



Featured Research: AGIO, EW, HOLX, SNSS, Medical Devices-Orthopedics

Initiations: None | **Rating Changes:** None | **Price Target Changes:** AGIO | **Estimate Changes:** SNSS, AGIO
| **MEDACorp:** Medical Devices-Orthopedics

Reference Tools:

[Catalyst Tracker](#) | [Calendar of Events](#) | [HC Conferences](#) | [Earnings Rundown](#) | [Abbreviations & Acronyms](#) | [Leerink Events](#)

Leerink Events - Please contact your Leerink Partners representative for details

3/10: Corporate Access: Intra-Cellular, ITCI, Chicago

3/11: Corporate Access: Orexigen, OREX, Chicago

3/7: Corporate Access: Fluidigm Corporation: FLDM, Chicago

3/10: Corporate Access: OvaScience: OVAS, Los Angeles

3/10: Corporate Access: OvaScience: OVAS, San Diego

3/14: Corporate Access: Sunesis Pharmaceuticals, Inc.: SNSS, San Francisco

Today's Healthcare Events

Investor Meetings: MDCO, OPHT

Medical Meeting: Future of Genomic Medicine

Today's Research

Medical Devices-Orthopedics | *Richard Newitter*

2014 AAOS Warm-Up: Surgeon Hip/Knee Perspectives

Outperform: JNJ, SYK, WMGI, ZMH

• **Bottom Line:** Yesterday, we hosted a MEDACorp Pulse Call with a hip/knee specialist ahead of the upcoming American Academy of Orthopedic Surgeons (AAOS) in New Orleans (March 11-15). Overall, we expect that AAOS should serve as a positive catalyst for ortho stocks (ZMH [OP], SYK [OP], and WMGI [OP]) especially if physician feedback from the conference echoes the specialist's overall bullish outlook on procedure volume growth trends. From a product-specific standpoint, at AAOS, the specialist will be focused on: (1) robotics platforms (SYK/MAKO & BlueBelt), (2) bone graft technologies (he's interested in offerings from WMGI, though didn't specify which), and (3) new knee offerings from ZMH and JNJ (he's currently using SNN's Journey II).

- On pages 3-6, we also include MEDACorp feedback from our most recent Jan. US hip/knee survey.
- Specialist Highlights (1) ACA as Driver of Strong 4Q Hip/Knee Volumes & (2) Expectations for Rising Surgery Demand in 2014.
- Robotics an Area of Interest for This Physician...
- ...And With Respect to SYK/MAKO, specifically, he thinks MAKO in SYK's hands could enhance the technology's appeal.
- Pricing Remains Under Scrutiny at the Specialist's Institution.
- We also expect bicruciate knees to generate some buzz at AAOS this year.

Sunesis Pharmaceuticals, Inc. (SNSS) | *Marko Kozul, M.D.*

Combinability of Vosaroxin May Be Bigger than VALOR; 4Q13 EPS; Reit OP & \$17PT

Outperform | **Market Cap:** \$435.7M | **Price:** \$7.25 | **Price Target:** \$17.00 | **Methodology:** DCF analysis

• **Bottom Line:** While the near-term SNSS story will be driven by Vosaroxin Investigator Sponsored Trials (ISTs) and the 3Q14 pivotal AML Phase III VALOR trial readout, we believe the emerging bigger picture theme revolves around the drug's combinability and synergistic activity with established standards of care (SOC) initially for hematologic and

potentially solid tumor cancers. Non-randomized Phase II AML trials have already demonstrated attractive safety, response rates and survival benefits. The Phase III VALOR trial may soon confirm this in the context of relapsed/refractory AML (acute myelogenous leukemia) in combination with full dose cytarabine. Preliminary MD Anderson AACR-2014 abstract is highly suggestive of safe and synergistic combinability of Vosaroxin with Decitabine in older AML/MDS patients. Another IST ~YE14 may demonstrate this synergism with Vidaza in a broader set of MDS (myelodysplastic syndrome) patients. In the future there may be potential to combine Vosaroxin with solid tumor SOC's. Along with ALNY, CLVS, XLRN and RCPT (all rated OP), SNSS remains a top pick for us in 2014 and we reiterate our Outperform (OP) rating and \$17 price target (PT).

