

MORNING ROUNDS

TODAY'S HIGHLIGHTS / JUNE 17, 2014 TODAY'S RESEARCH: BRKR. EW

INITIATIONS: NONE / RATING CHANGES: NONE / PRICE TARGET CHANGES: XLRN / ESTIMATE CHANGES: NONE / MEDACORP: EW, KPTI / PREVIOUS RESEARCH: PHARMACEUTICALS/ MAJOR, KPTI, CNC, MEDICAL DEVICES, AGIO, LIFE SCIENCE TOOLS AND DIAGNOSTICS, XLRN, MGLN

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: +5.00 (16,697); S&P500: +1.00 (1,929); NASD +4.00 (3,772)

LEERINK EVENTS:

June 19: MEDACorp Pulse Call: Specialists' Views on Arikayce (Inhaled Lipsomal Amikacin) for Nontuberculosis Mycobacteria Lung Infections, 2pm, EDT

6/18: Corporate Access: Sophiris: SPHS, Toronto

6/18: Corporate Access: Hyperion Therapeutics: HPTX, Boston

6/18: MEDACorp Pulse Call: Hot Topics In Foot & Ankle Surgey, 12:30PM EDT **6/23: Corporate Access:** Kythera Biopharmaceuticals, Inc.: KYTH, Philadelphia

6/24: Investor Tours / Site Visits: Health Net, Inc: HNT, Los Angeles

6/24: Corporate Access: Kythera Biopharmaceuticals, Inc.: KYTH, Baltimore

Please refer to Disclosure Appendix for Analyst Certification and Important Disclosures. Price charts and disclosures specific to covered companies are available on https://leerink.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.

6/24: Corporate Access: Kythera Biopharmaceuticals, Inc.: KYTH, Philadelphia

6/24: Corporate Access: Bristol - Myers Squibb Co.: BMY, Boston

6/24: Corporate Access: Abiomed, Inc.: ABMD, New York

6/25: Corporate Access: Kythera Biopharmaceuticals, Inc.: KYTH, Boston **6/25: Corporate Access:** Kythera Biopharmaceuticals, Inc.: KYTH, Montreal **6/26: Corporate Access:** Kythera Biopharmaceuticals, Inc.: KYTH, Boston

TODAY'S HEALTHCARE EVENTS:

FDA AdCom: Gastroenterology and Urology Devices

Medical Meetings: American Diabetes Association; American Society for Mass Spectrometry; New Clinical Drug Evaluation Annual Meeting; American Society of

Psychopharmacology

Shareholder Vote: ACT/FRX M&A

Investor Meetings: MGLN, 8:30 a.m.; NVS Day 1, 12:30 p.m.

TODAY'S RESEARCH:

BRUKER CORPORATION (BRKR) / DAN LEONARD

BRKR Flashes Clinical Ambitions at ASMS

Market Perform / Market Cap: \$3,761.5M / Price: \$22.21 / Price Target: \$23.00 / Methodology: 12.5x EV/EBITDA TTM Dec. 2015 ex options

- Bottom Line: While BRKR introduced new products at the American Society for Mass Spectrometry (ASMS) annual meeting, we thought it most interesting that the company prominently highlighted an existing product, its MALDI Biotyper instrument. We left BRKR's press and investor event with a view that its opportunity in diagnostics could be larger than we previously envisioned. Nonetheless, the BRKR investment narrative centers around margin improvement, and we remain Market Perform rated with a view that current prices fairly reflect the margin expansion opportunity. We maintain our price target of \$23.
- · Installed base of MALDI Biotyper continues to expand.
- More headroom to expand consumables menu than we previously considered.
- Clinical to grow in importance in BRKR's strategy over the next 10 years.
- Left unsaid is design toward profitability.

EDWARDS LIFESCIENCES CORP. (EW) / DANIELLE ANTALFFY

Sapien XT Approved At Last, Improves Competitive Positioning Vs. CoreValve

Outperform / Market Cap: \$8,510.7M / Price: \$78.44 / Price Target: \$100.00

- Bottom Line: Yesterday after the market close, EW announced FDA approval of its 2nd-gen Sapien XT transcatheter heart valve (THV) in both inoperable and high risk patients. While largely expected, we view the timely approval -- just one week after CoreValve secured FDA approval in high risk patients -- as incrementally positive given: (1) Increasing investor anxiety over approvability of Sapien XT given a delayed timeline relative to MDT's (MP) CoreValve; (2) The approval of high risk along with inoperable, which may explain the FDA's protracted timeline; and (3) Sapien XT now gives EW a stronger competitive position relative to CoreValve, with both an 18 Fr. delivery system similar to CoreValve and a 29 mm valve annulus size vs. just 23 mm and 26 mm for prior-gen Sapien. With inventory in hand, EW will start shipping Sapien XT immediately. Investor focus will now likely shift away from approval timelines and land more squarely on CoreValve market share gains. While we do assume EW loses significant U.S. market share in the near term -- we expect EW to exit CY2014 at 65% share -- we also now believe: (1) The timely Sapien XT approval leaves little downside to our EW market share estimates, with potential for incremental upside; and (2) Sapien XT and CoreValve should meaningfully expand the market in the near term, continuing to drive strong double-digit growth in line with our nearly 20% projection for 2014.
- · Reiterate OP, \$100 PT.
- · Sapien XT Strengthens Competitive Positioning.

