

MORNING ROUNDS

TODAY'S HIGHLIGHTS / AUGUST 26, 2014
TODAY'S RESEARCH:
ENTA

INITIATIONS: NONE / RATING CHANGES: NONE / PRICE TARGET

CHANGES: NONE / ESTIMATE CHANGES: NONE / MEDACORP: NONE

/ PREVIOUS RESEARCH: INGN, ITMN, BIOPHARMA

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: +63.00 (16,993); S&P500: +1.00 (1,995); NASD +3.75 (4,064)

LEERINK EVENTS:

9/2: MEDACorp Event: The Next Wave of Cancer (Immuno-)Therapy: Insights from Cutting-Edge Research, Houston

TODAY'S RESEARCH:

ENANTA PHARMACEUTICALS, INC. (ENTA) / HOWARD LIANG, PH.D.

Takeaways from Management Meetings

Outperform / Market Cap: \$735.1M / Price: \$39.95 / Price Target: \$45.00 / Methodology: DCF analysis

PREVIOUS DAY NOTES:

PREVIOUS NOTES:

INOGEN, INC. (INGN) / DANIELLE ANTALFFY

Direct to Consumer Momentum Builds, Focus Shifts to Execution

Outperform / Market Cap: \$383.9M / Price: \$19.10 / Price Target: \$26.00 / Methodology: Avg of DCF and comparable company analysis

INTERMUNE, INC. (ITMN) / HOWARD LIANG, PH.D.

Roche Acquisition Recognizes Asset Durability With Upside in Fibrotic Franchise

Outperform / Market Cap: \$5,337.0M / Price: \$53.80 / Price Target: $53.00 \rightarrow 74.00$ / Methodology: Proposed acquisition by Roche

BIOPHARMA / SEAMUS FERNANDEZ

2014 European Society of Cardiology Itinerary Planner

Outperform: BMY, NVS, REGN / Market Perform: AMGN, AZN, MRK, PFE, SAN FP

RESEARCH PREVIEWS:

August – Distributors - Department of Defense (DoD) Pharmaceutical Prime Vendor (PPV) Solicitation

ABC - OP - Dave Larsen

Close: \$76.92, Mkt Cap: \$14,053M

CAH - OP - Dave Larsen

Close: \$73.45, Mkt Cap: \$24,442M

MCK - OP - Dave Larsen

Close: \$193.91, Mkt Cap: \$40,788M

· We believe the U.S. military wants to keep multiple distributors in use in order to be able to move volume from one distributor to the other in the event of a war or disruptions in any one

company. We estimate that ABC's revenue under its current DoD contract is ~\$1.4B/year and CAH's revenue under its current DoD contract is ~\$0.5B/year.

- The 10-year contract renewal is split across different regions, and since the government will select at least two different vendors, we suspect it is likely that ABC and CAH will retain their existing books of business.
- · While it is possible that MCK could win one of the regions, we estimate that the business will remain split between ABC and CAH.

August 27 – Earnings – Before the Open

CDNA - OP - Dan Leonard

Close: \$9.90, Mkt Cap: \$117M

- · 2QE Leerink EPS/Rev: -\$0.11 / \$6.1M
- · 2QE Street EPS/Rev: -\$0.13 / \$6.3M
- · 2014E Leerink EPS/Rev: -\$0.60 / \$25.6M
- · 2014E Street EPS/Rev: -\$0.58 / \$25.6M
- · CC: 4:30pm EDT; Dial-in: 855-420-0616; Access Code: 73744990

August 31 - LCZ696 (Heart Failure) Data at ESC

NVS - OP - Seamus Fernandez

Close: \$89.11, Mkt Cap: \$195,009M

- · NVS still has not seen the PARADIGM-HF (heart failure) Ph III data, but mgmt remains confident that safety data will be positive, due in part to the trial's early stoppage due to positive results.
- · Relative risk reduction (RRR) on cardiovascular death is a primary concern, and the data is scheduled to be released on 8/31/14 (2:30 a.m. EDT) at the European Society of Cardiology (ESC) meeting in Barcelona.
- · We are looking for 20%+ RRR from the data, while a MEDACorp heart failure specialist estimates that a 15%+ RRR would allow LCZ696 to replace standard-of-care therapies over time.
- · NVS plans to file for approval in the US by YE14.
- · We estimate that LCZ696 will have peak sales of \$3.2B in 2026.
- **Next up:** 8/31, 11:00 a.m. EDT, NVS meeting at ESC to discuss results.

August 31- September 3 – Data from Several Studies on SNY/REGN's Alirocumab at ESC

SNY - MP - Seamus Fernandez

Close: \$53.72, Mkt Cap: \$141,660M

REGN – OP – Joe Schwartz

Close: \$347.91, Mkt Cap: \$27,438M

· Detailed results of several Alirocumab studies will be presented at the upcoming European Society of Cardiology (ESC, Coronary Artery Disease & Lipids Hot Line session on 8/31, 11:24 a.m. EDT).

