

MORNING ROUNDS

**TODAY'S HIGHLIGHTS / DECEMBER 10,
2014**

TODAY'S RESEARCH:
IMGN, MANAGED CARE, EARS

INITIATIONS: NONE / **RATING CHANGES:** NONE / **PRICE TARGET
CHANGES:** NONE / **ESTIMATE CHANGES:** EARS / **MEDACORP:**
MANAGED CARE / **PREVIOUS RESEARCH:** GWPH, KPTI, ALNY, EW, FGEN

REFERENCE TOOLS:

[Catalyst Tracker](#)

[Earnings Rundown](#)

[Abbreviations & Acronyms](#)

[Calendar of Events](#)

[HC Conferences](#)

[Leerink Events](#)

MORNING PRIMER:

Futures (as of 6:30am): DJIA: -71.00 (17,851); S&P500: -0.75 (2,058); NASD
-1.75 (4,291)

LEERINK EVENTS:

12/10: Investor Tours / Site Visits: Devices & DNA Bus Tour: AFFX, A, CDNA, CPHD, DXCM, EW, FLDM, GHDX, INGN, XENT, ISRG, MDT, NUVA, TECH, THOR, VCYT, VOLC, ZLTQ, California

12/10: Corporate Access: Immune Design Corp.: IMDZ, San Diego

12/11: Investor Tours / Site Visits: Devices & DNA Bus Tour: AFFX, A, CDNA, CPHD, DXCM, EW, FLDM, GHDX, INGN, XENT, ISRG, MDT, NUVA, TECH, THOR, VCYT, VOLC, ZLTQ, California

12/11: MEDACorp Pulse Call: Future Role of ASBT Inhibitors in Treatment of Liver Disease, 11:00AM EST

12/12: Corporate Access: Medivation Inc.: MDVN, San Antonio

12/15: Corporate Access: Acceleron Pharma Inc.: XLRN, Boston

12/16: Corporate Access: Acceleron Pharma Inc.: XLRN, New York

12/17: Corporate Access: Zafgen Inc: ZFGN, Chicago

12/17: Corporate Access: Insmmed Incorporated: INSM, Dallas

12/19: MEDACorp Pulse Call: Increased Political Scrutiny on Generic Inflation – Likely Drivers and Outcomes, 10:00AM EST

TODAY'S HEALTHCARE EVENTS:

MEDICAL MEETINGS:

12/6-10: American Society of Cell Biology

12/7-11: American College of Neuropsychopharmacology

12/7-11: mHealth Summit

12/9-13: San Antonio Breast Cancer Symposium (CELG, MDVN, MRK, Roche)

CORPORATE EVENTS:

12/10: Investor Meetings: BMRN, SHPG

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

IMMUNOGEN, INC. (IMGN) / MICHAEL SCHMIDT, PH.D.

Incremental ASH 2014 Updates on IMGN529 and BT062

Outperform / **Market Cap:** \$875.3M / **Price:** \$10.19

- **Bottom Line:** IMGN presented an update at ASH on the Phase I trial of IMGN529, an anti-CD37 antibody-drug conjugate (ADC), which is being evaluated in patients with relapsed/refractory non-Hodgkin's lymphoma (NHL). We continue to view the safety data from this update as mixed and remain cautious on IMGN529 despite the fact that IMGN529 does have strong early signs of activity, especially in patients with diffuse large B-cell lymphoma (DLBCL). An incremental update was presented on partnered compound BT062 (anti-CD138 ADC, Biotest AG) in relapsed/refractory multiple myeloma in which IMGN has opt-in rights. We believe BT062 data look promising. Next up will be top-line Kadcyla data from Roche's MARIANNE trial expected by year-end. **Maintain OP.**
- IMGN529 (anti-CD37 ADC) shows good early signs of activity.
- But IMGN529 safety data remain mixed.
- BT062 (anti-CD138 ADC) in combination with lenalidomide/dexamethasone (Len-Dex) continues to show promising data in earlier lines of therapy for relapsed/refractory multiple myeloma.

