

MORNING ROUNDS

# TODAY'S HIGHLIGHTS / APRIL 14, 2015 TODAY'S RESEARCH:

ICEL, GWPH, ZFGN

INITIATIONS: NONE / RATING CHANGES: ICEL / PRICE TARGET CHANGES: ICEL, GWPH / ESTIMATE CHANGES: NONE / MEDACORP: NONE / PREVIOUS RESEARCH: HEALTHCARE IT & DISTRIBUTION, MEDICAL DEVICES-CARDIOLOGY, MANAGED CARE, QURE, MDCO, ATHN

### **REFERENCE TOOLS:**

<u>Catalyst Tracker</u> <u>Earnings Rundown</u> <u>Abbreviations & Acronyms</u>

<u>Calendar of Events</u> <u>HC Conferences</u> <u>Leerink Events</u>

### **MORNING PRIMER:**

Futures (as of 6:30am): DJIA: -63.00 (17,973); S&P500: +0.25 (2,086); NASD +1.25 (4,403)

### **LEERINK EVENTS:**

**4/14: Investor Tours / Site Visits:** HIMSS Booth Tours: MDRX, CERN, IMPR, QSII, VCRA, Chicago

**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

### **TODAY'S HEALTHCARE EVENTS:**

### **REGULATORY EVENTS:**

**4/14:** FDA Adcom: Endocrinologic and Metabolic, CVOT for AZN Onglyza, diabetes **MEDICAL MEETINGS:** 

**4/12-16**: Healthcare Information and Management Systems Society (HIMSS), Contact your Leerink representative for information on the booth tours.

### **CORPORATE EVENTS:**

**4/14: Earnings BMO:** JNJ CC @ 8:30 AM at 866-527-6580, PC: 6366816

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

### CELLULAR DYNAMICS INTERNATIONAL (ICEL) / DAN LEONARD

# **Downgrade on Acquisition by Fujifilm**

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

- **Bottom Line:** We are downgrading ICEL from Outperform to Market Perform following the announced acquisition by Fujifilm. We believe this acquisition has a very high probability of closing at the offered \$16.50 / share and have thus increased our price target from \$11 to \$16.50.
- Premium, revenue multiple represent full value.

### GW PHARMACEUTICALS PLC (GWPH) / PAUL MATTEIS

# <u>Updated Epidiolex Data in Larger N Better than Expectations, PT to \$120</u>

Outperform / Market Cap: 1,971.7M / Price: \$96.18 / Price Target:

 $102.00 \rightarrow 120.00$  / **Methodology:** Sum-of-the-parts DCF, 11% discount rate, 2% terminal growth rate

• Bottom Line: Yesterday after the close, the AAN (American Academy of Neurology) disclosed updated Epidiolex data from 137 patients (versus 58 in the last update) in a press release that was intended to highlight exciting results from late breaking abstracts at the upcoming AAN meeting, April 19-25th. Across the board, we believe the Epidiolex data are better than Street expectations as they showed: (1) a much greater magnitude of overall seizure reduction than in the October update (54% versus 40% at weeks 9-12), and (2) a consistent, robust effect in larger samples of Dravet and Lennox Gastaut (LGS) patients. We are increasing our price target to \$120 from \$102 as we now assume higher Epidiolex peak market penetrations and more use in the broader refractory pediatric epilepsy population. Reiterate OP on GWPH.

- New Epidiolex data show a more robust effect in over 2x the sample size from the previous October update.
- In 23 Dravet and 11 LGS patients, Epidiolex generated 51% and 55% reductions in convulsive and atonic seizures.
- Safety continues to trend better than other anti-epileptic drugs (AEDs), with just 6% of patients dropping off treatment due to side effects.
- Additional detail expected at AAN on 4/22 includes longer-term Epidiolex durability data out to ~6 months, responder analyses, a GW conference call, and a breakfast with GWPH and epilepsy KOLs.

