

MORNING ROUNDS

TODAY'S HIGHLIGHTS / JUNE 11, 2014

TODAY'S RESEARCH:

MANAGED CARE, ELOS, HEALTHCARE,
ACHN

INITIATIONS: NONE / **RATING CHANGES:** NONE / **PRICE TARGET CHANGES:** NONE / **ESTIMATE CHANGES:** ELOS / **MEDACORP:** MANAGED CARE, ALDR / **PREVIOUS RESEARCH:** ALDR, PHARMACEUTICALS/ MAJOR, MRK, BIOPHARMA, FLDM

REFERENCE TOOLS:

[Catalyst Tracker](#)

[Earnings Rundown](#)

[Abbreviations & Acronyms](#)

[Calendar of Events](#)

[HC Conferences](#)

[Leerink Events](#)

MORNING PRIMER:

Futures (as of 6:30am): DJIA: +6.00 (16,936); S&P500: -6.25 (1,950); NASD -11.75 (3,800)

LEERINK EVENTS:

6/12: MEDACorp Pulse Call: ADA Preview: Assessing a Dynamic and Changing Competitive Landscape for Devices in Diabetes, New York, 2:00PM EDT

6/16: MEDACorp Event: UPDATE FROM ADA: BREAKFAST WITH MEDACorp KOL, San Francisco

6/16: MEDACorp Event: ADA FLOOR TOUR: ASSESSING THE COMPETITIVE LANDSCAPE AND FUTURE TRENDS FOR DEVICES IN DIABETES, San Francisco

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

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

TODAY'S HEALTHCARE EVENTS:

FDA: AdCom: Anesthetic and Analgesic Drug Products, SNY Cerdelga (Gaucher's Disease) PDUFA

MEDICAL Meetings: American Medical Association; International Conference on Complement Therapeutics; European Academy of Allergy and Clinical Immunology; European League Against Rheumatism; European Cystic Fibrosis Society; America's Health Insurance Plans; International Congress of Parkinson's Disease and Movement Disorders; Society of Nuclear Medicine and Molecular Imaging

TODAY'S RESEARCH:

MANAGED CARE / ANA GUPTE, PH.D.

MEDACorp PCP Pulse Call Highlights Healthcare Volume Uptick From ACA

Outperform: AET, CNC, HUM, WCG, WLP / **Market Perform:** HNT, MOH, UNH

- **Bottom Line:** We hosted what we believe was a market moving call on June 5 with three Primary Care Physicians (PCP) that offered real-time color on healthcare utilization trends. Overall, our panel confirms the recent MEDACorp survey results that the Affordable Care Act (ACA) is a driving up healthcare volumes within hospitals and labs from newly insured through Medicaid expansion and Exchanges. We see Medicaid expansion lives as likely to be modestly profitable for Managed Care (MC) as well, given the 50-200% higher premiums for expansion lives as compared to existing Medicaid favoring MOH (MP), HNT (MP), WLP (OP), UNH (MP), WCG (OP), CNC (OP), and AET (OP). For Exchanges, the generous 3Rs limit downside in 2014 with likely positive margin contribution in 2015. The panel and survey do not offer conclusive evidence that the economic recovery is not also driving up per capita healthcare consumption, though we are of the opinion that the healthcare volume slowdown to date is at least in part structural from high member cost share and increased risk bearing by providers.
- The call offered real-time color while reinforcing the results of our 36 PCP utilization survey published at the end of April that healthcare volumes are ticking up 5-10% from newly insured with access expansion.
- New patients sourced from Medicaid predominantly in California, and from Exchanges in Chicago, IL and New York, with our broader survey citing over 50% of the new volume from Medicaid expansion.
- Hospitals are likely to see a tailwind from the new volumes in California with a corresponding increase in inpatient bed days in Illinois, confirming earnings growth from volumes in addition to lower bad debt from a lower percentage of self paying patients.
- We continue to see Managed Care as attractive with Medicaid members likely to be low-single-digit margin profitable on a normalized basis given the 50-200% higher premiums for expansion lives as compared to legacy Medicaid. Exchange margins are protected from downside with the generous 3R regulations in 2014.

- PCP panel not designed to research per capita healthcare cost trends from an economic recovery after the weather tailwind in 1Q has subsided with a specialist survey a better vehicle to explore that controversy.