MANAGED CARE / ANA GUPTE, PH.D.**2015 Broker Survey; Public Exchanges Winning; Self-Insured Growth Continues****Outperform:** AET, ANTM, CI, HUM, UNH / **Market Perform:** HNT

- **Bottom Line:** We commissioned a MEDACorp survey of 65 fully insured Health Insurance brokers to gain insight into the ongoing transition within the channel of distribution for Employer Health benefits, as the employer mandate takes effect for 100+ worker employer groups, and the Supreme Court hearing creates uncertainty on the viability of Public Exchanges. The survey pointed to an evolution rather than a revolution in 2015 with over half to two-thirds of fully insured employers reported as continuing with group fully insured benefits in 2015. Early renewals remain the primary employer choice for health benefits, followed by mix shifts from group fully insured to self-insured and Public Exchanges. Private Exchanges are reported to be seeing little traction, consistent with 2015 broker/consultant membership statistics from AON Hewitt and recent health insurer commentary. We see the results as most positive for UNH (OP) given the top ranking given by a majority of the surveyed brokers to its products in both self-insured and fully insured group offerings and the cited preference for early renewals in 2015, which is its favored strategy. The survey is also positive for CI (OP) given the continued uptake of self-insured and the positive broker commentary on the strength of its self-insured offerings. We view the survey as modestly positive for ANTM (OP) and AET (OP), which should see a secular membership tailwind in Public Exchanges, though ANTM's product offerings were seen more favorably than those of AET.
- Shifts in the Employer Health insurance market continue, though the pace is evolutionary rather than revolutionary with over half to two-thirds of employers cited as staying with group fully insured health benefits in 2015.
- The transition to Public Exchanges continues and is expected to further accelerate past 2015.
- Little traction reported in Private Exchanges with only 5-7% of employers in the fully insured groups reported to be opting into them.
- Interestingly, mix shifts to self-insured were reported to be continuing, with close to a fifth of employers in the 101-500 worker groups opting for this, and as much as a fifth of employers even in the 51-100 groups seeking this option.
- Not-for-Profit Blue Cross Blue Shields are the winners with the best fully insured product and second only after UNH in the Self-Insured product categories.

AURIS MEDICAL HOLDING AG (EARS) / JOSEPH P. SCHWARTZ**3Q Recap: AM-101 on Track for Phase III Futility Analysis in 1Q15****Outperform / Market Cap:** \$138.3M / **Price:** \$4.61 / **Price Target:** \$10.00 / **Methodology:** DCF analysis with a 12% discount rate

- **Bottom Line:** We are updating our model to reflect 3Q14 results. Late-stage development of AM-101 remains on track to produce pivotal data from TACTT2 and TACTT3 studies in early 2016 with an interim futility analysis from the "Stratum B" arm of TACTT3 study scheduled for 1Q15. **Reiterate Outperform rating and \$10 price target on EARS.**

- EARS is getting close to completing the registration of clinical trial sites for the two Phase III trials (TACTT2 in North America and TACTT3 in Europe) for AM-101 in acute inner ear tinnitus with the last site expected to accrue in 1Q15.
- In 1Q15, the pre-specified interim analysis for futility testing in "Stratum B" of the TACTT3 trial is likely to present the first news flow from the Phase III program for AM-101.
- EARS has now received formal feedback and guidance from FDA on the pre-IND dataset for AM-111 in Acute Sensorineural Hearing Loss (ASNHL) as it prepares to embark upon late-stage development.
- **2014E EPS/REV:** (1.00) / 0.0 → (0.91) / 0.0
- **2015E EPS/REV:** (1.01) / 0.0 → (1.10) / 0.0

PREVIOUS DAY NOTES:

FIBROGEN, INC. (FGEN) / HOWARD LIANG, PH.D.

