.00 (4,162)

### TODAY'S HEALTHCARE EVENTS:

**1/6-7:** FDA AdCom: Oncologic Drugs

**1/6-9:** Digital Health Summit at the Consumer Electronics Show

### TODAY'S RESEARCH (including notes post prior day's close):

**CVS HEALTH CORPORATION (CVS)** / DAVID LARSEN, CFA

#### **CVS Signs Exclusive Deal with Gilead**

Outperform / **Market Cap:** \$107,945.0M / **Price:** \$94.16

- **Bottom Line:** CVS Health recently signed an exclusive arrangement with Gilead (OP) which we believe will be effective 1/7/15. This arrangement is not a surprise to us given that ESRX (OP) recently signed an exclusive arrangement with AbbVie for treatment of genotype 1 using Viekira Pak. We believe that given the move by Express Scripts, Gilead was likely far more willing to work with CVS to come to an arrangement. With respect to CVS we believe this is an exclusive arrangement and the AbbVie products are considered non-formulary. Harvoni is the preferred formulary agent for Hepatitis C genotype 1, and Sovaldi is a preferred agent for the treatment of other genotypes. We believe Viekira Pak will be considered non-formulary and available only via a medical exception or prior authorization for patients who have not yet initiated therapy. While a recent *Wall Street Journal* article uses the term "preferred status" in its headline, we believe the Gilead products are exclusive, and the AbbVie products are not on CVS' formularies. There are always medical necessity exceptions, and some plans we believe may be able to implement variations to formulary designs in some cases; however, essentially we believe CVS has entered into a tight, exclusive arrangement with Gilead. Co-pays and deductibles would vary depending on individual plan sponsors' designs.
- Harvoni and Sovaldi Will Be Exclusive on CVS Formulary.
- This Move Is Impressive but Not Overly Surprising.

## CR BARD, INC. (BCR) / RICHARD NEWITTER

### Model Update for FX; PT to \$174

Market Perform / **Market Cap:** \$12,588.7M / **Price:** \$164.99 / **Price Target:** \$158.00 → \$174.00 / **Methodology:** ~17.5x 2016E EPS of \$9.92

- **Bottom Line:** We are updating our model for BCR to reflect FX dynamics. Our new model reflects a stronger USD vs. foreign currencies such as the Euro & Yen, resulting in a slightly lower 2015E sales of \$3.42B vs. \$3.45B prior (organic growth [ex-royalty] of ~3.5% is unchanged). The flow through to the bottom line is minimal as we also take this opportunity to assume a lightly lower SG&A spend assumption in '15E, and this helps to offset the incremental negative FX impact through the P&L. We reiterate our MP rating; however our price target does increase to \$174 (vs. \$158 prior) reflecting a higher multiple (17.5x) applied to our \$9.92 2016E EPS --- primarily due to recent multiple expansion for the group though basically still in line with peer valuations.
- **2015E EPS/REV:** \$9.09 / \$3,445.0 → \$9.09 / \$3,422.0  
*Revenues in \$M.*

## INTUITIVE SURGICAL, INC. (ISRG) / RICHARD NEWITTER

### Model Update for FX; Increase PT to \$590

Outperform / **Market Cap:** \$18,980.3M / **Price:** \$514.37 / **Price Target:** \$570.00 → \$590.00 / **Methodology:** ~30x 2016E adj. non-GAAP (incl. SBC but ex-amort) + cash/share

- **Bottom Line:** We are updating our model for ISRG to reflect FX dynamics. Roughly 15% of ISRG's revenue are exposed to movements in exchange rates, and our new model reflects a stronger USD vs. foreign currencies such as the Euro & Yen. This results in slightly lower 2015E sales of \$2.35B (vs. \$2.40B prior) and assumes 10.4% WW procedure growth (8.5% US y/y procedure growth) --- an acceleration vs. 9.2% WW y/y growth forecast for '14 (6.5% US '14E y/y). In 2015 we project 440 system dV units to be sold (304 US / 136 OUS). On the bottom line, '15E EPS declines to \$18.10 from \$18.44 largely due to

the (1) FX adjustments, (2) a slightly lower GM assumption --- mostly as we expect a more negative “mix shift” drag as lower margin Xi systems & accessories (i.e., vessel sealer, etc.) increase as a percent of total, and (3) a slightly higher SG&A spend assumption vs. our prior thinking. We reiterate our OP rating. Our Price Target increases to \$590 (from \$570) primarily due to recent multiple expansion for the group--- to which we continue to believe ISRG deserves to trade at a significant premium given our conviction in double-digit top and mid-to-high teens bottom line growth over the intermediate to longer-term.

