LEERINK

MORNING ROUNDS

TODAY'S HIGHLIGHTS / MARCH 4, 2015

TODAY'S RESEARCH:

OREX, RCPT, MGLN, UAM, VEEV, FOLD, MGNX

INITIATIONS: NONE **/ RATING CHANGES:** NONE **/ PRICE TARGET CHANGES:** OREX, VEEV, FOLD **/ ESTIMATE CHANGES:** OREX, RCPT, MGLN, UAM, VEEV, FOLD, MGNX **/ MEDACORP:** OREX **/ PREVIOUS RESEARCH:** NUVA, SAGE, XLRN, HEALTHCARE SERVICES, MYL, ECYT, ALKS, ISRG, SYK

REFERENCE TOOLS:

Catalyst Tracker | Earnings Rundown | Abbreviations & Acronyms
Calendar of Events | HC Conferences | Leerink Events

MORNING PRIMER:

Futures (as of 6:30am): DJIA: -62.00 (18,248); S&P500: -7.25 (2,105); NASD -13.00 (4,456)

LEERINK EVENTS:

3/4: Corporate Access: Fluidigm: FLDM, New York
3/4: MEDACorp Pulse Call: March 4 SCOTUS Hearings; What Happened; What to Expect and Stock Implications, 2:00PM EST
3/5: Investor Tours / Site Visits: uniQure NV Site Visit: QURE, Lexington
3/5: MEDACorp Pulse Call: The 2016 PBM Selling Season, 2:00PM EST
3/12: Corporate Access: Calithera Biosciences, Inc.: CALA, Los Angeles
3/12: Corporate Access: Calithera Biosciences, Inc.: CALA, San Diego

Please refer to Disclosure Appendix for Analyst Certification and Important Disclosures. Price charts and disclosures specific to covered companies are available on https://leerink2.bluematrix.com/bluematrix/Disclosure2 or by contacting Leerink Partners Editorial Department. Statements of Valuation and Risk are available in the note following this publication or by contacting Leerink Partners Editorial Department. Rx trends derived from IMS Health data.

3/12: Corporate Access: Auris Medical Holding AG: EARS, Boston
3/13: Corporate Access: Auris Medical Holding AG: EARS, New York

TODAY'S HEALTHCARE EVENTS:

REGULATORY EVENTS:
3/4 Adcom: Vaccines & Related Biological Products; Science Board to the FDA
3/4: Supreme Court hears ACA arguments
MEDICAL MEETINGS:
2/28-3/5: Society of Interventional Radiology, BCR
3/2-5: Mobile World Conference
CORPORATE EVENTS:
3/4: Earnings BMO: ARQL, EBIO, GTXI; **Earnings AMC:** ALDR

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

OREXIGEN THERAPEUTICS, INC. (OREX) / PAUL MATTEIS

Specialist Feedback on Contrave LIGHT Interim Data Drives Our Higher Ests. & PT

Outperform / **Market Cap:** $1,130.0M / **Price:** $7.64 / **Price Target:** $8.00 → $11.00 / **Methodology:** DCF analysis with 0% terminal growth rate, 11% discount rate

- **Bottom Line:** Following positive MEDACorp KOL feedback coupled with our own assessment of the results of the LIGHT study 25% interim analysis, we are raising our Contrave revenue estimates and our PT to $11/share, from $8. While it's unclear whether or not the observed 41% reduction (0.59 hazard ratio [HR]) in Major Cardiovascular Adverse Events (MACE) will be sustained as the LIGHT trial data mature, KOLs note that their opinions of Contrave have improved significantly now that it appears almost certain the drug does not do any cardiac harm. Our updated model, reflecting our analysis and this feedback, assumes a slightly steeper US launch, greater peak sales, and provides OREX more credit for Contrave's potential in ROW markets. **Reiterate OP.**
- Even if Contrave's CV effect proves more modest as the LIGHT study data mature, MEDACorp KOLs note they will still hold a meaningfully improved opinion of the drug.
- Given the treatment protocol employed in LIGHT, we believe it's possible that the 0.59 HR observed at the 25% interim could trend slightly higher at the 50% interim.
- Unclear when data from the 50% interim analysis will be announced.
- **2015E EPS/REV:** ($0.83) / $21.6 → ($0.80) / $24.9
- **2016E EPS/REV:** ($0.63) / $37.1 → ($0.52) / $51.0

Revenues in MM.