Late-Stage Story with Transformative Potential in a Large Market; Initiate OP

Outperform / **Market Cap:** 1,587.6M / **Price:** \$28.00 / **Price Target:** \$52.00 / **Methodology:** DCF & sum of the parts using probability weighted revenues and 10% discount rate

- **Bottom Line:** We are initiating coverage of FGEN with an Outperform rating and price target of \$52. FGEN is a leader in developing novel agents targeting fibrosis and hypoxia pathways for the treatment of anemia and fibrotic diseases.
- Lead candidate roxadustat has a potential to be a transformative product in a large market. Roxadustat, a first-in-class prolyl-hydroxylase (PHD) inhibitor, mimics the body's natural response to hypoxia (low oxygen) conditions and has been shown in a large Phase II program involving nearly 1,300 patients to be safe and effective in treating anemia in patients with chronic kidney disease (CKD). Erythropoietin-stimulating agents (ESAs)
- The key investor concerns appear to be whether roxadustat is safe and whether there are safety liabilities associated with PHD inhibition and stabilizing hypoxia-inducible factor (HIF).
- We believe FibroGen is employing the right strategy in targeting the rapidly growing Chinese market.
- A source of potentially large upside may be the wholly owned anti-fibrotic compound.
- **2014E EPS/REV:** (\$0.84) / \$141.5
- **2015E EPS/REV:** (\$0.80) / \$202.0

Revenues in \$M; GAAP EPS presented; IPO 11.13.14

PREVIOUS NOTES:

GW PHARMACEUTICALS PLC (GWPH) / PAUL MATTEIS

Dinner with Mgmt and Epilepsy KOLs Highlights Compelling Epidiolex Anecdotes

Outperform / **Market Cap:** 1,427.0M / **Price:** \$69.61 / **Price Target:** \$110.00 / **Methodology:** Sum-of-the-parts DCF, 11% discount rate, 2% terminal growth rate

KARYOPHARM THERAPEUTICS, INC. (KPTI) / MICHAEL SCHMIDT, PH.D.**Positive Takeaways for Selinexor from ASH 2014 Presentations**Outperform / **Market Cap:** \$1,496.7M / **Price:** \$45.91**ALNYLAM PHARMACEUTICALS, INC. (ALNY) / MICHAEL SCHMIDT, PH.D.****Incremental ASH Updates for ALN-AT3 and ALN-CC5**Outperform / **Market Cap:** \$8,087.9M / **Price:** \$106.42**EDWARDS LIFESCIENCES CORP. (EW) / DANIELLE ANTALFFY****Analyst Day Balances Significant LT Growth With NT Conservatism; PT to \$155**Outperform / **Market Cap:** \$14,322.9M / **Price:** \$132.13 / **Price Target:** \$142.00 → \$155.00 / **Methodology:** ~32.7x our \$4.75 2016E EPS**RESEARCH PREVIEWS:****December 10 – SHPG R&D Day****SHPG – MP – Jason Gerberry****Close: \$206.28, Mkt Cap: \$27,509M**

- We expect SHPG's R&D Day to provide some incremental data for key pipeline products to help investors get more comfortable with mgmt's 2020 revenue guidance, which calls for \$3B in pipeline sales and \$800M in life cycle extension product sales.
- R&D Day focal points include:
- Lumena (May 2014 acquisition) assets for liver disease, with important Ph II data readouts throughout 2015.
- Premiplex for retinopathy of prematurity (ROP) -- a potentially transformative drug, with key de-risking Ph II data expected in late 2015.
- Lifitegrast for dry eye disease, for which the Ph III OPUS-3 was recently initiated to resolve mixed results from two previous Ph III studies. We recently increased our probability of success for Lifitegrast.
- See our note, [SHPG/R&D Day Preview: Bridging Gap Between Street Ests & 2020 Guidance/Market Perform](#)

December 12 – Senza-RCT Data (Back and Leg Pain) at NANS**NVRO – OP – Danielle Antalffy****Close: \$34.20, Mkt Cap: \$880.5M**

- NVRO is expected to present data from its Senza-RCT trial at the North American Neuromodulation Society (NANS) annual meeting (12/11-14).
- Though the data was released as part of its S1 filing for IPO, the complete dataset is expected to be released during the late-breaking clinical trial sessions at NANS.