SYNERON MEDICAL LTD. (ELOS) / RICHARD NEWITTER

Management Mtg Takeaways: UltraShape, New Rep Hires & Recurring Rev in Focus

Outperform / **Market Cap:** \$392.7M / **Price:** \$10.70 / **Price Target:** \$16.00 / **Methodology:** ~1.8x EV/15E Sales

- **Bottom Line:** Recent investor meetings with Chairman Shimon Eckhouse leave us reinforced in our view that key long-term sales/profit drivers---e.g., UltraShape, elure, Unilever JV, sales force investments, increasing consumables rev---should all position ELOS for improved sales/profitability growth over time. We reiterate our OP rating and \$16 PT and continue to see favorable risk reward at current valuation levels.
- UltraShape Represents an Important Incremental Sales Momentum Driver for 2015 and Beyond.
- 2014 Sales Force Investments Should Have Increasing Payoff in 2015 and Beyond.
- Driving Toward 50/50 Recurring Revenue Model.
- We are making some slight adjustments to our '14E P&L.
- **2014E EPS/REV:** \$0.27 / \$245.6 → \$0.26 / \$245.6

We present EPS on a non-GAAP basis. Rev in MM

HEALTHCARE /

Catalyst Tracker Previews Top 2H14 Catalysts – 6.10.14

Outperform: ABC, ABMD, ACOR, ACT, AET, ALDR, ALKS, ALNY, AMAG, ANTH, ARNA, ARRY, ATRC, AUXL, BAX, BIIB, BMRN, BMY, CAH, CBST, CELG, CEMP, CERU, CI, CLDX, CLVS, CNC, CORI, CSII, CYNO, CYTK, DRNA, EBIO, ELOS, ENDP, ENTA, EPZM, EW, FLDM, FMI, FRX, GILD, GMED, GWPH, HOLX, HPTX, HUM, IDIX, INCY, INSM, JNJ, KIN, KYTH, LLY, LMNX, MCK, MDVN, MGNX, MNTA, MRTX, MYL, NBIX, NPSP, NSTG, NUVA, NVS, NXTM, OGXI, OMED, ONTX, OREX, PBYI, PKI, PDD, QURE, RCPT, REGN, RIGL, RNA, RPTP, SGEN, SHPG, SLXP, SNSS, SPS, STJ, SYK, TEVA, THOR, THRX, TMO, TSRO, UNIS, VCYT, VRTX, VSTM, VVUS, WCG, WLP, WMGI, XLRN, XNCR, XNPT, ZGNX, ZLTQ, ZMH / **Market Perform:** AGN, AKRX, AMGN, AMRN, ARIA, AZN, BCR, BDX, BIO, BRKR, BSX, CPHD, DNDN, DXCM, DYAX, ECT, FOLD, GEVA, GSK LN, GTXI, HSP, ISIS, MDCO, MDT, MGLN, MNK, MOH, MRK, MYGN, PCYC, PFE, PRGO, QSII, SAN FP, SNY, SRPT, TECH, TFX, UAM, UNH, VOLC, WAT

- **Bottom Line:** Binary events in healthcare can be key determinants of investor performance. Medical meetings, data and FDA actions underscore the breadth and pace of innovation in healthcare. We highlight upcoming data at ESC (European Society for Cardiology) for NVS. Key data readouts are expected from BMY, VRTX, SLXP, PBYI and GWPH. Positive regulatory action is expected for EW with Sapien XT approval any day, OREX's Contrave (obesity) approval on its 6/11 PDUFA, and INSM's accelerated approval determination in June. In Managed Care, 2Q reporting is a key data point and catalyst that will impact Managed Care performance. Our sortable Excel sheet ([calendar](#)) has timelines and stock impacts, both Up/Down.

- In Managed Care, 2Q reporting is a key data point and catalyst.
- LCZ696 data at ESC (Cardiology, 8/30-9/3) are the crux of NVS's pipeline and our positive view of the stk; we remain bullish.
- Weighing on BMY stock is binary risk/reward heading into the 2nd line lung cancer survival studies in 2H14; we remain believers.
- We see Up/down +/- 50% for VRTX on mid-year release of Ph III data in the larger homozygous CF mkt. (40% of cystic fibrosis pts.).
- We expect positive data for SLXP's TARGET-3 Ph III trial (Xifaxin in IBS, irritable bowel syndrome).
- We est. PBYI's Up/down at +100-300%/-10% for Neratinib's Ph III data from PFE legacy trial in adjuvant setting, expected in 2Q.
- Our deep dive on GWPH's Epidiolex (epilepsy) increased our confidence in data, expected mid-2014.
- EW Sapien XT approval in US any day.
- We anticipate approval of OREX's Contrave (obesity) on its PDUFA date, 6/11.
- In June, we expect an announcement for INSM re: breakthrough therapy status for Arikace (Non-Tuberculous Mycobacteria, NTM) and whether it can file for accelerated approval (AA) based on Ph II results.

