

MORNING ROUNDS

TODAY'S HIGHLIGHTS / APRIL 15, 2015

TODAY'S RESEARCH:

MEDICAL DEVICES-ORTHOPEDICS,
PHARMACEUTICALS/ MAJOR, LIFE
SCIENCE TOOLS AND DIAGNOSTICS,
HEALTHCARE SERVICES, JNJ

INITIATIONS: NONE / **RATING CHANGES:** NONE / **PRICE TARGET CHANGES:** NONE / **ESTIMATE CHANGES:** JNJ / **MEDACORP:** MEDICAL DEVICES-ORTHOPEDICS / **PREVIOUS RESEARCH:** ICEL, GWPH, MDCO, ZFGN, HEALTHCARE, AZN

REFERENCE TOOLS:

[Catalyst Tracker](#)

[Earnings Rundown](#)

[Abbreviations & Acronyms](#)

[Calendar of Events](#)

[HC Conferences](#)

[Leerink Events](#)

MORNING PRIMER:

Futures (as of 6:30am): DJIA: +54.00 (17,910); S&P500: +0.25 (2,091); NASD -0.25 (4,398)

LEERINK EVENTS:

4/15: Investor Tours / Site Visits: HIMSS Booth Tours: MDRX, CERN, IMPR, QSII, VCRA, Chicago

4/16: Corporate Access: Dermira, Inc.: DERM, New York

4/16: MEDACorp Pulse Call: Live from ISHLT: Rapid Response on ENDURANCE – Impact to HTWR/THOR Market Shares and Volumes and, 10:00AM EDT

4/17: Corporate Access: Raptor Pharmaceutical Corp.: RPTP, London

4/17: Corporate Access: Dermira, Inc.: DERM, New York

4/20: MEDACorp Event: Immuno-Oncology & CAR-T Updates from AACR, Philadelphia

4/23: Corporate Access: Calithera Biosciences Inc: CALA, London

4/24: MEDACorp Event: Liver Disease Updates – KOL Luncheon during EASL, Vienna

4/24: Corporate Access: ArQule, Inc.: ARQL, Boston

TODAY'S HEALTHCARE EVENTS:

REGULATORY EVENTS:

4/15: FDA Adcom: Cardiovascular and Renal drugs, MDCO Cangrelor, MRK Januvia

MEDICAL MEETINGS:

4/15-18: European Lung Cancer Conference

4/15-18: Int'l Conference of Alzheimer's Disease International

4/15-18: Int'l Society for Heart & Lung Transplantation, CDNA, HTWR, THOR

4/15-18: Society of American Gastrointestinal and Endoscopic Surgeons

4/15-21: American Society of Andrology

CORPORATE EVENTS:

4/15-16: WBA Investor Meeting

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

MEDICAL DEVICES-ORTHOPEDICS / RICHARD NEWITTER

[Hip/Knee Survey – LSD Mkt Growth on Tap; Small Caps More Interesting into 1Q](#)

Outperform: GMED, JNJ, NUVA, SYK, WMGI, ZMH

- **Bottom Line:** Based on the 1Q MEDACorp survey of 68 US hip/knee surgeons, recent feedback at AAOS (March), and Biomet's & JNJ's [OP] results, we're braced for in-line 1Q US ortho recon trends and a +2-3% 2015 US hip/knee growth outlook. Pricing pressure likely continues to limit any real growth acceleration, and we think our 2015 US 2.3% hip/knee mkt estimate is achievable. In large-cap ortho we prefer ZMH (OP) on valuation and Biomet EPS accretion. Small-cap ortho is likely to generate more volatility on 1Q prints where our conviction in upside ranks: GMED (OP), NUVA (OP), WMGI (OP).
- 1Q Survey & JNJ/Biomet Results Suggest Relatively Stable Low-Single-Digit (LSD) US Hip/Knee Mkt Growth; OUS Trends a Bit Less Clear.
- And Physicians' NTM Growth Expectations Suggest LSD US Recon Trends to Continue.
- Hip/Knee Price Erosion Continues, Though Pace of Decline Appears Steady.
- For Large-Cap Ortho, FX Headwinds Remain but Expect in-Line CC Results & Reiterated CC guidance.

- We Still Prefer ZMH Near Term Given Valuation & Biomet Accretion; We See SYK as a Solid Long-Term Play Given Rev Diversification & B/S Flexibility.
- Turning to Small-Cap Ortho, We Are Bullish on Rev & EPS Achievability/Upside for Spine Players GMED (OP) & NUVA (OP).
- WMGI reports on 4/29 With Key Focuses to Include: US F&A Growth, Augment Approval, TRNX Deal-Close.

PHARMACEUTICALS/ MAJOR / SEAMUS FERNANDEZ

DPP-IV Panel Surprisingly Votes to Include hHF Safety Update for Nesina

Outperform: BMY / **Market Perform:** AZN, MRK

- **Bottom Line:** Somewhat unexpectedly, the FDA Advisory Committee (AdCom) panel voted in favor of including an hHF safety update in Takeda's Nesina (alogliptin) label (13 in favor of labeling change and 3 for no change). The panel voted unanimously that EXAMINE demonstrated an acceptable CV risk profile for Nesina. Despite compelling presentations from Takeda and a strongly stated view from an HF KOL that Nesina shows no clear evidence that hospitalizations for heart failure (hHF) are increased on Nesina, the panel could not rule out a signal. Some panelists raised concerns about a class effect when asked about the reason for the vote. Given the lack of a definitive signal, we expect Nesina to ultimately receive a lower grade warning than Onglyza, but panel recommendation likely will put the two drugs on more equal footing. We expect MRK's (MP) TECOS study of Januvia to be the final arbiter for the DPP-IV class.
- Confounded by post-hoc analyses, the panel errs on the side of caution.
- TECOS will be the final arbiter of the DPP-IV class; today's outcome could be positive for MRK.