- Senza-RCT is an 11-site, 241-patient randomized control trial that showed non-inferiority to BSX' Precision Plus SCS system, which was used as a control in the study.
- Post-hoc analysis of the data showed that NVRO's Senza is superior to the control in both back & leg pain.
- In late-2015/early-2016 (possibly after a FDA panel), NVRO expects FDA approval for its highly differentiated Senza SCS (spinal cord stimulation) system to treat chronic pain in the current \$1.5B global SCS market.

PREVIOUS NOTES:

UPDATED MODELS: [ARRY - Model](#), [MDT - Model](#), [SYK - Model](#), [ZMH - Model](#)

AMERICAN SOCIETY OF HEMATOLOGY (12/6-9)

[Biopharma/2014 ASH Itinerary Planner](#)

[Biopharma/ASH Preview Series: Takeaways from Lymphoma and CLL Call](#), Liang, Fernandez, Schmidt

[Biopharma/ASH Preview Series: Takeaways from MDS and Leukemia Call](#), Liang, Schmidt

[Biopharma/ASH Preview Series: Takeaways from Our Multiple Myeloma Call](#), Liang, Schmidt

[Biotechnology/ASH Preview Series: Takeaways from Our APS Call on Myeloproliferative Neoplasms](#)

[Biopharma/Takeaways from ASH 2014 Abstracts](#)

[Biopharma/ASH Abstracts: Impressive PD1 Responses in Hodgkin's w/ Activity in NHL](#)

[Biotechnology/ASH Abstracts - Updates for Companies Under Our Coverage](#)

SURVEYS

[Survey Offers Insight Into Bacteria, Yeast Testing Trends](#), Dan Leonard

[Biopharma/COPD Survey Suggests Slow Uptake for Breo and Anoro but Solid Long-Term Outlook](#), Biopharma Team

[Managed Care/'15 Comm. Pricing Survey; Publics Hardening; NFPs Mixed; Raising AET '15E EPS](#), Ana Gupte

[Biotechnology/MS Survey Highlights Strong Growth Outlook for Tecfidera, RPC1063](#), Joe Schwartz

[SIEN/Shaking Up The US Breast Product Mkt -- A Growth Story That "Gels"; Initiate OP/Outperform](#), Rich Newitter

[KYTH/3Q14 Survey Results: Physicians' Anticipation of ATX-101 Continues to Build/Outperform](#), Seamus Fernandez

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](#)

HEALTHCARE SERVICES ROUNDTABLE

[Healthcare IT & Distribution/Takeaways from Healthcare Services Roundtable](#), Dave Larsen

[Healthcare Services/Healthcare Policy Views from the Hill: Key Takeaways From Services RT Panel](#), Ana Gupte

[Healthcare Services/Paradigm Shifts to Value-Based Care Are Real: Takeaways from Recent Services RT](#), Ana Gupte

RARE DISEASE ROUNDTABLE

[Biotechnology/Orphan Drug Regulatory and Reimbursement Panels Project Continued Flexibility](#), Joe Schwartz

[Biotechnology/Takeaways from Rare Disease Roundtable](#), Howard Liang

[GWPH/Dinner With Management Previews Next Epidiolex Readout, Thoughts on Competition/Outperform](#), Paul Matteis

[AEGR/Dinner With Management Provides Insights on US Launch, PCSK9, Ex-US Biz/Outperform](#), Joe Schwartz

[Biotechnology/Takeaways from Rare Disease Roundtable on RNAi/GeneTx Stocks Under Our Coverage](#), Michael Schmidt

HEALTHCARE INSIGHTS CONFERENCE

[Healthcare/Healthcare Insights: Identifying the Industry's Key Trends & Growth Drivers](#), This Compendium Report from the Conference includes all the individual reports listed below.