RECEPTOS, INC. (RCPT) / JOSEPH P. SCHWARTZ

4Q Recap: Establishing a Major Footprint in Immunology Drug Development

Outperform / **Market Cap:** $4,124.7M / **Price:** $124.99 / **Price Target:** $186.00 / **Methodology:** DCF analysis with 12% discount & 2% terminal growth rate

- **Bottom Line:** We are updating our model to reflect 4Q financial results reported today after the close. RCPT reported 4Q EPS of ($1.32) vs. our estimate of ($1.14) and consensus of ($1.19). The company continues to advance its potentially best in class development programs in several blockbuster immunology areas, in our view. **Reiterate Outperform and $186 PT.**
- The ozanimod relapsing MS program is on track to report top line Phase III data beginning in 1H17, potentially ahead of original schedule.
- For UC, RCPT believes that it had robust discussions and achieved regulatory alignment in its end of Phase II and scientific advice meetings with the FDA and EMEA in December and January, respectively.
- Based on the strong mucosal improvements seen in TOUCHSTONE, RCPT is excited to initiate a Phase II study in CD in 2015, which should generate clinical data in 2H16.
- Phase II study enrollment for the anti-IL13 MAb is going well since being initiated in 4Q, and HEROES data are expected to be reported in 1H16.
- Management commented that the partnership process is progressing.
- **2015E EPS/REV:** ($5.49) / $2.0 → ($5.65) / 0.0

Revenues in MM.

MAGELLAN HEALTH SERVICES, INC. (MGLN) / ANA GUPTE, PH.D.

Out of Period Driven 4Q Beat; Downside Risk From Contract Expiry & BH Carve Ins

Market Perform / **Market Cap:** $1,743.5M / **Price:** $63.63 / **Price Target:** $62.00 / **Methodology:** 16.6x P/E on our 2015E adjusted EPS of $3.58 + $2.50 cash at Parent

- **Bottom Line:** MGLN reported a significant beat during 4Q with EPS of $0.82 as compared to us and consensus at $0.49, though $0.43 of the reported 4Q EPS relates to out of period items. While 2015 EPS guidance was raised by 3c at the mean from lower share count, we modestly raise our 2015E EPS from $2.20 to $2.25 with consensus at $2.42. We see potential downside risk from FL SMI contract in 2015, which is guided to low 90s MLR and which we see as the best possible case and estimate that downside can be as high as $1 per share if actual MLR is higher. The LA Behavioral care contract has been extended until November 2015 and does not pose material downside for 2015 (though 2016 will be adversely affected due to contract expiry). The recently released IA RFP also poses a significant downside risk for 2016 (current contract expires on June 30, 2016) with the behavioral carve-out contract expiring June 2015, though the company is better placed in the state with its HMO license. Further, we see the recent LA Behavioral Health contract carve-in as a potential indication of a broader trend toward carve-in rather than carve-out in Behavioral Health contracts and may spur earlier consolidation of MGLN with an existing Medicaid or diversified entity. We continue to view MGLN as a show-me story and reiterate our Market Perform and price target of $62 on 16.6x our adjusted '15E EPS (plus $2.50/share in parent cash) though take-out offers upside given attractive synergies to a Managed Care player.
- 4Q14 EPS beat of $0.33 though largely from out of period items.
- '15 EPS guidance raised by 3c at the mean from lower share count.

- The LA Behavioral care contract has been extended until Nov. 2015 and does not pose material downside for 2015 (though 2016 will be adversely affected due to contract expiry).
- We see the recent LA contract carve-in as a potential indication of a broader trend toward carve-in rather than carve-out in Behavioral Health contracts and may spur earlier consolidation of MGLN with an existing Medicaid or diversified entity.
- Strong balance sheet with $2.50 in parent cash per share and healthy CFO, which has been guided to $171 - $195MM for 2015 with an expected FCF yield of 7%.
- **2015E EPS/REV:** $2.20 / $4,475.0 → $2.25 / $4,462.0

Revenues in $MM; 2015E adjusted EPS of $3.58

UNIVERSAL AMERICAN CORPORATION (UAM) / ANA GUPTE, PH.D.

Modest 4Q EPS Miss; Room for Core MA MLR & SG&A Upside in '15; Reiterating MP

Market Perform / **Market Cap:** $749.2M / **Price:** $8.93 / **Price Target:** $11.00 / **Methodology:** Sum-of-parts analysis: Combination of Core HMO book, excess cash over RBC capital, and ACO model

- **Bottom Line:** UAM (MP) reported a modest 1c EPS miss during 4Q. While Medicare Advantage (MA) MLR missed expectations, the all-important Core Market MLR improved both sequentially & YoY. For FY15, the company has reset its Medicare Advantage business to focus on those markets where it can positively impact the quality and cost of healthcare. While 2014 was a big year of transition, management sees that continuing in 2015. For FY15E, our EPS is at $0.28, which is higher than consensus of $0.23 driven by better than guided MA SG&A ratio (by 40 bps) and 140 bps YoY improvement in MA MLR. The CEO looks to be a key driver and influencer of the recent CMS announcement to accelerate value-based payment to ACOs with the Medicare Shared Savings Plans (MSSP). In 2016E and beyond we do see EBIT growth returning to normalized levels of mid-single digits as Obamacare rate and Minimum MLR floor headwinds subside. Long term, management sees MA and MSSP as synergistic rather than competing and expects continued movement into value-based payment models including MSSP. We reiterate our Market Perform rating and price target of $11.
- EPS miss of ~1c during 4Q14 as compared to consensus and our expectation primarily driven by earnings loss across its segments of Traditional, MA and Corporate & Other combined with revenue and SG&A miss.
- MA MLR missed expectations, though the all-important Core Market MLR improved both sequentially & YoY.
- Strong open enrollment season.
- For FY15, the company has reset its Medicare Advantage business to focus on those markets where it can positively impact the quality and cost of healthcare.
- UAM CEO looks to be a key driver and influencer of the recent CMS announcement to accelerate value-based payment to ACOs with the Medicare Shared Savings Plans (MSSP), which now cover 7MM of the senior population.
- In 2016E and beyond we do see EBIT growth returning to normalized levels of mid single digits as Obamacare rate and Minimum MLR floor headwinds subside.
- Downside risk remains capped with tangible book value (TBV) at $5.57 and strong balance sheet with $137MM or $1.60 per share of unregulated parent cash (including ~$27MM received in Feb. 2015 from sale of its PR company) and a low Debt to Capital ratio at 19% with likely special dividends in the future.