LIFE SCIENCE TOOLS AND DIAGNOSTICS / DAN LEONARD

Trends Steady but Pressure on the Margin

Outperform: A, BRKR, CDNA, FLDM, GHDX, ILMN, NSTG, PKI, ROKA, TMO, TTOO, VCYT / **Market Perform:** AFFX, ALR, BIO, CPHD, FMI, ICEL, LMNX, MYGN, NVTA, QGEN, SIAL, TECH, WAT

- **Bottom Line:** We believe core trends remained steady in the Life Science Tools and Diagnostics group in the March-Q; however, we could see some pressure on the margins from Asia, industrial demand, and FX. We continue to rate Agilent (OP) our top pick in large-cap on margin expansion. We've elevated BRKR alongside FLDM and GHDX, all OP-rated, as our top picks in small-cap (margin expansion for the former, product cycles for the latter two). NSTG (OP) is now our top pick in micro-cap, with a view that its platform value is underappreciated at current levels.
- Academic/government funding trends appear mixed.
- Expect continued strength in pharma/biotech end markets.
- Industrial signals cautious on the margin.
- Healthcare utilization to remain a bright spot.
- Currency keeps a lid on upward revisions.

HEALTHCARE SERVICES / ANA GUPTE, PH.D.**Senate Passes Permanent SGR Fix; Positive for Both Managed Care and Hospitals****Outperform:** HUM

- **Bottom Line:** The Senate voted yesterday, with an overwhelming majority of 92-8, to permanently repeal the 1997 Sustainable Growth Rate (SGR) formula for physician payments, obviating the need of temporary “doc-fixes” every year to avoid an impending 21% payment cut. The legislation implies a 5-year period of annual updates of 0.5% for physicians followed by a shift from volume-based to a value-based payment model. The Senate repealed the formula for a price tag of \$213B with guaranteed funding of \$70B, coming 50% from wealthy Medicare beneficiaries through means testing and dialing back benefits in Medicare Supplemental. The remainder of \$35B is being targeted from \$20B reductions to hospitals through additional, but postponed, Medicaid DSH (Disproportionate Hospital Reductions) cuts and \$15B from a reduced 1% market basket adjustment replacing the current for post-acute care providers. The remainder of ~\$140B will be financed through fiscal deficit. We see it as a positive for our Medicare Advantage (MA) names as the increased burden on Medicare beneficiaries should accelerate penetration of private MA plans. We reiterate our bullish stance on Managed Care and more particularly our Outperform rating on HUM. This is also positive for our hospitals coverage given hidden positives like postponement of DSH cuts and prohibition of CMS from collecting the recoupment of \$8B in 2015-17 for previous overpayments to hospitals.
- Move away from Fee For Service (FFS) to Value-based model.
- CHIP program extended and Two Midnight rule delayed.
- Shift to Private MA to accelerate.
- Hospital offsets a mixed bag with some positives.

JOHNSON & JOHNSON (JNJ) / DANIELLE ANTALFFY**2015 Outlook: Underlying Sales Growth Accelerating Despite Headwinds**

Outperform / **Market Cap:** \$284,069.5M / **Price:** \$100.52 / **Price Target:** \$115.00 / **Methodology:** ~18x our \$6.35 2016E EPS

- **Bottom Line:** In 1Q15, JNJ delivered a solid start to the year, with underlying sales growth -- ex. FX, divestitures, and acquisitions -- of 5.7% vs. 5.0% growth realized for all of 2014. This underlying sales growth acceleration came in the face of ramping headwinds, most notably increasing Olysio competition as well as ramping Remicade generic competition OUS, increasing Zytiga competition, and pricing pressure in its Vision Care business. And JNJ expects to sustain this underlying sales growth acceleration throughout 2015 even as some of these headwinds ramp, guiding to underlying sales growth of 6% -- ex. FX, divestitures, acquisitions, and the impact of Hep C competition -- up from 5% in 2014, which to us represents top-tier growth among large-cap MedTechs.
 - **2015E EPS/REV:** \$6.15 / \$71,727.0 → \$6.08 / \$70,317.0
 - **2016E EPS/REV:** \$6.50 / \$75,614.0 → \$6.35 / \$73,486.0
- Revenues in MM.*



PREVIOUS DAY NOTES:

HEALTHCARE / LEERINK EQUITY RESEARCH

Catalyst Tracker Previews Top Upcoming Catalysts – 4.14.15

Outperform: AET, ALNY, BLPH, BMRN, BMY, CALA, CELG, CLDX, CLVS, EBIO, FOLD, GHDX, HCA, HRTX, HUM, INCY, INSM, KPTI, MGNX, MRTX, MYL, OMED, PBYI, QURE, REGN, RXDX, SAN FP, TEVA, TSRO, WCG, WMGI, ZMH / **Market Perform:** ACOR, AZN, EXEL, IMGN, MRK, THC