### 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

- Bottom Line: ZFGN shares have consolidated following uncertainty created by announcements on the 4Q call which we believe do not reduce the probability of success (and may actually increase it) for the ongoing Ph3 study of beloranib in Prader-Willi syndrome (PWS). Reiterate Outperform and \$61 price target.
- We recommend shares of ZFGN ahead of catalysts that should increase confidence that pipeline programs are on track.
- Investors have raised questions after the company reduced the bottom threshold entry criteria for BMI from 30 to 27 in the ongoing Ph3 "bestPWS" study.
- Although it was noted in company presentations/meetings at the beginning of 2015, investors have been wondering about the implications of the primary endpoint in bestPWS shifting from fat mass to body weight.
- Although Ph2 didn't hit the p<0.05 mark for body weight, ZFGN has improved its testing procedures to improve compliance with the weighing procedure,

### PREVIOUS DAY NOTES:

### 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

- **Bottom Line:** This morning FDA released the briefing documents ahead of the second Kangreal (cangrelor) advisory committee scheduled for Wed., 4/15, to discuss MDCO's response to the Complete Response Letter (CRL) received in Apr'14 to the original NDA. The document recommended that Cangrelor be approved as an adjunct to PCI for the reduction in risk of periprocedural ischemic complications, including myocardial infarction (MI) and stent thrombosis (ST) in patients in whom treatment with an oral P2Y<sub>12</sub> platelet inhibitor prior to PCI is not feasible and when glycoprotein IIb/IIa receptor antagonists are not anticipated to be used. **Reiterate OP on MDCO with a PT of \$35.**
- The requested sensitivity analysis on a supplemental primary endpoint of Death/MI, excluding Intra-Procedural ST (IPST), showed a stat. sig. (p=0.0123) improvement.

- Cangrelor may find utility in the ad-hoc PCI setting where P2Y12 receptor inhibitors are not typically administered prior to angiography.
- These briefing documents are a validation of mgmt.'s positive commentary at recent analyst/investor events on cangrelor's NDA.

### ATHENAHEALTH, INC. (ATHN) / DAVID LARSEN, CFA

# <u>Trinity a Large Enterprise Win, Docs Will Likely Self-Select ATHN Over Time</u> Outperform / Market Cap: \$4,581.3M / Price: \$120.56

- Bottom Line: This morning, ATHN announced a new relationship with Trinity Health to deploy athenaOne across select practices within the large multi-state health system. The press release notes that Trinity will begin implementing athenaOne in "some of its physician network offices as early as July 2015". Trinity will also be leveraging athenaCoordinator, and overall we view this as a meaningful win. The most likely scenario with Trinity is that ATHN will be deployed to several practices initially and over time the physicians will likely self-select ATHN as various groups successfully deploy the platform. Our industry checks indicate that when physicians are given a choice, they usually select ATHN. We remain positive on ATHN and view this large enterprise customer win as a positive that may help re-accelerate marquee enterprise deal announcements.
- Population health initiatives and single cloud-based platform among reasons Trinity selected ATHN.
- Large enterprise wins remain key to driving long-term 30% bookings growth.

#### **PREVIOUS NOTES:**

### HEALTHCARE IT & DISTRIBUTION / DAVID LARSEN, CFA

# ATHN's Compelling ROI and Customer Alignment Are Key to Market Share Gains

Outperform: ATHN, CERN / Market Perform: CPSI, MDRX, QSII, VCRA

#### MEDICAL DEVICES-CARDIOLOGY / DANIELLE ANTALFFY

# ISHLT Preview: MEDACorp Specialists Believe HVAD Likely to Hit Primary Endpoint

Outperform: HTWR, THOR

### MANAGED CARE / ANA GUPTE, PH.D.

# 1Q15 Beats from Hep C Comps & Exchange Margins: Commercial Names Offer Upside

Outperform: AET, ANTM, CI, CNC, HUM, MOH, UNH, WCG / Market Perform: HNT, MGLN, UAM

UNIQURE, N.V. (QURE) / MICHAEL SCHMIDT, PH.D.

### Risk/Reward Compelling Ahead of Potential Catalysts, in Our View

Outperform / Market Cap: \$514.8M / Price: \$28.44

#### **RESEARCH PREVIEWS:**

### **Earnings Releases**

JNJ Before Market Earnings Call: 8:30 AM at 866-527-6580, PC: 6366816.

**1Q15 Revenue Estimates:** Leerink: \$17,300.0B vs. St's \$17,307.4B EPS Estimates:

Leerink: \$1.60 vs St's 1.53.