- **2015E EPS/REV:** $0.26 / $1,980.3 → $0.28 / $1,885.9

Revenues in MM.

VEEVA SYSTEMS, INC. (VEEV) / STEVEN WARDELL

Solid Core CRM Results; Vault, Network Pick Up Steam; PT to $35 from $30

Market Perform / **Market Cap:** $4,854.5M / **Price:** $32.69 / **Price Target:** $30.00 → $35.00 / **Methodology:** DCF analysis

- **Bottom Line:** Yesterday after the close, Veeva Systems, Inc. reported F4Q15 revenue of $87m, 2% above Street expectations, and adjusted EBITDA of $24.9m, 3% above Street expectations. Mgmt guided to $87.5m revenue in F1Q16 and $392.5m revenue in FY2016, a 25% growth rate for the year, approximately in line with Street expectations. Revenue growth was driven by strong growth in subscriptions, and Vault and Network won new customers. We expect ST market weakness in the name due to FY2016 guidance in-line with the Street leading to disappointment. Increase PT to $35 from $30, maintain MP rating.
- High revenue growth driven by subscriptions.
- Strong earnings driven by operating leverage.
- Mgmt guided to FY2016 total revenue of $392.5m, reflecting YoY growth of 25% and roughly in line with Street expectations, though we expect to see ST weakness in the name as in our view the Street expected a larger guide-up.
- We maintain our MP rating and raise PT to $35 from $30 after aligning our model with FY16 mgmt guidance, raising EBIT margins consistent with guidance, and rolling forward our DCF model.
- **2016E EPS/REV:** $0.41 / $390.3 → $0.43 / $392.2
- **2017E EPS/REV:** $0.48 / $470.7 → $0.58 / $483.4

Revenue in millions. EPS are non-GAAP. Old FY2017 estimates last updated in Oct. 2014 and do not reflect 3Q14 & beyond reporting & guidance.

AMICUS THERAPEUTICS, INC. (FOLD) / JOSEPH P. SCHWARTZ

4Q Recap: Totality of Migalastat Data to Be Reviewed by FDA & EMA by Mid-2015

Outperform / **Market Cap:** $737.8M / **Price:** $8.48 / **Price Target:** $9.00 → $13.00 / **Methodology:** 6x probability-weighted 2020E sales disc. at 12% + net cash

- **Bottom Line:** Tuesday after the close, FOLD reported 4Q EPS of ($0.24) slightly below our estimate of ($0.22) mainly attributed to increased R&D spend due to the initiation of a long-term extension migalastat study and continued progress of two preclinical next-gen ERT programs in Fabry's and Pompe Disease. Both programs are anticipated to enter the clinic in 2015. After reviewing the implications of the totality of migalastat's Ph. 3 data being now presented to the FDA, we are raising our PT to $13 (from $9 previously) to reflect: (a) higher peak penetration of 50% (from 35% previously) in Fabry's with amenable mutations (combining both tx- naive and ERT-switch pts); and (b) raising the gross price to $300,000 (from $200,000 previously), in line with industry standards for an orphan drug launch.
- With a Type C FDA meeting already calendared to be held in two weeks and briefing document submitted, FOLD remains confident that: (a) disease substrate reduction (biomarker) and (b) kidney function stabilization (outcome) datasets should allow the company to complete a pre-NDA meeting and complete NDA filing by mid-2015.

- MAA submission of migalastat remains on track to be finished by mid-2015.
- Next-generation ERT program, ATB200 + chaperone in Pompe Disease, is on the cusp of completing IND-enabling toxicology studies and enter Ph. I testing in 2H15.
- **2015E EPS/REV:** ($0.77) / $10.0 → ($0.92) / 0.0

Revenues in MM.

MACROGENICS, INC. (MGNX) / MICHAEL SCHMIDT, PH.D.