ACHILLION PHARMACEUTICALS, INC. (ACHN) / HOWARD LIANG, PH.D.

Clinical and Regulatory Progress Sets Up Good News Flow, Shots on Goal

Outperform / **Market Cap:** \$754.1M / **Price:** \$7.79 / **Price Target:** \$12.00 / **Methodology:** Multiple-of-sales analysis

PREVIOUS DAY NOTES:

PREVIOUS NOTES:

ALDER BIOPHARMACEUTICALS, INC. (ALDR) / JOSEPH P. SCHWARTZ

Migraine Survey Highlights High Demand for New Prophylaxis Therapies, ALD403

Outperform / **Market Cap:** \$530.1M / **Price:** \$15.50 / **Price Target:** \$26.00 / **Methodology:** Sum-of-the-parts DCF analysis, 12% discount rate, 2.5% terminal growth

FLUIDIGM CORPORATION (FLDM) / DAN LEONARD

CyTOF Trends Reinforce Constructive View on FLDM

Outperform / **Market Cap:** \$741.4M / **Price:** \$27.56 / **Price Target:** \$48.00 / **Methodology:** ~10.5x EV/2015e revenue

RESEARCH PREVIEWS:

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

INSM – OP – Joe Schwartz

Close: \$13.00, 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 negative after 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.

June 8-12 – International Congress of Parkinson's Disease and Movement Disorders Meeting

NBIX – OP – Marko Kozul

Close: \$15.50, Mkt Cap: \$629M

- NBIX will present Phase II data in Tardive Dyskinesia (TD) 6.8-12.
- An end of Phase II meeting with FDA has been requested and should occur in June.
- Assuming productive negotiations, this should allow initiation of a pivotal TD Phase III program in 2H14.
- We model TD revenues starting in 2016E of \$37M and reaching \$338M in 2022E.

June 11 – Cerdelga (Eliglustat, Gaucher's disease) PDUFA

SNY – MP – Seamus Fernandez

Close: \$53.80, Mkt Cap: \$141,660M

- Cerdelga was granted a priority review in Dec. '13.
- We expect full approval and forecast an additional €20M in the first year of its launch and €770M peak sales by 2026.

June 11-12 – FDA AdCom – Anesthetic and Analgesic Drug

SLXP – OP – Jason Gerberry

Close: \$112.06, Mkt Cap: \$5,661M

- We expect the FDA AdCom on to result in a recommendation calling for sponsors to conduct large, Major Adverse Cardiac Event (MACE) outcomes studies to disprove "theoretical" cardiovascular safety concerns, likely leading to SLXP discontinuing its label expansion program.
- We see limited downside from a negative panel recommendation given modest Street expectations.

June 12 – FDA AdCom – Circulatory System Devices

BCR – MP – Rich Newitter

Close: \$141.05, Mkt Cap: \$10,372M

- We expect approval/launch of Lutonix (drug-coated balloon, DCB) in 2015 and model \$75M in Yr 1 sales.
- Management noted that review at a “top-tier” journal is ongoing, though investors will likely get detailed 12-month data ahead of this publication as the FDA review briefing documents are released.
- If the 12-mo. data is “broken” at panel, it’s unclear whether the journal will still move forward with publication.
- We believe is important in order to highlight Lutonix’ Levant II’s rigorous trial design as a point of differentiation from competing DCBs.
- This, especially in light of MDT’s (MP) positive 12-mo. IN.PACT Admiral DCB trial results, which mgmt acknowledged will likely look better vs. Levant II’s 12-mo. headline data.

June 12-15 – European Hematology Association

XLRN – OP – Marko Kozul

Close: \$33.70, Mkt Cap: \$1,123M

- 6.13.14 Sotarcept Phase II dose escalation β -Thal. Abstract released for presentation at Plenary session.
- Given that the β -Thal. Abstract was not released on 5.22, we would anticipate the SOT β -Thal. data should be even stronger than the already encouraging ACE-536 β -Thal. data made recently available in the EHA abstracts on 5.22.14.
- 6.14.14 at 8:15 and 8:45, CEST, data for Sotarcept / ACE-536 will have key data for all patients across the 4 dose groups through day 112 and data in NTD patients treated at 0.8mg/kg.
- 6.15.14 at 8:45 CEST, ACE-536 in Myelodysplastic Syndrome (MDS) will have additional data including the TD transfusion burden for patients treated at 1.0mg/kg.
- Abstract released on 5.21.14 showed impressive efficacy for ACE-536 and data for SOT/ AC-536 are maturing nicely for non-transfusion dependent and transfusion dependent patients.