• **2014E EPS/REV:** \$15.18 / \$2,088.6 → \$15.17 / \$2,086.4

• **2015E EPS/REV:** \$18.44 / \$2,395.5 → \$18.10 / \$2,348.8

*Revenues in MM. EPS ex 1x items, stock compensation expense, deferred revenue, and amortization.*

## TELEFLEX INCORPORATED (TFX) / RICHARD NEWITTER

### Model Update for FX; PT to \$122

Market Perform / **Market Cap:** \$4,911.3M / **Price:** \$112.13 / **Price Target:**

\$121.00 → \$122.00 / **Methodology:** ~17.5x 2016E EPS of \$7.00

• **Bottom Line:** We are updating our model for TFX to reflect FX dynamics. Our new model reflects a stronger USD vs. foreign currencies such as the Euro & Yen, resulting in a slightly lower 2015E sales of \$1.88B vs. \$1.90B prior (organic growth of ~3.8% is unchanged). On the bottom line, 2015E EPS declines to \$6.28 from \$6.40, a result of the negative FX impact. We reiterate our MP rating; however our price target does increase to \$122 (vs. \$121 prior), reflecting a higher multiple (~17.5x) applied to our \$7.00 2016E EPS.

• **2014E EPS/REV:** \$5.70 / \$1,839.8 → \$5.69 / \$1,837.6

• **2015E EPS/REV:** \$6.40 / \$1,901.3 → \$6.28 / \$1,880.3

*Revenues in MM.*

## PREVIOUS DAY NOTES:

### ZAFGEN, INC. (ZFGN) / JOSEPH P. SCHWARTZ

### Beloranib HIAO Data 1Q15 - Strong Results Could Double Mkt. Oppty, Read on PWS

Outperform / **Market Cap:** \$748.3M / **Price:** \$30.92 / **Price Target:** \$35.00 / **Methodology:**

Probability-weighted DCF analysis, 12% discount rate

• **Bottom Line:** After taking a closer look at beloranib's mechanism-of-action and the compelling data generated to date, we remain positively biased on ZFGN shares ahead of proof-of-concept Hypothalamic Injury-Associated Obesity (HIAO) data in 1Q15. HIAO has the potential to double the beloranib market opportunity, and positive Phase I/II results in January could render the Street more bullish on Phase III data in Prader-Willi Syndrome (PWS), which is expected by YE15. **Reiterate OP on ZFGN and \$35 price target.**

• HIAO presents a significant and orphan unmet medical need with ~6K patients in the US.

• Based on its mechanism-of-action, we believe beloranib's robust weight-loss effects in both Prader-Willi and Severe Obesity settings should translate over to HIAO.

• We see a +50%/-35% up/down for ZFGN shares in best case/worst case data scenarios.

## PREVIOUS NOTES:

### BECTON, DICKINSON AND COMPANY (BDX) / RICHARD NEWITTER

#### Model Update for FX; PT to \$142

Market Perform / **Market Cap:** \$27,412.6M / **Price:** \$139.86 / **Price Target:** \$137.00 → \$142.00 / **Methodology:** ~17x FY16E pro forma cash EPS of \$8.35

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### COVIDIEN PLC (COV) / RICHARD NEWITTER

#### Model Update for FX; PT to \$104

Market Perform / **Market Cap:** \$46,748.1M / **Price:** \$102.07 / **Price Target:** \$95.00 → \$104.00 / **Methodology:** Takeout price offered by MDT

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### STRYKER CORPORATION (SYK) / RICHARD NEWITTER

#### Model Update for FX

Outperform / **Market Cap:** \$35,951.2M / **Price:** \$93.99 / **Price Target:** \$106.00 / **Methodology:** ~18.7x 2016E EPS

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### ZIMMER HOLDINGS INC. (ZMH) / RICHARD NEWITTER

#### Model Update for FX

Outperform / **Market Cap:** \$19,331.7M / **Price:** \$112.59 / **Price Target:** \$135.00 / **Methodology:** ~16x 2016E pro forma cash EPS of \$8.56

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## RESEARCH PREVIEWS:

### Early January 2015 – XmAb5871 (Rheumatoid Arthritis) Phase Ib/Ila Data

#### **XNCR – OP – Michael Schmidt**

**Close: \$15.88, Mkt Cap: \$287M**

- The Phase IIa study includes 30 patients with active RA on methotrexate (MTX).
- XmAb5871 is a B-Cell inhibitor that simultaneously targets the B-cell proteins CD19 and FcγRIIb.
- XmAb5871 Phase Ia data showed immunosuppression with only transient B-cell reduction.
- Phase IIa RA disease activity data should provide further proof-of-concept for XmAb5871.
- XNCR plans to start clinical testing of XmAb5871 in IgG4-related disease in 201.
- XNCR recently announced it has regained all development and commercial rights to XmAb5871 from AMGN.
- We currently assign a 20% probability of success for '5871.