4Q14 Recap – Well Capitalized; Broad Pipeline Creates Upside Opportunities

Outperform / **Market Cap:** $970.2M / **Price:** $34.65 / **Price Target:** $52.00 / **Methodology:** Sum-of-the-parts DCF analysis, 12% discount rate

- **Bottom Line:** MGNX reported 4Q14 financial results and provided an update on its dev't pipeline. Near-term data read-outs include: (1) two preclinical presentations on new bispecific "DART" antibodies by PFE (MP) and MGNX, respectively, at AACR (April); (2) margetuximab (breast cancer) Ph I dose-expansion data at ASCO (May); and (3) MGA271 (anti-B7-H3) Phase Ib monotherapy dose-expansion data (solid tumors) in 2H15. MGNX's pipeline continues to advance and broaden rapidly with Ph III trial initiation for margetuximab, immuno-oncology (IO) combination trial initiations for MGA271, and Ph I initiations for 3 new DART molecules expected in 2015. MGNX is one of our top picks, with a diversified, expanding immunotherapy pipeline and 7 partnerships providing multiple sources of value creation within the current cash runway until 2018. MGNX ended 4Q with $158M in cash excluding $125M from JNJ (OP) in 1Q15. Updating ests to reflect 4Q results. **Reiterate OP and $52 PT.**
- Phase III margetuximab trial in metastatic breast cancer (mBC) to initiate in 3Q15.
- Initiation of MGA271 (anti-B7-H3) combo studies with IO agents expected in 2015.
- Three add'l DARTs to move into the clinic in 2015.
- Preclinical data at AACR could provide add'l. insight into MGNX early pipeline.
- **2015E EPS/REV:** ($2.50) / $48.0 → ($1.77) / $70.0

PREVIOUS DAY NOTES:

NUVASIVE, INC. (NUVA) / RICHARD NEWITTER

MDT Litigation Update Represents An Incremental Positive

Outperform / **Market Cap:** $2,260.3M / **Price:** $44.67

- **Bottom Line:** NUVA this morning announced a press release with an update on phase 1 of the MDT/NUVA patent litigation indicating that the Appeals Court affirmed the district court's findings of infringement, but vacates and remands damages awarded to MDT in the case the against NuVasive. All else held equal we believe this news should be viewed as a small, but incrementally positive piece of news with potential upside implications to NUVA's cash position--i.e., likely a lower royalty/damages assessment to come out of re-trial associated with the first phase of litigation.
- The key here, in our view, is that NUVA already had a "worst-case" baked into numbers & cash assumptions (for several years now) and there should now be upside to this consideration.
- NUVA Likely Has Been Over-Accruing For Damages in Phase 1 of MDT/NUVA trial in 2011.
- Update On Retrial & New Damages Could Come Later In 2015

SAGE THERAPEUTICS, INC. (SAGE) / JOSEPH P. SCHWARTZ

4Q14 Recap: '547 Phase III to Begin Mid-15; Platform Advancing

Outperform / **Market Cap:** $1,211.4M / **Price:** $43.89 / **Price Target:** $54.00 / **Methodology:** DCF analysis with 12% discount rate

- **Bottom Line:** We are updating our model to reflect 4Q14 results. 4Q14 OpEx were relatively in-line with our estimates and are expected to increase in 2015 as SAGE-547 advances into Phase III and early-stage pipeline programs mature. We continue to believe that the robust 71-78% response rates observed for '547 in SRSE (Super Refractory Status Epilepticus) de-risk the Phase III, regardless of whether or not it is structured as an open-label or placebo-controlled trial. **Reiterate OP on SAGE and $54 Price Target.**
- SAGE continues to expect clarity on the structure of the '547 Phase III by the end of 1Q15.
- Enrollment underway in exploratory Phase IIa trials of SAGE-547.
- SAGE continues to advance its pipeline of second-generation allosteric modulators.
- **2015E EPS/REV:** ($2.30) / 0.0 → ($2.68) / 0.0

GAAP EPS.

ACCELERON PHARMA (XLRN) / HOWARD LIANG, PH.D.

Multiple Data Catalysts in 2015 Ahead of Phase III Initiations

Outperform / **Market Cap:** $1,288.4M / **Price:** $39.89 / **Price Target:** $57.00 / **Methodology:** NPV analysis, 10% discount rate, 7x Terminal Value multiple

- **Bottom Line:** Following dalantercept data presentation in renal cell carcinoma (RCC) at ASCO GU over the weekend (LINK) and recent management update at our 2015 Global Healthcare Conference (LINK), the 4Q:14 earnings call provided incremental updates on XLRN's four clinical-stage compounds and outlined data presentation opportunities throughout the year. We see multiple data catalysts in 2015 that could provide upside potential for XLRN ahead of Phase III initiations for luspatercept and sotatercept in MDS and beta-thalassemia. In our view, key data include data solidifying biomarker selection for luspatercept in MDS (potentially at International Symposium on MDS (April 29-May 2) and EHA (June 11-14) and vascular calcification benefit for sotatercept (potentially at ERA-EDTA, May 28-31) as well as first ACE-083 clinical data that could include some efficacy readout (2H:15). We remain OP-rated with a price target of $57.
- Dalantercept combo with axitinib showed consistent signal in RCC; may retain a 2nd-line position despite evolving therapeutic dynamics in RCC.
- Rich data catalysts in 2015 ahead of Phase III initiations.
- **2015E EPS/REV:** ($2.11) / 0.0 → ($0.96) / $44.1

Revenue in MM.