- **Bottom Line:** Binary events in healthcare can be key determinants of performance. The upcoming SCOTUS (Supreme Ct.) decision is an overhang for hospital stocks, and we prefer Managed Care cos. Our top upcoming catalysts for the next 3-6 months are from ACOR, ALNY, BLPH, BMRN, BMY, CLVS, EBIO, EXEL, GHDX, HRTX, KPTI, MRK, MRTX, PBYI, QURE, REGN, RXDX, TEVA, TSRO, WMGI, ZMH. ASCO (Oncology, 5/29-6/2) is the largest medical meeting of the year and will highlight progress on many fronts. In addition to the cos. mentioned, there will be ASCO updates from CALA, CELG, CLDX, IMGN, INCY, MGNX, OMED, and others. Our sortable Excel sheet ([calendar](#)) has timelines and stock impacts, Up/down.
- Managed Care (MCOs) and Facilities – The expected end of June/early July SCOTUS ruling is a pivotal event.
- ACOR – We remain cautious near term.
- ALNY – We believe the shares will continue to appreciate as clinical catalysts further de-risk its RNAi pipeline.
- BLPH – Top-line data from European pivotal trial for BCM (prevention of CHF, Heart Failure) expected July/Aug. 2015. Up/down +\$3/-2.
- BMRN – BMN-111 Achondroplasia (dwarfism) data in late 2Q15 could provide important proof of concept.
- BMY – We recommend buying BMY looking ahead to CHECKMATE-057 (2nd-line non-squamous NSCLC) and -025 (2nd-line kidney cancer) data, Up/down +/-8-10%.
- CLVS – Updated results from rociletinib (NSCLC) around ASCO and an anticipated filing expected in mid-15, Up/down +/-20%.
- EBIO – We believe Ph III data in dry eye disease (DED) in May 2015 is a substantial market oppt'y.
- EXEL – Top-line METEOR Phase III data in renal cell carcinoma (RCC) expected 2Q15, Up/down +50%/-70%.
- GHDX – Its Genomic Prostate Score (GPS) could receive a positive draft coverage decision from Medicare contractor Palmetto in mid-2015, Up/down +/-2.
- HRTX – Ph III data for Sustol (MAGIC trial) in May 2015 has 80% probability-of-success, Up/down to \$18/\$7.40.
- KPTI – Solid tumor updates at ASCO (5/29-6/2) should highlight selinexor's multiple shots on goal.
- MRK – Januvia's TECOS Ph III cardiovascular data expected at ADA (Amer. Diabetes Assoc., 6/5-6/9/15) has broad implications for the DPP4 class and AZN, BMY.
- MRTX – Important proof-of-concept data for MGCD265 (NSCLC, lung cancer) in mid-15, Up/down +/-30%.
- PBYI's – Full Ph III ExteNET data for neratinib (adjuvant HER2+ breast cancer) at ASCO may help address carcinogenicity concerns, Up/down +/-10%.
- QURE – 3Q15 is expected to be a major inflection point with data on both Hemophilia B and Sanfilippo B, Up/down +200%/-15%.

- REGN/SNY – REGN1033 Ph I/II lean mass index data at ICFSR'15 on 4/24 should allow REGN to retain its first-mover advantage in a highly underserved sarcopenia market. Worth ~\$5/share at 20% POS and a highly conservative \$2B peak market oppt'y, but at 100% POS and a reasonable \$8B peak market oppt'y could be worth ~\$85/share.
- RXDX – Important Phase I data presentation at ASCO could position RXDX as a leader in Trk targeted therapy, Up/down +20-50%/-5-20%.
- TEVA – A settlement to launch g-eipen (MYL) expected 6/22/15.
- TSRO – Results from the gBRCA and non-gBRCA cohorts of niraparib's NOVA trial (ovarian maintenance) expected 2H15, Up/down +/-30%.
- WMGI – Upcoming catalysts are Augment approval in 2Q15 (Upside +10%), divestiture news mid-year & closing the TRNX acquisition in 2H15 (+5-10%).
- ZMH – BMET deal closing and new combined guidance expected in early 3Q, Up/down +3.5% apiece.

ASTRAZENECA PLC (AZN) / SEAMUS FERNANDEZ

FDA Panel Votes Only to Include hHF Safety Update in Onglyza Label; Positive

Market Perform / **Market Cap:** \$86,944.9M / **Price:** \$68.84

- **Bottom Line:** Today the FDA Advisory Committee (AdCom) panel voted that the safety data from SAVOR trial on AZN [MP]'s Onglyza (saxagliptin) demonstrated an acceptable CV risk profile (13 Yes, 1 No, 1 Abstain), but the panel recommended safety information for hospitalizations for heart failure be included in the label (14 for including new safety information in the label, 1 for withdrawing from the market, 0 for no change in label and 0 for restrict distribution). The panel did not express significant concerns over the possibility that the slight imbalance in mortality seen in the study was either real or warranted further warnings or restrictions. We view the outcome, while largely expected, as a slight positive for AZN/BMY [OP]'s Onglyza franchise as the questions raised by the agency in the documents did not rise to the level of serious concern. We do believe that the SAVOR study outcome could be a counter-detailing oppt'y for competitors (MRK (MP), LLY (OP), Takeda) if their CV outcomes studies do not show an hHF (Hospitalization for Heart Failure) signal, but we believe this impact is already partially reflected in sales of Onglyza/Kombiglyze.
- As expected, panel conclusion balanced and limited to hHF label update.
- DPP-IVs viewed as an important diabetes treatment with hHF viewed as a manageable risk.
- All eyes on TECOS now for the DPP-IV class.

PREVIOUS NOTES:

CELLULAR DYNAMICS INTERNATIONAL (ICEL) / DAN LEONARD

Downgrade on Acquisition by Fujifilm

Outperform → Market Perform / **Market Cap:** \$260.7M / **Price:** \$16.50 / **Price Target:** \$11.00 → \$16.50 / **Methodology:** acquisition price

GW PHARMACEUTICALS PLC (GWPH) / PAUL MATTEIS**Updated Epidiolex Data in Larger N Better than Expectations, PT to \$120**Outperform / **Market Cap:** 1,971.7M / **Price:** \$96.18 / **Price Target:**\$102.00 → \$120.00 / **Methodology:** Sum-of-the-parts DCF, 11% discount rate, 2% terminal growth rate**THE MEDICINES COMPANY (MDCO) / JOSEPH P. SCHWARTZ****Cangrelor Briefing Docs Look Constructively Positive Ahead of the Apr 15 AdCom**Outperform / **Market Cap:** \$1,989.4M / **Price:** \$29.56**ZAFGEN, INC. (ZFGN) / JOSEPH P. SCHWARTZ****Sell-off Following 4Q14 Call Creates Attractive Buying Opportunity**Outperform / **Market Cap:** \$1,088.6M / **Price:** \$37.80 / **Price Target:** \$61.00 / **Methodology:**