[Biopharma/Investment Insights from Lymphoma/CLL Panel](#)

[Biopharma/Investment Insights from HCV Panel: Growing Patient Pool Bullish for Launches](#)

[Biopharma/Key Stock Impacts from Our Therapeutics Panels](#)

[Biopharma/Investment Insights from the IO and Targeted T-Cell Therapy Panel](#)

[Biopharma/Investment Insights from the Lung Cancer Panel](#)

[Biopharma/Investment Insights from the Breast Cancer Panel](#)

[Biotechnology/Investment Insights from Liver Disease Panel: Cautious on ICPT's OCA](#)

[Medical Supplies and Devices/Investment Insights from the MIS/Robotics Surgery Panel](#)

[Healthcare IT & Distribution/Investment Insights from the HCIT Panel: Robust Replacement Markets](#)

[Healthcare IT & Distribution/Investment Highlights from PBM Panel: Service Challenges Weigh on ESRX](#)

[Managed Care/Investment Insights from the Managed Care Panel on the Future of ACOs](#)

[Life Science Tools and Diagnostics/Investment Insights from Nextgen Seq Dx Panel: Clinical Growth Opportunity](#)

[STJ/Investment Insights from the CardioMEMS Panel: Large Market; Gradual Ramp/Outperform](#)

LONG SHELF LIFE REPORTS

[Digital Health/Future of Digital Health](#), Steven Wardell

[SHPG/Est. Brands & Lean Spending Drive Strong 3Q; Remain MP/Market Perform](#), Jason Gerberry

[Healthcare Facilities/Puts & Takes in Dynamic Landscape of Reform & Recovery; UHS, CYH, HCA OP](#), Ana Gupte

[ISRG/Higher Confidence In Procedure Acceleration & Xi; Upgrade To OP/Outperform](#), Rich Newitter

[Biopharma/Future of Treatment of Lymphoid Malignancies](#), Howard Liang

[GWPH/Deep Dive on GWP42003 for UC: Cannabis Anecdotes Reminiscent of CBD in Epilepsy/Outperform](#), Paul Matteis

[Biopharma/P&A V - Partnerships & Acquisitions in Biopharma: Our New Top Ten List](#), 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

12/15: NVS Ceritinib (NSCLC) PDUFA

12/18: FDA AdCom: Joint Meeting of the Bone, Reproductive and Urologic Drugs and the Drug Safety and Risk Management Committees

12/21: ENTA Paritaprevir (HCV) PDUFA

12/30: VRTX Kalydeco Cystic Fibrosis - R117H mutation sNDA PDUFA

1/3: AZN, Olaparib (ovarian cancer) PDUFA

1/4: ACT, Nemedra-ER (Alzheimer's) PDUFA

1/8: IPXL, Rytary(Parkinson's) PDUFA

1/22: Anti-Infective Drugs Advisory Committee Meeting

1/24: NPSP, Natpara (hypoparathyroidism) PDUFA

MEDICAL MEETINGS

12/11-14: North American Neuromodulation Society (NVRO)

1/8-1/11/15: Consumer Electronics Show

1/10-1/14/15: Plant and Animal Genome

1/14-1/17/15: Scientific Meeting of American Academy of Cosmetic Surgery

1/15-1/17/15: Gastrointestinal Cancers Symposium

1/16-1/18/15: American College of Surgeons

1/17-1/21/15: Society of Critical Care Medicine

1/21-1/24/15: American Association for Hand Surgery

1/24-1/28/15: Society of Thoracic Surgeons

1/31-2/3/15: Annual Dialysis Conference

CORPORATE EVENTS

12/11: Investor Meetings: AET, ATHN, See our recent [note](#)

12/12: Investor Meetings: ALNY, CNC, TBPH

12/16: 2015 Guidance: MGLN

12/17: Investor Meeting: OVAS

12/23: Earnings BMO: WAG

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 09/30/14				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	138	69.30	51	37.00
HOLD [MP]	61	30.70	2	3.30
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.

Important Disclosures

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