MYLAN, INC. (MYL) / JASON M. GERBERRY, JD

4Q Update: Favorable Guidance Considering Fx & Pot'l EpiPen Headwind

Outperform / **Market Cap:** $23,040.2M / **Price:** $57.89 / **Price Target:** $62.00 → $67.00 / **Methodology:** ~15x our '16E EPS

- **Bottom Line:** We caught up with MYL's CFO John Sheehan this morning following the company's in-line 4Q and 2015 guidance. Our main takeaways from the call were while the threat of an AB-rated generic EpiPen (TEVA - OP) could weigh on the stock, MYL's EpiPen branding initiatives should mitigate genericization and the ABT margin profile is likely better than we originally forecasted. Stepping back, we believe the risk/reward on MYL is still favorable in '15 as (1) M&A -- either MYL pushes forward leveraging its infrastructure to acquire highly accretive assets or potentially succumbs to a merger with a larger pharma; (2) EpiPen Gx -- approval of an AB-rated generic in July is a toss up and failure of generic to get approved represents upside to our ests; (3) MYL's underlying portfolio is relatively diverse & profits are durable limiting downside risk. We currently value MYL at $67/shr & remain OP. Our 2- and 5- year EPS growth CAGR's are ~10% and ~8% respectively.
- We believe g-EpiPen risk can be mitigated.
- We forecast modest growth for the ABT portfolio.
- Changes to our model.
- **2015E EPS/REV:** $3.78 / $8,214.0 → $4.17 / $9,942.0
- **2016E EPS/REV:** $4.09 / $8,580.0 → $4.48 / $10,390.0

Revenues presented in $M. Adjusted diluted EPS.

ENDOCYTE, INC. (ECYT) / HOWARD LIANG, PH.D.

Increasing Visibility of Second-Gen SMDCs in 2015 Key to Outlook

Market Perform / **Market Cap:** $252.5M / **Price:** $6.05 / **Price Target:** $7.00 / **Methodology:** Sum-of-parts analysis

- **Bottom Line:** On ECYT's earnings call, management highlighted a better safety profile for the two second-generation SMDC (small molecule drug conjugate) assets EC1456 (folate tubulysin) and EC1169 (PSMA tubulysin) and what management views to be early signs of activity for EC1456 from Phase I dose escalation studies. Although final overall survival (OS) data from the Vynfinit (vintafolide) TARGET trial (in NSCLC) won't be available until mid-2015, EC1456 is already considered as a better asset in NSCLC based on current data. While EC1456 and EC1169 data at Targeted Anticancer Therapies (TAT) Congress (March 4) will likely be incremental, updates at ASCO (May 29-June 2) could provide more clarity on efficacy. Our price target for ECYT is $7.
- Better safety seen for EC1456 in a Phase I dose escalation study.
- Catalysts in 2015.
- Model update.
- **2015E EPS/REV:** ($1.64) / 0.0 → ($1.28) / 0.0

Revenues in $MM; GAAP EPS. Quarterly figures may not sum to annual total due to rounding and/or change in shares out.

STRYKER CORPORATION (SYK) / RICHARD NEWITTER

$2B Share Repo a Positive - Doesn't Take M&A Off the Table Either, in Our View

Outperform / **Market Cap:** $36,771.8M / **Price:** $96.01

- **Bottom Line:** SYK this morning announced a $2B share repo program, leaving us more comfortable in upside potential to our current 2015-2016E EPS. SYK's balance sheet has been very much in focus as it

represents a key avenue to shareholder value creation, in our view, for the company. M&A has historically been the first priority, followed by share repos and then dividends. While this buyback announcement is larger than prior authorizations, we don't think it takes M&A off the table by any stretch. However, at the margin it could be viewed as a sign that larger M&A (i.e., a much speculated potential bid for SNN)---at least over the nearer term---is less likely. In all, we view SYK's balance sheet flexibility favorably, and we view buybacks as one of a number of cash deployment mechanisms at the company's disposal to drive higher shareholder value.

- $2B Announcement a Step-Up from Last Share Repurchase Plan.
- Announcement Represents ~$0.30-$0.35 Upside to 2016E by Our Math.

PREVIOUS NOTES:

HEALTHCARE SERVICES / ANA GUPTE, PH.D.

The Future of American Health Insurance

Outperform: AET, ANTM, CI, CNC, CYH, HCA, HUM, MOH, UHS, UNH, WCG / **Market Perform:** HNT, LPNT, THC, UAM

ALKERMES PLC (ALKS) / MICHAEL SCHMIDT, PH.D.