Probability-weighted DCF analysis, 11% discount rate

RESEARCH PREVIEWS:**April 15 – FDA AdCom Cardiovascular and Renal Drugs****MDCO – OP – Joe Schwartz****Close: \$28.97, Mkt Cap: \$1,902M**

- The panel will review cangrelor injection for the proposed indication of reduction of thrombotic cardiovascular events.
- Mgmt has stated that it addressed in the NDA all issues that led to a prior complete response letter (CRL).
- We forecast approval and model \$11M in sales in '15 peaking at \$137.5M in '20.
- See recent note: [Flash -- MDCO/Cangrelor Briefing Docs Look Constructively Positive Ahead of the Apr 15 AdCom/Outperform](#)
- **Next up:** June 2015 Cangrelor PDUFA.

April 15-16 – WBA – Investor Meetings – OP – David Larsen**Close: \$91.98, Mkt Cap: \$86,980M**

- In addition to an update on operations and strategy, we expect added color from some initiatives announced on the 4/9 earnings call including guidance and potential M&A.
- WBA issued F2015 guidance which calls for adjusted EPS of \$3.45-\$3.65, and also reaffirmed its F2016 EPS goal of \$4.25-\$4.60.
- We think the company is considering both vertical and horizontal deals and management anticipates driving additional synergies through M&A in the future since mgmt. stated “the American market is ready for another round of consolidation”

- The company will devote a half-day session to financial performance of the combined entity.

April 16 – HTWR ENDURANCE Data at International Society of Heart & Lung Transplantation (ISHLT)

HTWR – OP – Danielle Antalffy

Close: \$91.96, Mkt Cap: \$1,585M

- Ongoing and upcoming clinical trials in 2015 are likely to supplement market growth for both HTWR and THOR (OP).
- In April, HTWR's initial data for the 2-year follow-up cohort for the ENDURANCE trial of its current generation destination therapy (DT) will read out at ISHLT.
- While the initial cohort from ENDURANCE is likely to demonstrate a high hemorrhagic stroke rate, we believe: (a) Those data alone aren't likely to change clinical practice; (b) HTWR appropriately powered the 2nd cohort to offset the likely higher stroke rate in the initial cohort in order to secure DT approval.
- Also, HTWR expects a number of other heartware ventricular assist device (HVAD)-related commercial use data presentations, which we expect to be favorable based on our past MEDACorp physician conversations.
- We believe that a better-than-expected outcome from ISHLT data is likely, offering upside.
- Next up: MEDACorp Pulse Calls Postview of ENDURANCE Trial Data at ISHLT and Impact on HTWR and THOR, 4/16 @10AM
- See our recent notes: [ISHLT Preview: MEDACorp Specialists Believe HVAD Likely to Hit Primary Endpoint](#) and [Medical Devices-Cardiology/ISHLT Preview: Survey Suggests ENDURANCE HVAD Data Likely Less Bad Than Feared](#)

April 18-22 – American Association for Cancer Research (AACR) Preview

[-Biopharma/2015 AACR Itinerary Planner](#)

ARIA – MP – Howard Liang

Close: \$8.67, Mkt Cap: \$1,603M

- ARIA presentations relate to preclinical profiles of AP26113, Iclusig activity outside CML, as well as its work on EZH2.
- ARIA abstracts include #2827 on discovery of AP26113 as a potent, orally active inhibitor of anaplastic lymphoma kinase and clinically relevant mutants, #781 on AP26113 that can overcome mechanisms of resistance to first and second-generation ALK TKIs in preclinical models, #783 on ponatinib's antitumor activity in RET- and FGFR-driven patient-derived xenografts, and #3597, which is entitled "EZH2 D1 domain mutants confer acquired resistance to EZH2-targeted inhibitors and reprogram B-cell transcription".
- Additionally, GSK (MP) scientists are presenting preclinical work on their EZH2 inhibitor (abstract 5379).

AZN – MP – Seamus Fernandez

Close: \$71.02, Mkt Cap: \$88,900M

- AZN data on the combination of AZD9291 (3rd Gen EGFR TKI) and AZD6094 (MET inhibitor) worth watching as combos ramp up.

- A number of presentations highlight the need for additional pathway blockade in EGFR/mt NSCLC beyond 3rd gen EGFR TKIs, and AZN's presentation highlighting the potential of T790M and MET inhibition continues to draw our attention to the company's Ph I trial (NCT02143466) investigating 9291 with a variety of agents including 6094, selumetinib (MEK inhibitor), and MEDI4736 (PDL1).
- Incremental data on CAR-T, and CD40 could also be of interest. Researchers will also present data from the combination of anti-CD40 antibody (CP-870,893) and AZN's tremelimumab in melanoma (abstract #CT137), which may be of interest given Roche's increasingly broad development CD40 development program.

BMJ – OP – Seamus Fernandez

Close: \$64.03, Mkt Cap: \$97,577M

- BMJ's randomized Opdivo + Yervoy data in 1st line melanoma will highlight the first randomized combo data.
- CHECKMATE-069 Ph II data in 150 pts will be presented for the first time and is part of the official press program.
- Critically important will be survival, response rate, response kinetics (speed and magnitude of response) and perhaps most important -- safety.
- Given the challenges of managing side effects with this combo, continued demonstration of previously striking survival data needs to be confirmed to support broad 1st line use.
- The Ph III 900- patient CHECKMATE-067 study is not far behind and likely critical for the combo as the first randomized test of the combo vs. Opdivo monotherapy.

CLVS – OP – Howard Liang

Close: \$86.35, Mkt Cap: \$1,903M

- CLVS ARIEL2 data on BRCAness diagnostic test could be updated at AACR (abstract 4670).
- Also, there are presentations on the resistance mechanism and the role of IGF1R activity of rociletinib that could be interesting (abstracts 793, 927, 3595).
- In addition, abstract 784 will describe preclinical data on the activity of lucitanib in FGFR3 translocated tumor models.