- 4Q13 EPS updates demonstrate that SNSS is positioned financially well beyond potential early Vosaroxin commercialization.
 - The MD Anderson MDS/AML Vosaroxin-Decitabine AACR-14 IST abstract demonstrates early synergistic efficacy vs. Decitabine monotherapy in AML/MDS and attractive safety.
 - **2014E EPS/REV:** (\$0.40) / \$8.0 → (\$0.48) / \$8.0
Revenues in MMs; non-GAAP EPS.
-

Agios Pharmaceuticals, Inc. (AGIO) | Howard Liang, Ph.D.

Earlier-Than-Expected Initial Clinical Data at AACR May Support Platform

Outperform | **Market Cap:** \$1,245.8M | **Price:** \$39.93 | **Price Target:** \$38.00 → \$51.00 | **Methodology:** NPV and Sum of the parts

- **Bottom Line:** AGIO announced initial Phase I data presentation for the lead candidate AG-221 in IDH2 mutant hematologic malignancies at the upcoming AACR (American Association for Cancer Research) conference. Although the abstract is still not available (to be released at 1pm, April 4), the data come substantially ahead of prior guidance (ASH) and in light of prior management statement that it only intends to present meaningful clinical data, it would appear to us that some activity has already been observed while the dose escalation continues and a maximal tolerated dose (MTD) has not been reached. We believe potential proof of principle data on the lead IDH2 inhibitor could have positive read-through on the IDH1 program (entering Phase I in early 2014) and could potentially provide valuable early clinical validation for AGIO's broader technology platform in cancer metabolism. With two more assets on track entering clinical development (AG-120, IDH1 inhibitor and AG-348, PKR activator), we believe AGIO is transforming into an interesting clinical story in 2014 with good amount of news flow in the next 1-2 years. We are increasing our valuation from \$38 to \$51 based on higher probability of success in clinical programs.
 - AG-221 initial data could be promising.
 - On track to initiate two trials for AG-120 (IDH1).
 - **2014E EPS/REV:** (\$1.77) / \$7.3 → (\$1.99) / \$20.5
Revenues in millions.
-

Edwards Lifesciences Corp. (EW) | Danielle Antalfy

Making Progress With First in Man Transcatheter Mitral Valve Implants

Outperform | **Market Cap:** \$8,048.6M | **Price:** \$72.51 | **Price Target:** \$80.00

- **Bottom Line:** This morning, EW announced the successful completion of the first three implants of the FORTIS transcatheter mitral valve repair (TMVR) in humans. Following the prolonged delay of first-in-man (FIM) implants due to regulatory approval timing, we view today's announcement as a positive step forward for EW and a critical milestone in what has historically been a difficult pipeline project given the complexity of the disease and the intricacies of the device. We view TMVR as a key driver of EW's long-term growth story but acknowledge that we are still a long way from commercialization, with a likely rigorous clinical trial program ahead that makes it unlikely the product comes to market for at least another 5-7 years. In the near-term, we expect that the initial outcomes from these FIM implants could be presented at medical meetings over the next year or so and will be an important driver of EW stock performance.
- We Expect Several More FIM Cases, Followed By A CE Mark Trial Possibly Later This Year/Early Next Year.
- Published 3/6/14, intra-day.

Hologic, Inc. (HOLX) | *Richard Newitter*

AMA CPT Panel Results a Positive First Step toward Formal Reimbursement

Outperform | **Market Cap:** \$5,953.6M | **Price:** \$21.61 | **Price Target:** \$25.00

• **Bottom Line:** HOLX this morning announced that its application for breast tomosynthesis was accepted for 3 Category I CPT codes at the February 6-8 AMA CPT Editorial panel. The company has been pursuing several routes on securing reimbursement, including (1) securing a G-code and lobbying payers, and (2) CMS coverage. Today's positive announcement represents a first step on the latter route (CMS reimbursement), but there are still a number of additional steps to be taken and agreed upon before reimbursement is formalized (if the subsequent steps have positive outcomes, the new CPT codes would be implemented Jan 1, 2015). Ultimately, we think it will come down to how CMS chooses to (or not to) recognize/incorporate pricing, language and recommendations with respect to the current 2D coding framework (i.e., how much of an additional payment will be given for 3D vs. 2D). We continue to believe that Tomo adoption will be one of the key primary drivers in HOLX's growth acceleration, and while reimbursement is still important to adoption, current guidance for accelerating tomo sales (>500 placements expected in FY14) is not predicated on the creation of a formal code.