PREVIOUS DAY NOTES:

PREVIOUS NOTES:

PHARMACEUTICALS/ MAJOR / SEAMUS FERNANDEZ

Highlights from Day 1 at ADA: LLY's Biosimilar Looks Like a Contender

Outperform: LLY / Market Perform: SAN FP

KARYOPHARM THERAPEUTICS, INC. (KPTI) / MICHAEL SCHMIDT, PH.D.

Selinexor Data in Multiple Myeloma at EHA Highly Promising

Outperform / Market Cap: \$1,399.5M / Price: \$47.12 / Price Target: \$63.00 / Methodology: DCF, 12% discount rate

CENTENE CORPORATION (CNC) / ANA GUPTE, PH.D.

June 13 I Day Recap; Continuing Growth Story and Upside; OP at PT of \$84

Outperform / Market Cap: \$4,403.3M / Price: \$74.13 / Price Target: \$84.00 / Methodology: 20x the average of our 2014E and 2015E EPS

MEDICAL DEVICES / DANIELLE ANTALFFY, RICHARD NEWITTER

MDT to Acquire COV, Creates Formidable Leader in MedTech

Outperform: COV, JNJ, SYK, ZMH / Market Perform: ABT, MDT

AGIOS PHARMACEUTICALS, INC. (AGIO) / HOWARD LIANG, PH.D.

AG-221 EHA Update Provides Initial Evidence of Durability and Activity in MDS

Outperform / Market Cap: \$1,610.3M / Price: \$47.50 / Price Target: \$65.00 / Methodology: NPV + \$500M for Platform / Pipeline + Cash

LIFE SCIENCE TOOLS AND DIAGNOSTICS / DAN LEONARD

Incremental Improvements on Display at ASMS

Outperform: A, TMO / Market Perform: BRKR, WAT

ACCELERON PHARMA (XLRN) / MARKO KOZUL, M.D.

Robust EHA Datasets in Both MDS & β-Thal Drive Our New \$57 PT; Reit. OP

Outperform / Market Cap: \$1,026.6M / Price: \$33.88 / Price Target: $52.00 \rightarrow 57.00$ / Methodology: DCF analysis; 10% discount rate; 1% terminal growth rate

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

June 17 I-Day- An Opportunity to Educate & Likely Positive Catalyst; MP, PT \$65

Market Perform / Market Cap: \$1,740.5M / Price: \$61.94 / Price Target: \$65.00 / Methodology: 16.3x average of '15E & Drice: \$439;16E EPS + Parent Cash of \$10.70E

RESEARCH PREVIEWS:

June - Readout Regarding Breakthrough Therapy Status for INSM's Arikace

INSM - OP - Joe Schwartz

Close: \$12.76,Mkt Cap: \$665M

- · We expect an announcement re: breakthrough therapy status for Arikace (Non-Tuberculous Mycobacteria, NTM) in June.
- · We believe Arikace has a good shot of being awarded breakthrough, given its ability to produce 21 culture conversions to negativeafter 3-6 months in NTM patients who were at least 6 months refractory to the standard-of-care.

- The FDA / EMEA also seem to be focused on culture conversion endpoint but the question will be if the Ph II data is enough for accelerated approval (AA) because that endpoint was not the trial's primary endpoint, but a secondary endpoint.
- · INSM also expects to hear if it will be granted accelerated approval status around June as well and we assign AA status a 60% probability.
- · Next up: MEDACorp Pulse Call on 6/19 at 10:00am EDT.

June 16-19 – American Society of Clinical Psychopharmacology

ALKS - OP - Michael Schmidt

Close: \$47.31,Mkt Cap: \$3,170M

- · ALKS expects to present the full dataset for aripiprazole lauroxil (AL, schizophrenia) Phase III data at the 2014 American Society of Clinical Psychopharmacology meeting, 6/16-19. IND submission is expected in 3Q14.
- · We model launch in 3Q15 following a 12-month FDA review.
- · We now break out aripiprazole lauroxil separately in our DCF and value it at \$25/share based on our estimates.
- · We expect AL to be highly profitable and model 10% COGS and a 12.5% tax rate on aripiprazole lauroxil net profits.

PREVIOUS NOTES:

ASCO Takeaways

<u>Biotechnology/Highlights of Monday's ASCO Presentations in Our Coverage</u>, Howard Liang et al.