EPZM – OP – Howard Liang

Close: \$19.25, Mkt Cap: \$650M

- For EPZM, multiple preclinical data presentations support new epigenetic targets.
- EPZM will have preclinical data from 5 poster presentations at AACR (#97, 2437, 5376, 2144, 104) on new histone methyltransferase targets (HMTs).
- EPZM has not revealed timelines for clinical advancement of its new HMT inhibitors but in a recent regulatory filing, EPZM disclosed that it has made small molecule inhibitors against 17 of the 20 prioritized HMT targets.
- Also, EPZ-5676 (EPZM/**CELG** [OP]) preclinical data showed resistance mechanism, synergistic activity with cytarabine and azacitidine. In a cell line model of MLL rearranged

leukemia, acquired EPZ-5676 (DOL1L) resistance emerged after 3 weeks of continued treatment with EPZ-5676. Two mechanisms have been identified that were either dependent or independent on ABCB1 (#2701). Another preclinical study in MLL-r rearranged cells and nude mouse showed that EPZ-5676 in combination with cytarabine or azacitidine had a synergistic effect (#5383).

MRK – MP – Seamus Fernandez

Close: \$57.76, Mkt Cap: \$161,178M

- MRK will present a significantly expanded NSCLC dataset at AACR. Data will include 495 pts (nearly 2x the 262 pts presented at ESMO), representing most of the ~550 non-small cell lung cancer (NSCLC) patients enrolled in -001, and the basis of MRK's planned mid-2015 filing.
- MRK remains bullish on prospects for a successful accelerated filing of Keytruda in lung cancer regardless of biomarker status. MRK's presentations on the transient nature of PDL1 expression/sampling variation hints at why MRK (and most KOLs) argue that PD1 biomarkers should not be used as a pt selection tool.
- MRK will also present data on gene expression profiling and its value in identifying already revealed expansion cohort data in H+N, bladder, TNBC, and gastric cancers.
- Additionally, MRK will present data from KEYNOTE-028 in mesothelioma (abstract #CT103). Given that this study is designed to identify biomarker-positive tumors with clinically meaningful RRs, we expect a positive outcome.

NVS – OP – Seamus Fernandez

Close: \$103.24 Mkt Cap: \$222,257M

- UPenn researchers will present data regarding the safety and feasibility of CART-meso (abstract #CT105), which is one of the early ventures of CAR-T therapy in solid tumors.

OMED – OP – Howard Liang

Close: \$27.13, Mkt Cap: \$839M

- OMED data suggest a role of targeting DLL4 in immuno-oncology (IO).
- The abstract (# 255) notes that dual targeting of DLL4 and PD1 may be an effective and durable cancer therapy by increasing anti-tumor immune response and promoting long-term immunological memory.
- Additional OMED data highlight the development and validation of a biomarker for prospective selection of Notch1 activation in solid tumor patients for anti-Notch1 antibody OMP-52M51 (abstract 1549), enhanced antitumor efficacy by sequential application of Wnt pathway antagonists in combination with taxanes (abstract 2576), discovery and evaluation of pharmacodynamic and predictive biomarkers for anti-RSPO3 (abstract 4367), Wnt pathway antagonist ipafricept (FZD8-Fc, OMP-54F28) that inhibits tumor growth and reduces tumor-initiating cell frequency in ovarian patient-derived xenograft models (abstract 4233), and tarextumab (Anti-NOTCH2/3) activity in reversing NOTCH2 and NOTCH3-dependent tumorigenicity and metastases in small cell lung cancer (abstract 2323).

SGEN – OP – Howard Liang**Close: \$37.49, Mkt Cap: \$3,983M**

- Abstract #2469 highlights a rationale for combining SGEN's Adecetris with IO agents.
- Preclinical data to be presented at AACR appear to suggest that Adecetris may induce a specific type of cell death known as Immunogenic Cell Death (ICD), which may in turn initiate an antitumor immune response.
- While normal apoptosis is not immunogenic, certain chemotherapeutic agents such as oxaliplatin have been shown to induce ICD.
- According to the abstract, CD30+ Hodgkin lymphoma cells killed by Adecetris exhibited hallmark ICD markers similar to those seen with oxaliplatin.
- While this effect remains to be explored in patients, it nevertheless provides an intriguing rationale for potential synergies between Adecetris and checkpoint inhibitors.
- We note that an investigator-sponsored trial (IST) of Adecetris plus Yervoy in HL is ongoing and SGEN and BMJ are planning trial of Adecetris plus Opdivo in both HL and NHL.
- SGEN also has several other presentations focusing on its earlier stage products, including an update from the Phase I trial of SGN-CD33A in AML (#DDT02-04; no new data contained in the abstract), preclinical data on SGN-CD70A (#946), and two preclinical studies of SGN-CD19A in combo with CVAD in ALL models (#1339) and R-ICE or R-CHOP in NHL models (#2541).

April 22 – Epidiolex (Epilepsy) Phase II Data at AAN**GWPH – OP – Paul Matteis****Close: \$108.75, Mkt Cap: \$1,335M**

- A data update for the Epidiolex (treatment-resistant childhood-onset epilepsy) IND program is expected at the American Academy of Neurology (AAN) that could include both (1) results from a sample size that is ~2x larger as the last update in Oct. 2014 (58 pts.) and (2) durability data showing Epidiolex's effectiveness out to 6+ months in some individuals.
- GWPH also may use IND (investigational new drug) data to inform the development of Epidiolex in additional orphan epilepsies as sample sizes in different disease subsets become more meaningful.
- See recent note: [GWPH/Updated Epidiolex Data in Larger N Better than Expectations, PT to \\$120/Outperform](#)
- **Next up:** 4/22 Investor Call after data released at 6:15m EDT; and Investor Event, 4/23 a.m. (both at AAN).