- The Next Step is a RUC Panel (Relative Value Scale [RVS] Update Committee),
- Published 3/6/14, intra-day.

Research Previews

March 7 – OPHT Investor Meeting - NYC

OPHT – OP – Joe Schwartz

Close: \$38.25, Mkt Cap: \$1,285M

- OPHT will provide details on the underlying science and its development strategy for the ongoing Fovista Phase III and its plans to develop Zimura in both wet and dry AMD.
- Overall 10 clinical trials are ongoing or expected to be initiated in 2014, leading to data beginning to emerge in 2015.

ACHN – OP – Howard Liang

Close: \$3.43, Mkt Cap: \$638M

- 4Q13A EPS/Revs: -\$0.20/\$0. Cash of \$159M
- 4Q13E Leerink EPS/Rev: -\$0.20 / \$0
- 4Q13E Street EPS/Rev: -\$0.18 / \$0.0M
- '14 Guidance: EPS of -\$0.70, R&D of \$55-60M and Opex of \$60-65M
- 2014E Leerink EPS/Rev: -\$0.76 / \$0.0
- 2014E Street EPS/Rev: -\$0.77 / \$0.0

March 10 – Earnings – After the Close

ONTX – OP – Howard Liang

Close: \$7.89, Mkt Cap: \$174M

- 4Q13E Leerink EPS/Rev: -\$0.95 / \$1.1M
- 4Q13E Street EPS/Rev: NA / \$1.1M
- 2014E Leerink EPS/Rev: -\$2.36 / \$27.1M
- 2014E Street EPS/Rev: -\$2.30 / \$13.6M
- **CC:** 4:30pm EST; **Dial-in:** 877 312-5881, **Access Code:** 9033414

March 11 – Earnings – Before the Open

ICEL – MP – Dan Leonard**Close: \$15.46, Mkt Cap: \$239M**

- 4Q13E Leerink EPS/Rev: -\$0.39 / \$4.0
- 4Q13E Street EPS/Rev: -\$0.30 / \$4.0M
- 2014E Leerink EPS/Rev: -\$1.32 / \$26.3M
- 2014E Street EPS/Rev: -\$1.13 / \$28.7M
- **CC:** 8:00am EST; **Dial-in:** 877 312-5886, **Access Code:** 3865935

March 11 – Earnings – After the Close**OGXI – OP – Howard Liang****Close: \$12.29, Mkt Cap: \$192M**

- 4Q13E Leerink EPS/Rev: -\$0.40 / \$9.9M
- 4Q13E Street EPS/Rev: -\$0.48 / \$10.0M
- 2014E Leerink EPS/Rev: -\$1.80 / \$25.0M
- 2014E Street EPS/Rev: -\$1.77 / \$32.5M
- **CC:** 4:30pm EST; **Dial-in:** 877 606-1416, **Access Code:** --

March 12 – Earnings – After the Close**OREX – OP – Marko Kozul****Close: \$6.99, Mkt Cap: \$443M**

- 4Q13E Leerink EPS/Rev: -\$0.18 / \$1.0M
- 4Q13E Street EPS/Rev: -\$0.19 / \$0.9M
- 2014E Leerink EPS/Rev: -\$0.55 / \$3.4M
- 2014E Street EPS/Rev: -\$0.47 / \$121.7M
- **CC:** 5:00pm EST; **Dial-in:** 888 895-5479, **Access Code:** 36782629

March 21 – WLP Investor Day – NYC**WLP – OP – Ana Gupte****Close: \$91.52, Mkt Cap: \$27,096M**

- We view WLP's analyst day as an important catalyst for the stock, it's their first investor day in 2 years and the first with a new CEO.