Analyst & Investor Event Highlights CNS Pipeline Value

Outperform / **Market Cap:** $10,498.9M / **Price:** $71.47

INTUITIVE SURGICAL, INC. (ISRG) / RICHARD NEWITTER

Defense Logistics Notice an Incremental Positive

Outperform / **Market Cap:** $18,771.4M / **Price:** $503.26

RESEARCH PREVIEWS:

March 4 – Supreme Court Hearing on Federal Exchange Subsidies

Managed Care and Healthcare Facilities – Ana Gupte
AET (OP, $99.79), ANTM (OP, $145.99), CI (OP, $121.11), CNC (OP, $62.16), CYH (OP, $49.59), HCA (OP, $70.79), HNT (MP, $56.40), HUM (OP, $112.86), LPNT (MP, $71.47), MGLN (MP, $63.63), MOH (OP, $61.68), THC (MP, $47.06), UAM (MP, $8.93), UHS (OP, $112.73), UNH (OP, $112.86), WCG (OP, $89.00)
· In light of the SCOTUS decision to grant a hearing to the case of King vs. Burwell on March 4 with a decision likely by June, we analyzed the earnings impact of Federal Exchanges on our Managed Care and Healthcare Facilities coverage.

- Our analysis shows that the absolute EPS risk is low for our Managed Care names, given MCO's lower margin expectations, less Federal Exchange exposure, and offsets from better Commercial MLR as employers reduce their propensity to "dump" workers into this channel. In the bear case, 2016E earnings exposure to Federal Exchanges across our coverage is in the order: HUM (2.5%) >AET (1.9%) > CNC (1.8%) > HNT (1.0%) > CI (0.8%) > ANTM (0.7%) > MOH (0.1%) = UNH (0.1%).
- For our Healthcare Facilities names, the earnings impact would be material as a % of EBITDA with the exception of UHS. EBITDA contribution by Federally run Exchanges is highest for THC at 2.6% followed by HCA (2.5%) > CYH (2.4%) > LPNT (2.2%) > UHS (0.4%). However, the challenge would present an impact as a % of 2016 EBITDA in the order: CYH (5%) > THC (4%) = HCA (4%) >LPNT (3%) > UHS (1%) given bed market share is disproportionately skewed toward Federal Exchanges.

· The case will determine the legality of Exchange subsidies administered by the Federal Government in the 36 marketplaces to date, and we expect that there will be workarounds were the court to rule Federal Exchange subsidies illegal.

· There is a desire on the part of both Hospitals and Health Plans to coordinate workarounds with individual states, and Steve Filton, UHS CFO, commented at GHC that he believes only states that chose to expand Medicaid (relatively accommodative to ACA) would likely implement workarounds.

· Please dial in, on March 4 at 2:00 p.m. EST, for our MEDACorp Pulse Call: **March 4 SCOTUS Hearings; What Happened; What to Expect and Stock Implications,** which will feature a legal and regulatory specialist who was in the courtroom for the oral arguments.

March – Mysimba (Obesity) EMA Approval

OREX – OP – Paul Matteis
Close: $7.64, **Mkt Cap:** $748M

· Following a positive opinion from the CHMP, OREX expects a final opinion from the EMA on the Mysimba (Contrave) marketing authorization application (MAA).

· We currently model peak ex-US risk-adjusted Mysimba revenues of $50M in 2025 off which we project OREX receives $15M in royalties.

· OREX is currently in discussions with potential ex-US partners, and a collaboration agreement with a company that has a large EU/ROW footprint could render our projections conservative, we believe.

March 9 – ATX-101 (Submental Fat Reduction) FDA Adcom

KYTH – OP – Seamus Fernandez
Close: $39.69, **Mkt Cap:** $915M

· In our opinion, KYTH is positioned to deliver a positive FDA AdCom, with a strong chance at approval on the May 15 PDUFA, followed by a careful but seamless launch of ATX-101 in mid-2015.

· **Briefing documents for the Dermatologic and Ophthalmic Drugs Adcom will be released on March 5.**

· Our recent conversations with CEO Keith Leonard and CMO Frederick Beddingfield highlight deep preparation for the upcoming FDA Advisory Committee meeting to discuss ATX-101.
· By our analysis, ATX-101 satisfies all key efficacy and safety parameters necessary for approval – and compares favorably with approved aesthetic agents.
· Mgmt's early efforts to raise awareness will be key to maximizing the $500M+ market oppt'y for this first-in-class product for submental contouring (double chin reduction).
· A recent MEDACorp survey predicts strong update of ATX-101 in the first two years following launch.
· We estimate ATX-101 US revenues of $11M in 2015, reaching a peak of $428M in 2023.
· KYTH plans multiple OUS filings by 2Q15. We estimate OUS revenues of $11M in 2016, reaching a peak of ~$200M in 2024.

March 14 – Brilinta (ACS) Data at ACC

AZN – MP – Seamus Fernandez
Close: $68.28, **Mkt Cap:** $88,890M
· The PEGASUS study, which followed 21K patients who had heart attacks, found that long-term use of Brilinta plus aspirin helped prevent additional heart attacks, strokes, and CV death--and did so better than long-term aspirin plus placebo.
· With PEGASUS, KOLs expect the results in these 21K patients to drive use of the P2Y12 inhibitor in more ACS (Acute Coronary Syndrome) patients while also extending the duration of therapy.
· Additional PEGASUS data are expected to be presented on 3/14 as late-breaker at the American College of Cardiology (ACC) annual meeting; CV mortality benefit, and/or impressive 60 mg dose would be clear wins.
· We see two potential upsides when PEGASUS results are presented at ACC: (1) a meaningful benefit on all cause or cardiovascular (CV) mortality, directionally supporting the 16% RRR seen in PLATO; and/or (2) a superior risk-benefit profile for the 60 mg dose vs. the currently marketed 90 mg dose.
· We estimate peak Brilinta sales of $3B in 2022.