- · SNY CEO Chris Viehbacher noted a statistically significant benefit on CV events and death in the Ph III ODYSSEY Long-term study. While events are likely very small, a directional benefit on both non-fatal myocardial infarction (MI) and CV death should firm up SNY/REGN's prospect of an on-time approval with a relatively broad label in 2015.
- · AMGN's (MP) Evolocumab and SNY/REGN's Alirocumab are likely to reach market simultaneously in 2H15. SNY and REGN announced, on 7/30, their intention to use a Priority Review Voucher (PRV), previously acquired from BMRN (OP), providing a 6-month expedited review (vs. standard 10 months) positioning Alirocumab competitively against Evolocumab.
- **Next up:** 9/2, 8:30 a.m. EDT, SNY/REGN CC from European Society of Cardiology, **Dialin:** 866-907-5928, **Access Code:** 289012; SNY Investor Meeting on 11/20.

August-September 2014 – FDA Regulatory Decision

DXCM – MP – Danielle Antalffy Close: \$43.91, Mkt Cap: \$2,567M

- · We expect FDA approval of the Animas Vibe Pump by the end of 3Q14.
- · On a recent MEDACorp Pulse call it was stated that as technology continues to evolve as more pumps become integrated with CGMs, the clinical benefits of pump therapy will become increasingly evident.
- · If the MEDACorp physician's views play out, this could mean the insulin pump market could more than double from current levels.

September – DoD Final RFP Issued for Electronic Health Record

CERN – OP – Dave Larsen

Close: \$56.76, Mkt Cap: \$19,107M

MDRX - OP - Dave Larsen

Close: \$14.70, Mkt Cap: \$2,764M

- The DoD EHR is expected to be a 10-year contract worth \$11B with the RFP likely to be issued around September 2014 and a contract award is slated for F3Q:15.
- · We view this as a significant opportunity for Epic (private) and CERN (OP) and MDRX (OP) as well as other HCIT vendors that will likely bid on the business.
- · We estimate that the DoD contract could drive +2-7% of annual EPS accretion for CERN and +8%-25% of annual EPS accretion for MDRX assuming a \$1-3B contract for each company, prorated over 10 years.

3Q14 - Medicare Coverage Decision on Prosigna

NSTG – OP – Dan Leonard

Close: \$11.44, Mkt Cap: \$252M

- · A positive coverage decision by Medicare on the Prosigna breast cancer prognostic test would be one the most impactful catalysts for NSTG in 2H14.
- · NSTG hired a reimbursement team that has been in active discussions with major third-party payers, including three Medicare advisory committee meetings to date.

· Medicare could make a positive coverage decision on Prosigna as early as 3Q14.

PREVIOUS NOTES:

SURVEY NOTES:

JAZZ/Defibrotide Survey Reaffirms Our Ests; Docs Bullish on Usage in Next 12-24 Mos/ Outperform, Jason Gerberry

CDNA/Post-Transplant Pure Play; Initiate at Outperform/Outperform, Dan Leonard

KYTH/2Q14 Survey Results: Physicians' Anticipation of ATX-101 Continues to Build/ Outperform, Seamus Fernandez

AGN/2Q14 Cosmetic Survey Shows Stable Growth; DARPin Data at ASRS & VRX in Focus/Market Perform, Seamus Fernandez

PCYC/Upgrade to OP on Survey Feedback on CLL Market Outlook and Imbruvica Launch/ Outperform, Howard Liang

BMRN/Vimizim Survey Highlights Strong Demand; Adj. Ramp for Timing of Patient Starts/ Outperform, Joe Schwartz

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.

Healthcare/Healthcare Insights Conference: Therapeutics Day Reference Guide

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

<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

8/28: PDUFA: NVS Promacta (aplastic anemia)

9/3-5: AdCom: Nonprescription drugs

9/9-10: AdCom Cardio Vascular & Renal Drugs **9/11-12:** AdCom Endocrinologic & Metabolic Drugs

MEDICAL MEETINGS

8/30-9/4: European Society of Cardiology (ARIA, NVS, REGN, SNY)

9/2: SNY/ REGN Alirocumab (PCSK9, hypercholesterolemia) CC from ESC

8/30-9/4: World Congress of Pharmacy and Pharmaceutical Science

9/4-6: Breast Cancer Symposium

9/6-10: European Respiratory Society (ERS)

9/6-9: Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)

9/7-10: Association for Vascular Access (AVA) College of American Pathologists (CAP)

9/10-13: American Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) - Joint with ECTRIMS; RCPT

9/12-15: American Society for Bone and Mineral Research, MRK

9/13-17: Cardiovascular Research Foundation: Transcatheter Cardiovascular Therapeutics (TCT)

CORPORATE EVENTS

9/4: WAG Monthly Sales

9/17: Investor mtgs: ELOS, SYK

9/18: Investor mtg: MYL

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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 06/30/14 IB Serv./Past 12 Mos				
Rating	Count	Percent	Count	Percent
BUY [OP]	138	69.00	50	36.20
HOLD [MP]	62	31.00	2	3.20
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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