March 29-31 – American College of Cardiology – Washington, DC**MDT – MP – Danielle Antalfy****Close: \$59.77, Mkt Cap: \$47,102M**

- MDT will present high risk CoreValve data at the ACC medical meeting.
- With CoreValve now launching in the U.S. in the Extreme Risk patient population – only the second company to get U.S. TAVR approval – we view MDT as well-positioned to drive accelerating sales growth within its Structural Heart businesses.

Previous Notes**March 6**

- [ARQL/4Q:13 Update Better Defines Phase III Timelines and 2014 News Flow/Outperform](#), Howard Liang
- [Flash -- AZN/AACR Could Make It a Hat-trick of Interesting Medical Mtgs for AZN in 2Q:14/Outperform](#), Seamus Fernandez
- [KPTI/4Q13 Recap - Selinexor Development Broadening; Increasing Price Target/Outperform](#), Michael Schmidt

MNTA/MS Survey Validates Copaxone Switch Strategy; Oppty Still Big Enough for M-356/Outperform, Jason Gerberry

RCPT/Two Mid-14 Catalysts; Adding 1063 UC Revenues to Model Drives New \$60 PT/Outperform, Marko Kozul
SNSS/Encouraging AACR-14 Vosaroxin MDS/AML Abstract Drives our New \$17 PT; Reit OP/Outperform, Marko Kozul

TEVA/Signs of Cash Flow Stability Suggest M&A Activity Likely to Accelerate/Outperform, Jason Gerberry

Flash -- UAM/4Q13: EPS Miss of 5c on Modest Revenue Beat; High Expenses Offset Lower MLR/Market Perform, Ana Gupte

ZGNX/In-line 4Q & No Major Zohydro Updates; We Remain OP/Outperform, Jason Gerberry

Life Science Tools and Diagnostics/Recent Diligence Highlights Pockets of Growth for Mass Spec, Dan Leonard

Managed Care/Another Fix to Obamacare: Implications of Extension on Non-Compliant Policies, Ana Gupte

Flash -- Managed Care/2015 Obama Budget Cuts: Pharma, Post-Acute Impacted; MA Reductions Manageable, Ana Gupte

Managed Care/4Q13 Review: Not the Quiet Quarter That Was Hoped For, Ana Gupte

Updated Models: ARQL - Model, CLDX - Model, DNDN - Model, GTXI - Model, HNT - Model, KPTI - Model, RCPT, RIGL - Model, SNSS - Model UNH - Model, ZGNX - Model

AACR (4/5-9) Preview Notes

Flash -- AZN/AACR Could Make It a Hat-trick of Interesting Medical Mtgs for AZN in 2Q:14/Outperform, Fernandez

SNSS/Encouraging AACR-14 Vosaroxin MDS/AML Abstract Drives our New \$17 PT; Reit OP/Outperform, Kozul

Pharmaceuticals/ Major/AACR Preview: CDK 4/6 & MRK's IO Presentations Set the Pre-ASCO Table, Fernandez

Leerink Partners 2014 Global Healthcare Conference

Managed Care/Takeaways from our 2014 GHC Conference: Panel on Exchanges, Ana Gupte

Medical Supplies and Devices/Takeaways from 2014 Leerink Global Healthcare Conference, Antalfy/Newitter

Pharmaceuticals / Major/Takeaways from Our 2014 Global Healthcare Conference, Seamus Fernandez

Biopharma/Takeaways from Our 2014 Global Healthcare Conference: Immuno-oncology, Fernandez/Liang/Schmidt

Biopharma/Takeaways from our Global Healthcare Conference - The Hepatitis C Panel, Howard Liang

Biotechnology/Takeaways from our 2014 Global Healthcare Conference, Michael Schmidt