2Q15 Revenue Estimates: Leerink: \$18,176.0B vs. St's \$17,946.4. 2Q15 EPS Estimates:

Leerink: \$1.67 vs St's \$1.69

### April 14 – FDA AdCom Endocrinologic and Metabolic

**AZN – MP – Seamus Fernandez** 

Close: \$68.84, Mkt Cap: \$88,900M

- · Unexpected discussion of all cause mortality will be AZN's biggest challenge at today's panel.
- · FDA's briefing documents for today's DPP-IV AdCom meeting focused on heart failure (HF) hospitalizations but also raised an unexpected concern over an on-treatment evaluation of all-cause mortality from the SAVOR trial results.
- · Because a similar signal did not emerge in Takeda's EXAMINE study, we believe this opens the possibility that the panel could draw more product specific conclusions on AZN's (MP) Onglyza/ Kombiglize (saxagliptin) franchise.
- · We were surprised to see the option for restricting distribution and withdrawing saxagliptin from the market, among the options for the response to the question, "Which action do you recommend FDA take regarding the totality of the safety information (Cardiovascular and other) obtained in SAVOR?"
- · We model peak Onglyza franchise sales at \$1.8B in 2023 and note a 50% cut to our peak estimates would remove ~\$2-3/ADR.
- · Lateral impact: MRK (MP) Januvia, Takeda's Nesina, LLY/BI's Tradjenta, NVS' Galvus.

### **April 15 – FDA AdCom Cardiovascular and Renal Drugs**

MDCO - OP - Joe Schwartz

Close: \$29.30, Mkt Cap: \$1,923M

- 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 our 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: \$91.71, Mkt Cap: \$86,725M

- · 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: \$92.56, Mkt Cap: \$1,596M

- · 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: \$68.84, 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.

# **BMY - OP - Seamus Fernandez**

Close: \$63.95, Mkt Cap: \$97,577M

- · BMY'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: \$87.49, 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: \$19.74, 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: \$56.73, 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: \$102.34 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: \$26.68, 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) thatinhibits 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: \$37.90, Mkt Cap: \$3,983M

- · Abstract #2469 highlights a rationale for combining SGEN's Adectris with IO agents.
- · Preclinical data to be presented at AACR appear to suggest that Adcetris 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 Adcetris exhibited hallmark ICD markers similar to those seen with oxalaplatin.
- · While this effect remains to be explored in patients, it nevertheless provides an intriguing rationale for potential synergies between Adcetris and checkpoint inhibitors.
- · We note that an investigator-sponsored trial (IST) of Adcetris plus Yervoy in HL is ongoing and SGEN and BMY are planning trial of Adcetris 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 – Epidolex (Epilepsy) Phase II Data at AAN GWPH – OP – Paul Matteis

Close: \$96.18, Mkt Cap: \$1,335M

· Additional data update for the Epidiolex (treatment-resistant childhood-onset epilepsy) IND program is expected at the American Academy of Neurology (AAN) that could include 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 our 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: \$162.49, 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: \$26.81, 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: \$14.90, Mkt Cap: \$440M

· 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.
- $\cdot$  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.

### **PREVIOUS NOTES:**

**UPDATED MODELS:** <u>HNT - Model</u>; <u>MOH - Model</u>; <u>UAM - Model</u>; <u>WCG - Model</u>

### **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

<u>Life Science Tools and Diagnostics/Survey Augments MYGN Forecast; Share Loss, but Growth Market, Dan Leonard</u>

#### **GLOBAL HEALTHCARE CONFERENCE**

Biopharma/Takeaways from Our 2015 Global Healthcare Conference, Gena Wang

<u>Biopharma/Takeaways from Our 2015 Global Healthcare Conference</u>, 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

<u>Life Science Tools and Diagnostics/Takeaways from Our 2015 Global Healthcare</u> Conference; Dan Leonard

Medical Supplies and Devices/2015 Leerink Global Healthcare Conference Takeaways; Danielle Antalffy, Rich Newitter

Biopharma/Takeaways From Biosimilar Panel: US Market Quickly Coming Into View; Seamus Fernandez and Jason Gerberry

<u>Biopharma/Takeaways from Lymphoid Malignancies Panel at Our 2015 GHC</u>, Howard Liang <u>Biotechnology/Takeaways From Our MS Panel At 2015 Global Healthcare Conference</u>, 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 Antalffy

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

<u>UAM/Takeaways from GHC Presentation on Feb. 11; Raise PT to \$11/Market Perform;</u> Ana Gupte

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

<u>UHS/Takeaways from Investor Dinner & Meetings on Feb. 11-12 with CFO Steve Filton/Outperform;</u> 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

### **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:** 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, 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

# 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 IB Serv./Past 1				
Rating	Count	Percent	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.

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