March 19 – THRX Breo/Ellipta (Asthma) FDA AdCom

THRX – MP – Gena Wang
Close: $19.56, **Mkt Cap:** $2,205M
· The FDA's Pulmonary-Allergy Drugs and the Drug Safety and Risk Management AdComs will jointly discuss GSK/THRX's sNDA for fluticasone furoate and vilanterol inhalation powder (Breo Ellipta) for the once daily maintenance treatment of asthma in patients 12 years of age and older.
· The discussion will include efficacy data, but the focus of the meeting will be safety, including the adequacy of the safety database to support approval, and whether a large safety trial to evaluate serious asthma outcomes is recommended.
· Breo/Ellipta is approved in the US for COPD, and in the EU for COPD and asthma.
· Breo's initial weak launch was largely due to poor insurance coverage according to mgmt.

· 2015 has several potentially positive regulatory and clinical catalysts; however, Breo and Anoro sales performance has the final say for 2015.
· We model Breo/Ellipta 2015 WW sales of $422M rising to $1.7B in 2022, providing royalties to THRX of $63M and $251M, respectively.
· **Next up:** 4/30 Breo Ellipta PDUFA.

March 24 – INSM Investor Meeting

INSM – OP – Joe Schwartz
Close: $18.42, **Mkt Cap:** $939M
· Following its recent 4Q14 earnings report, INSM aims to provide more meaningful updates on its clinical programs and FY15 financial guidance during its Analyst and Investor Day scheduled for March 24.
· INSM will also provide additional granularity on the statistical assumptions behind Arikayce's (non-tuberculous mycobacteria [NTM]) Phase III pivotal study.
· The study is currently enrolling. We expect data in mid-2016 with potentially an NDA filing to follow. An already granted Breakthrough Therapy Designation may allow for an expedited review timeline.
· We expect INSM also to provide color on the dynamics of the NTM market opportunity in both the US & EU.

Late 1Q15/Early 2Q15 – Sustol (CINV-HEC) Phase III Marketing Study Data

HRTX – OP – Jason Gerberry
Close: $13.02, **Mkt Cap:** $210M
· 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). The Sustol Phase III marketing study data is expected in late 1Q15/early 2Q15.
· 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.

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

HTWR – OP – Danielle Antalffy
Close: $84.70, **Mkt Cap:** $1,448M
· 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.

April 18-25 – Epidolex (Epilepsy) Phase II Data at ANA

GWPH – OP – Paul Matteis
Close: $79.55, **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 at least 2x as large 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 plans to use the 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.
· **Next up:** Four **Phase III Epidiolex** pivotal studies in Dravet and Lennox-Gastaut syndrome are expected to begin in late 1Q15/early 2Q15. GWPH expects to announce data from at least one of the **Epidiolex** Dravet studies by YE15, putting it on track to file its NDA in 2016, we believe.

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

WMGI – OP – Rich Newitter
Close: $25.00, **Mkt Cap:** $1,373M
· WMGI management expects a mid-2Q Augment approval and $10-12M in 2015 US revenues, which is in line with our estimates on timing and amount.
· 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.

EARNINGS RUNDOWN:

							4Q14E				1Q15E			
Ticker	Release Date	Release Time	CC Date	CC Time EDT	CC Tel	CC Pass	Revs Leerink	Revs Street	EPS Leerink	EPS Street	Revs Leerink	Revs Street	EPS Leerink	EPS Street
ARQL	3/4	Before Market	3/4	9:00 AM	(877) 868-1831	-	1.3	1.9	(0.16)	(0.13)	-	1.3	-	(0.13)
EBIO	3/4	Before Market	3/4	8:30 AM	844-831-3025	87544666	0.8	0.8	(0.33)	(0.36)	0.2	0.2	(0.44)	(0.42)
GTXI	3/4	Before Market	3/4	9:00 AM	866-314-5232	85796452	-	-	(0.09)	(0.07)	-	-	-	-
ALDR	3/4	After Market	3/4	5:00 PM	(877) 430-4657	81724486	-	5.8	(0.19)	(0.21)	-	2.0	(0.44)	-
ICEL	3/5	After Market	3/6	8:00 AM	(877) 312-5886	91254777	5.5	5.0	(0.44)	(0.45)	-	5.0	-	(0.40)
SIEN	3/11	After Market	3/11	4:30 PM	(844) 464-3933	92616700	10.8	10.7	(1.32)	(0.35)	-	11.8	-	(0.37)
INGN	3/12	After Market	3/12	4:30 PM	(855) 427-4393	-	25.3	26.6	0.02	0.03	28.9	28.8	0.09	0.09
WBA	4/9	Before Market	4/9	8:30 AM	webcast	-	26,800.0	26,544.6	0.98	0.94	29,400.0	28,731.1	0.98	0.94