Biotechnology/Takeaways from our 2014 Global Healthcare Conference, Joe Schwartz

Biotechnology/Takeaways from our 2014 Global Healthcare Conference, Marko Kozul

Specialty Pharmaceuticals/Takeaways from our 2014 Global Healthcare Conference, Jason Gerberry

Life Science Tools and Diagnostics/Takeaways from our 2014 Global Healthcare Conference: Clinical NGS, Dan Leonard

HCIT/Takeaways from our 2014 Global Healthcare Conference, Dave Larsen

Deep Dive Analyses

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

Recent Surveys

TEVA/Signs of Cash Flow Stability Suggest M&A Activity Likely to Accelerate/Outperform, Jason Gerberry

Managed Care/Broker Survey Points to Stable Market for 2014, Shifts to Exchanges in 2015, Ana Gupte

KYTH/Survey Reactions to ATX-101 Validate Expectations for Successful 2015 Launch/Outperform, Seamus Fernandez

Medical Supplies and Devices/Hemophilia Physician Survey: BAX Share Loss Likely in Line with Estimates, Danielle Antalfy

[AGN/4Q:13 Cosmetic Survey Highlights Stable Growth Trends, Cont'd AGN Strength/Market Perform](#), Seamus Fernandez

[Medical Devices-Orthopedics/Hip/Knee Survey Highlights 4Q Seasonality & Possible Positive Sign for 1H14](#), Richard Newitter

[EW/TAVR Survey Suggests Weak 4Q13, Supports Long-Term Market Potential/Outperform](#), Danielle Antalffy
[Pharmaceuticals/ Major/MEDACorp Diabetes Survey: Solid SGLT2 Prospects & A Tough Januvia \(MRK\) Outlook](#), Seamus Fernandez

[Life Science Tools and Diagnostics/Survey Offers Mixed Feedback on Forthcoming Sequencing Demand](#), Dan Leonard

White Papers

[Specialty Pharmaceuticals/ Generics/Future of Respiratory Generics - Next Major Generic Product Class](#), Jason Gerberry, JD

[Medical Devices-Orthopedics/The Future Of Growth & Innovation In US Extremities Ortho Reconstruction](#), Rich Newitter

[Biotechnology/Future of Dynamic Multiple Sclerosis Landscape](#), Marko Kozul, M.D.

[Healthcare IT & Distribution/The Future of HCIT Population Health Management](#), Dave Larsen

[Life Science Tools and Diagnostics/The Future of DNA Sequencing](#), Dan Leonard - Life Science Tools and Diagnostics

[Biopharma/Future of Cancer Treatment - Immuno-Oncology](#), Seamus Fernandez

[Biopharma/Future of Orphan Drugs: Neuro Nirvana](#), Joseph P. Schwartz - Biotechnology

[Biopharma/Future of Hepatitis C Treatment](#), Howard Liang, Ph.D. - Biotechnology

[Medical Devices-Cardiology/Future of Atrial Fibrillation](#), Danielle Antalffy - Medical Devices

Upcoming Healthcare Events

Regulatory Events

3/12: FDA AdCom: Microbiology Devices

3/14: FDA AdCom: Ophthalmic Devices

Medical Meetings

3/2-6: Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy

3/6-7: Future of Genomic Medicine

3/8-9: American Academy of Pain Medicine

3/6-10: European Congress of Radiology

3/9-12: Healthcare Distribution Management Association

3/11-12: International Plasma Protein Congress

3/11-15: American Academy of Orthopaedic Surgeons, SYK, WMG, ZMH, See our note: [2014 AAOS Warm-Up: Surgeon Hip/Knee Perspectives](#)

3/12-14: Society for the Immunotherapy of Cancer

3/12-15: Society of Surgical Oncology

3/12-16: National Comprehensive Cancer Network

Corporate Events

3/7: OPHT Investor meeting

3/7: MDCO Investor meeting

3/12: SIAL Business Update Call

Disclosures Appendix

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Distribution of Ratings/Investment Banking Services (IB) as of 12/31/13				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	118	64.50	30	25.00
HOLD [MP]	65	35.50	2	3.00
SELL [UP]	0	0.00	0	0.00

Explanation of Ratings

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

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

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

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

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