- MGNX has a similar molecule that is partnered with Takeda currently in preclinical studies.

## January 9 – PDUFA for IPXL Rytary (Parkinson's)

### IPXL – MP – Jason Gerberry

**Close: \$30.41, Mkt Cap: \$1,752M**

- On the 2Q earnings call, management appeared confident in Rytary's approval prospects.
- Management believes the NDA has been decoupled from the Hayward facility (under a Warning Letter).
- Also management believes that it have addressed all the issues in the FDA's CRL and is optimistic that its responses to the FDA's 483 will be sufficient for approval.
- We think Rytary sales can reach \$220M in Year 5 but question the durability of this asset, given its reliance on formulation patents.

## January 24 – Natpara (Hypoparathyroidism) PDUFA for BLA

### NPSP – OP – Joe Schwartz

**Close: \$38.13, Mkt Cap: \$3,115M**

- NPSP is optimistic on approval by Natpara's new 1.24.15 PDUFA date and remains confident that both AdCom & endocrinology specialists view the drug's risk/benefit as well suited for chronic treatment (i.e., no two-year treatment limit).
- NPSP has made significant pre-launch progress for Natpara as ~2,000 hypoparathyroidism patients have requested its e-book and emergency resource kit.
- We view Natpara as an asset for which NPSP deserves more credit given its strong safety/efficacy profile and the lack of approved agents that can treat the root cause of hypoPTH.

## By Jan. 2015 – BIIB Anti-LINGO (Optic Neuritis) Phase II Interim Data Review

### BIIB – OP – Joe Schwartz

**Close: \$336.74, Mkt Cap: \$66,072M**

- We expect optic neuritis Phase II RENEW data for anti-LINGO in January 2015 to augment investor interest in the stock ahead of LINGO MS data in 2016.
- The primary end point is a functional of improved visual acuity but an improved anatomical condition would be an additional positive
- For full approval, we model a 33% probability of approval.

## By Jan. 2015 – BMY Opdivo (Squamous Lung Cancer) Phase III Interim Data Review

### BMY – OP – Seamus Fernandez

**Close: \$58.58, Mkt Cap: \$87,219M**

- We think BMY's leadership in PD1 is poised to accelerate with up to 4 monotherapy studies to report positive survival data likely by YE15.
- CHECKMATE-017 (NCT01642004) has a 70%+ chance of reporting a positive Overall Survival data at the interim look, expected by mid-Jan. 2015.

- Other trials include: in melanoma (CHECKMATE-066 – complete), in non-squamous lung (CHECKMATE-057 – interim projected in 1H15 with final analysis in late 2015/early 2016 according to the 3Q14 conference call), and kidney cancer (CHECKMATE-025).
- Given BMY's trial design and the powerful tail/functional cures seen in a substantial minority of patients treated in these 4 tumors to date, our confidence in the ultimate success of Opdivo in these 4 studies is high.

## 1Q15 – ALKS 3831 (Schizophrenia) Phase II Data

### ALKS – OP – Michael Schmidt

**Close: \$59.38, Mkt Cap: \$3,170M**

- Randomized-controlled Phase II data in early 1Q15 could position ALKS 3831 competitively vs. Zyprexa (olanzapine).
- We believe positive Phase II results could indicate ALKS 3831 may benefit a larger number of patients than olanzapine, currently fourth-most used antipsychotic in the US.
- Key in our view is for data to show the addition of ALKS 3831 doesn't impact the antipsychotic activity of olanzapine and that longer 12 weeks treatment increases weight gain difference to olanzapine alone.
- Primary endpoint is PANSS score reduction, and key secondary endpoints are percent change in body weight from baseline and proportion of subjects exhibiting significant weight gain among others.
- In Phase I, ALKS showed 26% less weight gain vs. olanzapine in 106 healthy volunteers following 3 weeks of treatment.