April 29 – FDA Adcom: Joint Meeting of the Cellular, Tissue and Gene Therapies Advisory Committee and Oncologic Drugs**AMGN – MP – Howard Liang****Close: \$162.57, Mkt Cap: \$121,124M**

- The FDA AdCom will review AMGN's TVEC, which uses immune-therapy for metastatic melanoma.

- The PDUFA date is 10/28 and we expect approval.
- We model revenues of \$38M in '15 growing to \$338M in '20.
- **Next up:** 4/27 Briefing documents released.

Mid-2Q15 – Augment (Ankle/Hindfoot Fusion) Approval

WMGI – OP – Rich Newitter

Close: \$26.21, Mkt Cap: \$1,379M

- WMGI mgmt's guidance assumes a mid-2Q Augment approval and \$10-12M in 2015 US revenues, which is in line with our estimates on timing and amount. Recent commentary suggests a late 2Q or early 3Q approval is possible, but guidance is based on a mid-2Q assumption."
- Augment -- a recombinant human platelet-derived growth factor (rhPDGF) that WMGI acquired through its Biomimetic acquisition -- received an approvable letter from the FDA in 4Q14.
- As the first clinically proven alternative for ankle and/or hindfoot fusion, this is an important product that should provide a meaningful new (high-margin) growth driver within WMGI's biologics business and offers surgeons an alternative to autograft in this ~\$300M US market.
- Our MEDACorp physician checks/surveys have suggested a high level of interest in this product.
- WMGI is primed and ready to begin commercial launch of Augment as soon as it gets the final nod from the FDA.

April/May – Sustol (CINV-HEC) Phase III Marketing Study Data

HRTX – OP – Jason Gerberry

Close: \$14.51, Mkt Cap: \$428M

- The Sustol Phase III marketing study data was expected to complete enrollment by the end of 1Q and is expected to report top-line data in April/May.
- HRTX has completed a Phase III study demonstrating Sustol's benefit in chemo induced nausea & vomiting (CINV) patients but is running a Phase III marketing study to demonstrate benefit in patients with delayed symptoms who get highly potent chemotherapy (HEC).
- Sustol contains a 5HT3 receptor antagonist granisetron, the same active ingredient used in standard of care CINV treatment. Sustol is different in that it uses polymers to delay release of the active pharmaceutical ingredient (API) and provides benefit to patients with delayed symptoms.
- If the ongoing Phase III is successful, Sustol would be the only CINV drug indicated for delayed HEC, ~20% of the market.
- With a positive study & differentiated label, we forecast peak US Sustol sales of \$420M and 70% upside on data, 15% on label, & 30% on strong launch.
- A failed Phase III marketing study would result in approval of Sustol with an undifferentiated label. In that scenario, we forecast peak US Sustol sales of \$125M and -10% downside.
- We place 80% odds of success on a positive HEC study as historical performance of the Sustol arm suggests an 85-90% complete response vs. 65% for the comparator.

EARNINGS RUNDOWN

Updated on:

	1Q15E									
Ticker	Release Date	Release Time	CC Date	CC Time EDT	CC Tel	CC Pass	Revs Leerink	Revs Street	EPS Leerink	EPS Street
UNH	4/16	Before Market	4/16	8:45 AM	(877) 876-9177	UNHQ115	34,500.0	34,598.3	1.36	1.35
AMGN	4/21	After Market	4/21	5:00 PM	(877) 233-5736	6641564	4,789.0	4,926.0	1.98	2.11
ILMN	4/21	After Market	4/21	5:00 PM	888.679.8034	50211546	528.0	525.3	0.73	0.72
ISRG	4/21	After Market	4/21	4:30 PM	(877) 209-9921	-	531.5	535.5	3.85	2.82
SYK	4/21	After Market	4/21	4:30 PM	(866) 436-9172	38313484	2,359.0	2,383.2	1.06	1.09
ABT	4/22	Before Market	4/22	9:00 AM	(773) 799-3472	Abbott Earnings	4,763.0	4,854.9	0.41	0.42
STJ	4/22	Before Market	4/22	8:00 AM	866-393-8590	7361202	1,309.0	1,319.4	0.91	0.91
TMO	4/22	Before Market	4/22	8:30 AM	(877) 201-0168	-	4,073.8	4,004.6	1.72	1.60
CNMD	4/22	After Market	4/22	4:30 PM	877-280-4961	CONMED	171.7	175.5	0.41	0.43
ALXN	4/23	Before Market	4/23	10:00 AM	877-874-1571	8676867	590.0	595.7	1.33	1.33
BAX	4/23	Before Market	4/23	8:30 AM	877-894-0694	35112171	3,667.0	3,697.7	0.86	0.88
LLY	4/23	Before Market	4/23	9:00 AM	(612) 234-9959	356843	4,600.0	4,658.8	0.75	0.76
NVS	4/23	Before Market	4/23	10:00 AM	877 280 2296	9229036	-	12,935.8	-	1.09
BCR	4/23	After Market	4/23	5:00 PM	(800) 230-1059	-	810.3	813.2	2.07	2.07
CPHD	4/23	After Market	4/23	5:00 PM	-	-	126.4	125.5	(0.16)	(0.17)
EW	4/23	After Market	4/23	5:00 PM	(877) 407-8037	-	585.3	585.4	1.05	1.04
VCRA	4/23	After Market	4/23	5:00 PM	866-700-0133	3715 7947	23.5	22.8	(0.14)	(0.12)
AZN	4/24	Before Market	4/24	11:00 AM	webcast	-	6,200.0	5,960.3	1.02	1.09
BIIB	4/24	Before Market	4/24	8:00 AM	(877) 650-1145	-	2,689.9	2,660.0	3.97	3.92
IMGN	4/24	Before Market	4/24	8:00 AM	913-312-0966	2370723	22.2	20.4	(0.27)	(0.24)