<u>Biotechnology/Highlights of ASCO Weekend Data in Our Biotech Coverage</u>, Howard Liang et al.

<u>Biopharma/IO Insights from MEDACorp KOLs: Takeaways and Expectations, Seamus Fernandez et al.</u>

CLVS/Attractive CO-1686 PFS & Safety at ASCO Should Rule the Day; Reit. OP & \$122 PT/Outperform, Marko Kozul

SNSS/Further Positive Qinprezo-Decitabine AML/MDS Combo Data at ASCO; Reit OP, \$17PT/Outperform, Marko Kozul

XLRN/Encouraging Dal-Axitinib at ASCO & SOT ß-Thal at EHA Could Surprise; Reit \$52PT/ Outperform, Marko Kozul

<u>Flash -- INCY/Positive Updates for INCB24360 and Jakafi at ASCO/Outperform, Michael Schmidt</u>

Flash -- IMGN/ASCO Presentations Include Encouraging Data on Partnered Products/ Outperform, Michael Schmidt

<u>Flash -- KPTI/Selinexor Phase I Update at ASCO Confirms Safety/Efficacy Profile/</u> Outperform, Michael Schmidt

Flash -- CERU/Minor CRLX-101 Update at ASCO/Outperform, Michael Schmidt

Recent Surveys

ILMN/Survey Reflects Positively on Key ILMN Investment Debates/Outperform, Dan Leonard KYTH/MCP Survey: Bullish Physician Sentiment for ATX-101 Unchanged; We're Buyers/Outperform, Seamus Fernandez

<u>Biopharma/Survey Finds Frequent Off-Label Use of Sovaldi & Projects Cont'd Market Growth</u>, Howard Liang

CBST/Survey Predicts Better-Than-Expected Sivextro Pricing vs. Generic Zyvox/ Outperform, Marko Kozul

Medical Devices-Orthopedics/1Q Hip/Knee Survey Highlights Anticipated Seasonality; We Still Like Ortho, Rich Newitter

Long Shelf Life Reports

<u>P&A V - Partnerships & Acquisitions in Biopharma: Our New Top Ten List,</u> Joe Schwartz et al.

BMRN/Deep Dive on BMN111: Compelling Logic/Early Efficacy Warrant Investor Attention/ Outperform, Joseph Schwartz

DYAX/Deep Dive on DX2930: Value Warranted for Novel HAE Monoclonal Antibody/

Outperform, Joseph Schwartz

SHPG/Deep Dive on Ph. III Pipe; Feedback on Lifitegrast Surprisingly Constructive/ Outperform, Jason Gerberry

UPCOMING HEALTHCARE EVENTS:

REGULATORY EVENTS

6/17: FDA AdCom: Gastroenterology and Urology Devices

6/20: CBST Sivextro (ABSSSI) PDUFA

6/25: FDA AdCom: Oncologic Drugs, AZN olaparib (ovarian cancer) **6/28**: NPSP Gattex (Short Bowel Syndrome; STEPS data) PDUFA

7/10-11: FDA AdCom: Obstetrics and Gynecology Devices

MEDICAL MEETINGS

6/13-17: American Diabetes Association, ISIS, LLY, OREX, SNY

6/15-19: American Society for Mass Spectrometry

6/16-19: New Clinical Drug Evaluation Annual Meeting

6/16-19: American Society of Psychopharmacology, ALKS

6/18-21: American Orthopaedic Association/Canadian Orthopaedic Association Joint Meeting

6/18-21: European Heart Rhythm Association EUROSPACE

6/18-21: Int'l Society for Computer Assisted Ortho Surgery

6/18-21: International Society for Stem Cell Research

6/21-24: ENDO 2014

6/21-25: American Society for Virology

6/22-25: Healthcare Financial Management Association

6/23-26: Int'l Society on Thrombosis and Haemostasis

6/23-26: BIO International Conference

6/25-26: Bone Research Society

6/25-28: Federation of Clinical Immunology Societies

6/26-28: International Cancer Care Symposium

6/26-27: Plasma Protein Forum

6/26-29: American Headache Society

7/12-17: Alzheimer's Association

CORPORATE EVENTS

6/17: ACT/FRX M&A shareholder vote

6/17: Investor Meetings: MGLN, 8:30 a.m., NVS Day 1, 12:30 p.m.

6/18: Investor Meeting: NVS Day 2, 10:30 a.m.

6/24: WAG earnings release

6/25: MCK Investor Day

6/25: PRGO Proair Patent Trial

7/3: WAG monthly sales 7/9: SLXP Investor Day 7/10: VSTM R&D Day

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 03/31/14 IB Serv./Past 1 Mo: | | | | |
|-----------|---|---------|-------|---------|--|
| Rating | Count | Percent | Count | Percent | |
| BUY [OP] | 131 | 68.23 | 46 | 35.11 | |
| HOLD [MP] | 61 | 31.77 | 3 | 4.92 | |
| 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.

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