## 1Q15 – ALKS 8700 (Multiple Sclerosis) Phase I Proof-of-Concept Data

### ALKS – OP – Michael Schmidt

**Close: \$59.38, Mkt Cap: \$3,170M**

- ALKS 8700 is a patented (composition-of-matter IP until 2033) oral controlled-release prodrug of monomethyl fumarate (MMF), the active metabolite of Tecfidera.
- It is designed to be differentiated from Tecfidera based on (1) dosing frequency, and (2) tolerability.
- Randomized-controlled Phase I data in 1Q15 should provide early proof-of-concept for proprietary MS asset, which could provide an early de-risking dataset to address another billion dollar market opportunity.
- Outcome measures include safety, tolerability and pharmacokinetics.

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## PREVIOUS NOTES:

**UPDATED MODELS:** [AET - Model](#), [BDX - Model](#), [COV - Model](#), [HNT - Model](#); [SYK - Model](#), [WBA - Model](#); [ZMH - Model](#)

## IMMUNO-ONCOLOGY



## [The \\$40B+ IO Market](#)

[BMJ vs. MRK: IO Reimbursement Likely Limited to Labels](#)

## **AMERICAN SOCIETY OF HEMATOLOGY (12/6-9)**

[Biotechnology/Takeaways from ASH 2014](#), Howard Liang

[Biotechnology/Takeaways from ASH 2014 Weekend Presentations](#), Howard Liang

[Flash -- IMGN/Incremental ASH 2014 Updates on IMGN529 and BT062/Outperform](#), Michael Schmidt

[Flash -- ALNY/Incremental ASH Updates for ALN-AT3 and ALN-CC5/Outperform](#), Michael Schmidt

[Flash -- ISIS/FXI Publication in NEJM Should Aid Partnering Discussions/Market Perform](#), Michael Schmidt

## **SURVEYS**

[Managed Care/2015 Broker Survey; Public Exchanges Winning; Self-Insured Growth Continues](#), Ana Gupte

[Survey Offers Insight Into Bacteria, Yeast Testing Trends](#), Dan Leonard

[Biopharma/COPD Survey Suggests Slow Uptake for Breo and Anoro but Solid Long-Term Outlook](#), Biopharma Team

[Managed Care/'15 Comm. Pricing Survey; Publics Hardening; NFPs Mixed; Raising AET '15E EPS](#), Ana Gupte

[Biotechnology/MS Survey Highlights Strong Growth Outlook for Tecfidera, RPC1063](#), Joe Schwartz

[SIEN/Shaking Up The US Breast Product Mkt -- A Growth Story That "Gels"; Initiate OP/Outperform](#), Rich Newitter

[KYTH/3Q14 Survey Results: Physicians' Anticipation of ATX-101 Continues to Build/Outperform](#), Seamus Fernandez

## **CV OUTCOMES SERIES**

[CV Outcomes Series: Big Pot'l for MRK & LLY's CETPi's but Conviction Low](#)

[Biopharma/CV Outcomes Series: Highlights from Our PCSK9 Conference Call](#)

[Biopharma/Highlights from Our MEDACorp Acute Heart Failure Conference Call](#)

[Biopharma/CV Outcomes Series: IMPROVE-IT Expected to Support the LDL Hypothesis](#)

[Biopharma/CV Outcomes Series: NVS's LCZ696 Poised to Transform Treatment of CHF](#)

## **HEALTHCARE SERVICES ROUNDTABLE**

[Healthcare IT & Distribution/Takeaways from Healthcare Services Roundtable](#), Dave Larsen

[Healthcare Services/Healthcare Policy Views from the Hill: Key Takeaways From Services RT Panel](#), Ana Gupte

[Healthcare Services/Paradigm Shifts to Value-Based Care Are Real: Takeaways from Recent Services RT](#), Ana Gupte

## **RARE DISEASE ROUNDTABLE**

[Biotechnology/Orphan Drug Regulatory and Reimbursement Panels Project Continued Flexibility](#), Joe Schwartz

[Biotechnology/Takeaways from Rare Disease Roundtable](#), Howard Liang  
[GWPH/Dinner With Management Previews Next Epidiolex Readout, Thoughts on Competition/Outperform](#), Paul Matteis  
[AEGR/Dinner With Management Provides Insights on US Launch, PCSK9, Ex-US Biz/Outperform](#), Joe Schwartz  
[Biotechnology/Takeaways from Rare Disease Roundtable on RNAi/GeneTx Stocks Under Our Coverage](#), Michael Schmidt

## HEALTHCARE INSIGHTS CONFERENCE

[Healthcare/Healthcare Insights: Identifying the Industry's Key Trends & Growth Drivers](#), This Compendium Report from the Conference includes all the individual reports listed below.