Sources: Leerink Estimates, FactSet, Company Information

PREVIOUS NOTES:

UPDATED MODELS: ATHN - Model, CAH - Model, CERN - Model, CTRX - Model, CVS - Model, DPLO - Model, ENDP - Model, ESRX - Model, EVDY - Model, HSIC - Model,IMS - Model, MCK - Model, MDAS - Model, MDRX - Model, OMI - Model, UHS - Model

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 Antalffy, 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 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
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

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/Outperform
Biotechnology/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
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

SURVEYS
Medical Devices-Cardiology/TAVR Survey: Modest but In-Line Sequential Volume Decline After a Strong 3Q14, Danielle Antalffy
Medical Devices-Cardiology/Survey: LVAD Growth Poised to Accelerate in 2015, HTWR Gains Share, Danielle Antalffy
Medical Devices-Orthopedics/4Q Survey: Cycling a Tough Comp but NTM Procedure Growth Outlook Looks Healthy, Ana Gupte
Survey Offers Insight Into Bacteria, Yeast Testing Trends, Dan Leonard
OREX/Obesity Survey Suggests Takeda Marketing Power Can Drive Robust Contrave Launch/Outperform, Paul Matteis

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

2015 OUTLOOK
Healthcare/2015 Outlook: Key Drivers in Place for Continued Strong Performance
Healthcare Strategy/2015 Outlook: Healthcare Strategy
Biotechnology/Launches, Clinical Data, Emerging Therapeutic Areas Could Shape Biotech in '15
Biotechnology/2015 Outlook: Bispecific Antibodies Poised to Shine
Biotechnology/2015 Outlook: Our View on Key Issues Impacting our 10 Most Controversial Stocks
Pharmaceuticals/ Major/2015 Outlook: Big Data, Decisions, Launches, Deals & Surprises
Specialty Pharmaceuticals/2015 Outlook: Selective M&A, Jockeying for Complex Gx's & Addressing Overhangs
Life Science Tools and Diagnostics/Puts and Takes for Tools in 2015
Medical Supplies and Devices/2015 Outlook: We're Optimistic - M&A/Cash Deployment Still Likely Stock Drivers
Managed Care/Good Set-up in '15; Accelerated Growth in '16; Top Picks HUM & WCG

Healthcare Facilities/Healthcare Facilities - 2015 Outlook Presentation
Healthcare IT & Distribution/2015 Outlook - Top 10 Trends, Themes and Surprises
Digital Health/2015 Outlook: A Bright Year Ahead; Highlighting WBMD, EVDY, WAGE, CSLT, IMPR

UPCOMING HEALTHCARE EVENTS:

REGULATORY EVENTS

3/4: FDA Adcom: Vaccines & Related Biological Products; Science Board to the FDA
3/4: Supreme Court hears ACA arguments
3/5: FDA AdCom briefing documents released for KYTH, ATX-101 (reduction of submental fat), followed by 3/9 AdCom
3/17: FDA Adcom: Arthritis, JNJ Remicade (Crohn's)
3/18: FDA Adcom: Anesthetic & Analgesic
3/19: FDA Adcom: Pulmonary-Allergy, THRX Breo Ellipta

MEDICAL MEETINGS

2/28-3/5: Society of Interventional Radiology, BCR
3/2-5: Mobile World Conference
3/5-8: ENDO 2014
3/5-8: European Academy of Dermatology and Venerology
3/5-9: European Congress of Radiology
3/5-6: Future of Genomic Medicine VII (Scripps Health)
3/8-11: Healthcare Distribution Management Association
3/8-12: Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy (PITTCON)
3/10-14: American Academy of Periodontology
3/10-14: Association of Academic Physiatrists
3/10-11: International Plasma Protein Congress
3/10-11: Plasma Protein Forum
3/11-15: American Academy of Osteopathy
3/12-13: EORTC Groups Annual Meeting
3/12-15: National Comprehensive Cancer Network
3/13-22: South by Southwest - Digital Health
3/14-16: American College of Cardiology, AZN Brilinta data
3/18-22: International Conference on Alzheimer’s and Parkinson’s Diseases
3/18-19: International Society of Dermatopathology
3/19-22: American Academy of Pain Medicine
3/19-22: American Association of Physicists in Medicine

CORPORATE EVENTS

3/4: Earnings BMO: ARQL, EBIO, GTXI; **Earnings AMC:** ALDR
3/6: Earnings BMO: ICEL

3/6: **CC**: AVEO Tivozanib Ph II predefined biomarker analysis of its BATON-CRC study, 2pm, Dial-in: 1-877-280-4954, PC: 38640881
3/10: Earnings AMC: TBPH, ZGNX
3/11: Earnings AMC: SIEN
3/12: Earnings AMC: INGN, KIN, OMED
3/12: ALR Investor Mtg
3/17: Earnings AMC: CDNA

Disclosures Appendix

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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 12/31/14

Rating	Count	Percent	IB Serv./Past 12 Mos. Count	IB Serv./Past 12 Mos. Percent
BUY [OP]	150	70.00	61	41.00
HOLD [MP]	64	30.00	0	0.00
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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