June 13-17 – American Diabetes Association

SNY – MP – Seamus Fernandez

Close: \$53.80, Mkt Cap: \$141,660M

- EDITION 3 results in treatment naïve Type 2 diabetes patients failed to show a benefit in nocturnal hypoglycemia or overall severe hypoglycemia at 6 months.
- However, a meta-analysis of EDITION 1, 2 and 3 did show a benefit on nocturnal HG and overall HG, but the frequency of either severe overall or severe nocturnal HG was exceeding low in both groups, raising questions about the clinical importance of U300 vs. U100 Lantus given the extremely low frequency of severe AEs with both products.

ISIS – MP – Joe Schwartz**Close: \$34.17, Mkt Cap: \$4,640M**

- ISIS-GCGRx could address the large market in diabetes, but we think a large expensive Phase III trial from a resource-rich partner will be necessary to capitalize on the opportunity.
- ISIS recently announced that GCGRx demonstrated dose dependent, statistically significant reductions in HbA1c, measure of glucose control.
- Full data will be presented at the ADA as a late breaker.

OREX – OP – Marko Kozul**Close: \$6.81, Mkt Cap: \$591M**

- OREX is making progress with its life cycle management strategy, which includes combining in a single formulation NB32 with DDP-4s or sodium-glucose co-transporter 2 (SGLT2) inhibitors for prediabetes and diabetes.
- Supporting presentations on this front will be made at ADA.

June 16-19 – American Society of Clinical Psychopharmacology**ALKS – OP – Michael Schmidt****Close: \$48.37, 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**

[Biotechnology/Highlights of Monday's ASCO Presentations in Our Coverage](#), Howard Liang et al.

[Biotechnology/Highlights of ASCO Weekend Data in Our Biotech Coverage](#), Howard Liang et al.

[Biopharma/IO Insights from MEDACorp KOLs: Takeaways and Expectations](#), Seamus Fernandez et al.

[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 \$\beta\$ -Thal at EHA Could Surprise; Reit \\$52PT/Outperform](#), Marko Kozul

[Flash -- INCY/Positive Updates for INCB24360 and Jakafi at ASCO/Outperform](#), Michael Schmidt

[Flash -- IMGN/ASCO Presentations Include Encouraging Data on Partnered Products/Outperform](#), Michael Schmidt

[Flash -- KPTI/Selinexor Phase I Update at ASCO Confirms Safety/Efficacy Profile/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

[Biopharma/Survey Finds Frequent Off-Label Use of Sovaldi & Projects Cont'd Market Growth](#), 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

[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

6/11: SNY Cerdelga (Gaucher's Disease) PDUFA

6/11: OREX Contrave (obesity) PDUFA - delayed 3 mos as of 6/11.

6/11-12: FDA AdCom: Anesthetic and Analgesic Drug Products, SLXP, Relistor

6/12: FDA AdCom: Circulatory System Devices - Drug Coated Balloons, BCR Lutonix

6/17: FDA AdCom: Gastro-enterology 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

MEDICAL MEETINGS

6/6-11: International Conference on Complement Therapeutics, ALNY
6/7-11: American Medical Association, European Academy of Allergy and Clinical Immunology, Society of Nuclear Medicine and Molecular Imaging
6/8-12: International Congress of Parkinson's Disease and Movement Disorders, NBIX
6/11-13: European League Against Rheumatism, America's Health Insurance Plans
6/11-14: European Cystic Fibrosis Society
6/12-15: European Hematology Association, XLRN
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
6/25-26: 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

6/11: XNPT Board Representation Proxy Vote
6/13: Investor Meeting: CNC, 8am
6/13: XLRN, Sotatercept Beta-Thal. abstract released for plenary session at EHA
6/16: LLY conference call from ADA, 9:30am
6/16: SNY conference call from ADA, 12:00pm
6/17: ACT/FRX M&A shareholder vote
6/17: Investor Meetings: MGLN, 8:30am, NVS Day 1, 12:30pm
6/18: Investor Meeting: NVS Day 2, 10:30am
6/24: WAG earnings release
6/25: MCK Investor Day
6/25: PRGO Proair Patent Trial
7/3: WAG monthly sales

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				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			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.

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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