Source: Leerink estimates, FactSet, Company Information

PREVIOUS NOTES:

UPDATED MODELS: [GWPH - Model](#)

ALZHEIMER'S DISEASE

[BIIB/MEDACorp Pulse Call Recap: Growing Interest in BIIB037's Upcoming Datasets/Outperform](#)[BIIB/Raising PT to \\$475 Following Deep Dive on BIIB037 and Its Development Strategy/Outperform](#)[BIIB/MS Survey, Specialist Checks and LINGO/Pipeline Optionality Support OP/OutperformBiotechnology/MS Survey Highlights Strong Growth Outlook for Tecfidera, RPC1063](#)

IMMUNO-ONCOLOGY

[Biopharma/Phacilitate Forum Wrap-Up: The Next Leg of IO \(& Immunotherapy\) Development](#)[MRK/More Credit for Keytruda Warranted in Lung Cancer; PT Now \\$66/Market Perform](#)

[BMY/\\$72 PT Reflects Heightened Confidence in Non-Squamous & Kidney Survival Studies/ Outperform](#)

[Flash -- BMY/'017 Stopped Early; Opdivo Kicks Off '15 with a Bang/Outperform](#)

[Biopharma/The \\$40B+ IO Market: How'd We Get Here & Where We're Headed in 2015](#)

[Pharmaceuticals/ Major/BMY vs. MRK: IO Reimbursement Likely Limited to Labels; A Pot'l Edge for BMY](#)

[Biopharma/SITC 2014 Highlights What's Next in Cancer Immunotherapy](#)

CONSOLIDATION

[Biotechnology/P&A VI - Partnerships and Acquisitions in Biopharma; Our New Top Ten List](#)

[Life Science Tools and Diagnostics/Consolidation to Continue as Industry Growth Driver](#)

[Life Science Tools and Diagnostics/Puts and Takes for Tools in 2015](#)

[Life Science Tools and Diagnostics/Quick Takes from Recent Management Meetings](#)

[Medical Supplies and Devices/2015 Outlook: We're Optimistic - M&A/Cash Deployment Still Likely Stock Drivers](#)

[Medical Devices-Orthopedics/Specialist Call Lends Perspective on Pending and Future Ortho Consolidation](#)

[Medical Supplies and Devices/Devices & DNA Bus Tour Wrap-Up](#)

[Biopharma/POLARxPRESS 2014: Highlights and Themes from Meetings with Management Teams](#)

[Specialty Pharmaceuticals/2015 Roadmap for Specialty/Generic Pharma](#)

[Specialty Pharmaceuticals/2015 Outlook: Selective M&A, Jockeying for Complex Gx's & Addressing Overhangs](#)

[Pharmaceuticals/ Major/2015 Outlook: Big Data, Decisions, Launches, Deals & Surprises](#)

[Biotechnology/Launches, Clinical Data, Emerging Therapeutic Areas Could Shape Biotech in '15](#)

[Healthcare/2015 Outlook: Key Drivers in Place for Continued Strong Performance](#)

[Healthcare IT & Distribution/2015 Outlook - Top 10 Trends, Themes and Surprises](#)

[Managed Care/Good Set-up in '15; Accelerated Growth in '16; Top Picks HUM & WCG](#)

[Managed Care/Investor Presentations Confirm Our View of a Good Set Up for MCOs in 2015](#)

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](#)

SURVEYS

[SHPG/Natpara Survey Affirms B'buster Pot'l; Remain MP, Conservative on Catalysts/Market Perform](#), Jason Gerberry

[ACOR/Survey Suggests Stroke Could More Than Double Ampyra Oppty; IP & 1x/Daily Key/ Market Perform](#), Paul Matteis

[BIIB/MS Survey Suggests Tecfidera PML Case Not as Impactful as We had Expected/Outperform](#), Joe Schwartz

[Healthcare IT & Distribution/Survey Shows Solid Market for CERN and ATHN's Need for an Inpatient Solution](#), Dave Larsen

[Life Science Tools and Diagnostics/Survey Augments MYGN Forecast; Share Loss, but Growth Market](#), Dan Leonard

GLOBAL HEALTHCARE CONFERENCE

[Biopharma/Takeaways from Our 2015 Global Healthcare Conference](#), Gena Wang

[Biopharma/Takeaways from Our 2015 Global Healthcare Conference](#), Seamus Fernandez, Howard Liang, Michael Schmidt

[Biotechnology/Takeaways From Our 2015 Global Healthcare Conference](#), Howard Liang

[Biotechnology/Takeaways From Our 2015 Global Healthcare Conference](#), Joe Schwartz

[Biotechnology/Takeaways From Our 2015 Global Healthcare Conference](#), Paul Matteis

[Healthcare Services/Themes From UNH, HUM, UHS, UAM Management Meetings at 2015 Conference](#); Ana Gupte

[Healthcare IT & Distribution/ABC and CAH Well Positioned Long Term; ATHN Also Poised to Reaccelerate Growth](#), David Larsen

[Life Science Tools and Diagnostics/Takeaways from Our 2015 Global Healthcare Conference](#); Dan Leonard

[Medical Supplies and Devices/2015 Leerink Global Healthcare Conference Takeaways](#); Danielle Antalfy, Rich Newitter

[Biopharma/Takeaways From Biosimilar Panel: US Market Quickly Coming Into View](#); Seamus Fernandez and Jason Gerberry

[Biopharma/Takeaways from Lymphoid Malignancies Panel at Our 2015 GHC](#), Howard Liang

[Biotechnology/Takeaways From Our MS Panel At 2015 Global Healthcare Conference](#), Joe Schwartz

[Healthcare IT & Distribution/HCIT Panel Themes: Replacement Market, Care Coordination & Hosted Solutions](#), Howard Liang