[Biopharma/Investment Insights from Lymphoma/CLL Panel](#)  
[Biopharma/Investment Insights from HCV Panel: Growing Patient Pool Bullish for Launches](#)  
[Biopharma/Key Stock Impacts from Our Therapeutics Panels](#)  
[Biopharma/Investment Insights from the IO and Targeted T-Cell Therapy Panel](#)  
[Biopharma/Investment Insights from the Lung Cancer Panel](#)  
[Biopharma/Investment Insights from the Breast Cancer Panel](#)  
[Biotechnology/Investment Insights from Liver Disease Panel: Cautious on ICPT's OCA](#)  
[Medical Supplies and Devices/Investment Insights from the MIS/Robotics Surgery Panel](#)  
[Healthcare IT & Distribution/Investment Insights from the HCIT Panel: Robust Replacement Markets](#)  
[Healthcare IT & Distribution/Investment Highlights from PBM Panel: Service Challenges Weigh on ESRX](#)  
[Managed Care/Investment Insights from the Managed Care Panel on the Future of ACOs](#)  
[Life Science Tools and Diagnostics/Investment Insights from Nextgen Seq Dx Panel: Clinical Growth Opportunity](#)  
[STJ/Investment Insights from the CardioMEMS Panel: Large Market; Gradual Ramp/Outperform](#)

## LONG SHELF LIFE REPORTS

[Digital Health/Future of Digital Health](#), Steven Wardell  
[SHPG/Est. Brands & Lean Spending Drive Strong 3Q; Remain MP/Market Perform](#), Jason Gerberry  
[Healthcare Facilities/Puts & Takes in Dynamic Landscape of Reform & Recovery; UHS, CYH, HCA OP](#), Ana Gupte  
[ISRG/Higher Confidence In Procedure Acceleration & Xi; Upgrade To OP/Outperform](#), Rich Newitter  
[Biopharma/Future of Treatment of Lymphoid Malignancies](#), Howard Liang  
[GWPH/Deep Dive on GWP42003 for UC: Cannabis Anecdotes Reminiscent of CBD in Epilepsy/Outperform](#), Paul Matteis  
[Biopharma/P&A V - Partnerships & Acquisitions in Biopharma: Our New Top Ten List](#), Joe Schwartz et al.  
[BMRN/Deep Dive on BMN111: Compelling Logic/Early Efficacy Warrant Investor Attention/Outperform](#), Joseph Schwartz



[DYAX/Deep Dive on DX2930: Value Warranted for Novel HAE Monoclonal Antibody/Outperform](#), Joseph Schwartz  
[SHPG/Deep Dive on Ph. III Pipe; Feedback on Lifitegrast Surprisingly Constructive/Outperform](#), Jason Gerberry

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## **UPCOMING HEALTHCARE EVENTS:**

### **REGULATORY EVENTS**

**1/6-7:** FDA AdCom: Oncologic Drugs (NVS' biosimilar to AMGN's Neupogen, 1/7)  
**1/8-9:** FDA workshop re: Lab developed tests  
**1/9:** IPXL, Rytary (Parkinson's) PDUFA  
**1/12:** FDA AdCom: Endocrinologic and Metabolic Drugs  
**1/22:** FDA Adcom: Anti-Infective Drugs  
**1/24:** NPSP, Natpara (hypoparathyroidism) PDUFA  
**1/30:** GILD Cobicistat (HIV), TEVA LeCette (contraception), ZGNX Nextgen Zohydro (chronic pain) PDUFA

### **MEDICAL MEETINGS**

**1/6-1/9:** Digital Health Summit at the Consumer Electronics Show  
**1/10-1/14:** Plant and Animal Genome  
**1/14-1/17:** Scientific Meeting of American Academy of Cosmetic Surgery  
**1/15-1/17:** Gastrointestinal Cancers Symposium  
**1/16-1/18:** American College of Surgeons  
**1/17-1/21:** Society of Critical Care Medicine  
**1/21-1/24:** American Association for Hand Surgery  
**1/24-1/28:** Society of Thoracic Surgeons  
**1/31-2/3:** Annual Dialysis Conference

### **CORPORATE EVENTS**

**1/7:** LLY Guidance Call

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## Disclosures Appendix

### Analyst Certification

Each analyst certifies that the views expressed in this report accurately reflect their views and that no part of their compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	138	69.30	51	37.00
HOLD [MP]	61	30.70	2	3.30
SELL [UP]	0	0.00	0	0.00

### Explanation of Ratings

**Outperform (Buy):** We expect this stock to outperform its benchmark over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform in line with its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark over the next 12 months. The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark will be the S&P 600® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over \$2 billion.

### Important Disclosures

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