[ATHN/Management Dinner Reaffirms our Positive Outlook, Pipeline Growth Robust/Outperform](#); David Larsen

[Flash -- ABT/Management Breakfast Highlights Sustainable Double Digit EPS Growth, Likely M&A/Market Perform](#); Danielle Antalfy

[Flash -- HOLX/Mgmt Dinner Suggests HOLX's Turnaround Story Still Has Lots of Momentum/Outperform](#); Richard Newitter

[GILD/Takeaways from Management Dinner/Outperform](#); Howard Liang

[UAM/Takeaways from GHC Presentation on Feb. 11; Raise PT to \\$11/Market Perform](#); Ana Gupte

[UNH/Takeaways from Dinner and Fireside Chat with Optum and UHC; Raise PT to \\$130/Outperform](#); Ana Gupte

[UHS/Takeaways from Investor Dinner & Meetings on Feb. 11-12 with CFO Steve Filton/Outperform](#); Ana Gupte



UPCOMING HEALTHCARE EVENTS:

REGULATORY EVENTS

- 4/15:** FDA Adcom: Cardiovascular and Renal drugs, MDCO Cangrelor, MRK Januvia
- 4/17:** FDA Adcom: Neurological Devices
- 4/22:** PDUFA MRK Sugammadex, the reversal of neuromuscular blockage
- 4/29:** FDA Adcom: Joint Meeting of the Cellular, Tissue and Gene Therapies Advisory Committee and Oncologic Drugs, AMGN, T-Vec
- 4/30:** PDUFA: THRX/GSK, Breo/Ellipta, asthma
- 4/30-5/1:** FDA Adcom: Medical Devices, Ear, Nose, and Throat Devices
- 5/12:** FDA Adcom: Pulmonary-Allergy Drugs, VRTX, lumacaftor/ivacaftor (CF)
- 5/12:** FDA Adcom: Vaccines and related biological products, Ebola vaccines
- 5/13:** FDA Adcom: Blood products, testing
- 5/14-15:** FDA Adcom: Gastroenterology and Urology

MEDICAL MEETINGS

- 4/15-18:** European Lung Cancer Conference
- 4/15-18:** Int'l Conference of Alzheimer's Disease International
- 4/15-18:** Int'l Society for Heart & Lung Transplantation, CDNA, HTWR, THOR
- 4/15-18:** Society of American Gastrointestinal and Endoscopic Surgeons
- 4/15-21:** American Society of Andrology
- 4/17-21:** American Society of Cataract and Refractive Surgery
- 4/17:** American Association for Cancer Research (AACR), Late breakers and clinical trial presentations released
- 4/18-22:** American Association for Cancer Research (AACR), 4/19 AZN data on the combination of AZD9291 (3rd Gen EGFR TKI) and AZD6094 (MET inhibitor)
- 4/21-23:** American Head and Neck Society
- 4/22-26:** American Society for Laser Medicine and Surgery
- 4/22-26:** International Liver Congress (EASL)
- 4/22-26:** Joint Int'l Congress of Liver Transplantation Society
- 4/25-30:** Joint International Congress of Liver Transplantation Society
- 4/25-30:** American Society of Neuroradiology
- 4/25-30:** Society of NeuroInterventional Surgery
- 4/26-28:** Clinical Virology Symposium and Annual Meeting of the Pan American Society for Clinical Virology
- 4/27-5/1:** Society for Pediatric Radiology (SPR)
- 5/2-6:** American Society of Transplant Surgeons
- 5/3-6:** American College of Occupational and Environmental Medicine
- 5/3-5:** American Telemedicine Association Conference
- 5/3-7:** Association for Research in Vision and Ophthalmology
- 5/4-5:** Medical Informatics World Conference
- 5/4-8:** The Essential Protein Engineering Summit
- 5/5-7:** Interphex Annual Meeting
- 5/8-12:** American Association of Immunologists

5/11-13: eHealth Week

5/13-17: American Association of Clinical Endocrinologists

5/13-16: Heart Rhythm Society

CORPORATE EVENTS

4/15-16: WBA Investor Meeting

4/16: **Earnings BMO:** UNH; WBA Investor Meeting

4/17: Investor event: THOR

4/20: INCY company event (at AACR)

4/21: **Earnings AMC:** AMGN, ILMN, ISRG, SYK

4/22: **Earnings BMO:** ABT, STJ, TMO; **Earnings AMC:** CNMD; Investor call (at AAN): GWPH

4/23: **Earnings BMO:** ALXN, BAX, LLY, NVS; **Earnings AMC:** BCR, CPHD, EW, VCRA; Investor event (at AAN): GWPH

4/24: **Earnings BMO:** AZN, BIIB, IMGN

4/27: **Earnings AMC:** OMI

4/28: **Earnings BMO:** AET, BMY, BSX, CNC, MRK, PFE, WAT; **Earnings AMC:** ESRX

4/29: **Earnings BMO:** ANTM, HUM; **Earnings AMC:** AFFX, ATRC, CSII, DXCM, HOLX, MDAS, VRTX, WMGI

4/30: **Earnings BMO:** ABC, CAH, CELG, CI, INCY, MGLN, SNY, ZMH; **Earnings AMC:** ATHN, EXEL, PKI, PODD, SGEN

5/1: Investor Mtg: BSX

5/4: **Earnings AMC:** LMNX, NUVA

5/5: **Earnings BMO:** HNT, MDCO, MNK, THC

5/6: **Earnings BMO:** CYH, GSK, NXTM, QGEN, WCG

5/7: **Earnings BMO:** BDX, REGN; **Earnings AMC:** CERN, MDRX, MOH

5/11: **Earnings AMC:** FMI

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 03/31/15				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	151	70.20	55	36.00
HOLD [MP]	64	29.80	2	3.00
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.

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