May 15, 2014

**OUTPERFORM**

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LEERINK

Reason for report:

**COMPANY UPDATE**

# ACCELERON PHARMA

## Positive Updates on 1Q14 EPS Call & Our Biotech Bus Tour; Reit OP & $52PT

• **Bottom Line:** XLRN provided broad and meaningful pipeline updates on its 1Q14 EPS call, and we obtained additional clarity by visiting the company with our Boston Biotech Bus tour. XLRN's proprietary Dalantercept (Dal) program in 2nd-line renal cell carcinoma (RCC) is advancing with provocative ASCO abstract data defined by high response rates (RR) and safety. Additional presentations at ASCO should further reinforce this data with Part-2 reading out in 2H15. An important new development in the Sotatercept end stage renal disease (ESRD) program is that XLRN now plans to report bone mineral density (BMD) and vascular calcification data from Part-1 (dose escalation) of this Phase II trial at the American Society of Nephrology (11.11-16.14). This makes us cautiously optimistic the data will be an upside surprise given XLRN previously did not plan to announce this type of data from a small dose escalation trial given it would be unlikely to show any trend. We remain focused on near-term pipeline presentations (three at ASCO, four at EHA) and reiterate our Outperform rating and $52 price target.

• **The proprietary Dal program is maturing and advancing very solidly.** ASCO Abstract 4566 data for the Dal-Axitinib (see our 5.14.14 note) combo RCC trial actually already included dose expansion data (not just dose escalation) per an ASCO policy that allows sponsors the option to supplement abstracts submitted by the 2.4.14 deadline. New updates include: (1) no DLTs in the RCC trial; (2) 0.9mg/kg was selected as the recommended Phase II dose (RP2D); (3) at ASCO we can expect additional data for a few patients, greater detail on patient characteristics/ prior therapies and emerging duration of response data. The Phase II Part-2 randomized trial will start shortly with the goal of increasing PFS by ~3 months to 7-8 months total from ~4.8 with Axitinib monotherapy. Part-2 will allow enrollment of prior immunotherapy patients, with data in 2H15.

• **An important new development is that XLRN now plans to report Sotatercept ESRD data at ASN 2014 (11.11-16.14) that will include actual BMD and vascular calcification data from Part-1 (dose escalation) of the Phase II trial.** With 6-8 patients per cohort and 4 cohorts there could be data on 24-32 patients. We are cautiously optimistic these data will be an upside surprise given XLRN's previous message that BMD and vascular calcification data in a small dose escalation trial would likely be insufficient to show any trends and thus XLRN was not planning to report it… and now it is. Interpreting these data in the context of natural history progression will be important. Possible outcomes could be that Sotatercept has: (1) no effect; (2) slows progression; (3) prevents further calcification, or (4) even reverses calcification. All but having no effect would be important and characterize a first-in-class new therapeutic.

| **Key Stats:** | **(NASDAQ:XLRN)** |
|---|---|
| **S&P 600 Health Care Index:** | **1,224.81** |
| **Price:** | **$31.56** |
| Price Target: | $52.00 |
| Methodology: | DCF analysis; 10% discount rate; 1% terminal growth rate |
| 52 Week High: | $57.89 |
| 52 Week Low: | $15.00 |
| Shares Outstanding (mil): | 30.3 |
| Market Capitalization (mil): | $956.3 |
| Book Value/Share: | $1.32 |
| Cash Per Share: | $7.06 |
| Dividend (ann): | $0.00 |
| Dividend Yield: | 0.0% |
| *Cash Per Share:* | |


| Dec Yr | 1Q | 2Q | 3Q | 4Q | FY Rev | 1Q | 2Q | 3Q | 4Q | FY EPS | P/E |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **2013A** | $15.0 | $26.4 | $4.3 | $11.5 | $57.2 | $0.13 | $0.64 | ($0.66) | ($0.64) | ($4.15) | NM |
| **2014E - New** | **$3.3A** | **0.0** | **$30.0** | **0.0** | **$33.3** | **($0.30)A** | **($0.55)** | **$0.39** | **($0.60)** | **($1.06)** | **NM** |
| **2014E - Old** | 0.0 | 0.0 | $30.0 | 0.0 | $30.0 | ($0.50) | ($0.53) | $0.40 | ($0.58) | ($1.22) | NM |
| **2015E - New** | **--** | **--** | **--** | **--** | **0.0** | **--** | **--** | **--** | **--** | **($2.29)** | **NM** |
| **2015E - Old** | -- | -- | -- | -- | 0.0 | -- | -- | -- | -- | ($2.20) | NM |

*Source: Company Information and Leerink Partners LLC Research*
*Revenue in MM.*
*GAAP EPS presented.*

# INVESTMENT THESIS

**We rate XLRN Outperform.** We believe XLRN shares are poised to appreciate near/longer term driven by progress with CELG-partnered compounds Sotatercept/ACE-536 and proprietary Dalantercept (ACE-041). XLRN has multiple significant data read-out catalysts during almost every quarter until YE14. Pivotal catalysts through 2014: (1) Preliminary Dalantercept Phase II RCC data in 2Q14; (2) top-line Sotatercept and ACE-536 Phase II MDS and β-Thal. (4 trials) data at EHA in 2Q14; (3) final Sotatercept and ACE-536 Phase II MDS and β-Thal. (4 trials) data at ASH in 4Q14; (4) initiate pivotal MDS and/or β-Thal. trials by YE14. MEDACorp KOLs are very bullish and encouraged by emerging pipeline data and science. We assume probability of success in the low 30s percent range for Sotatercept/ACE-536 in MDS, 40% for β-Thal., 20% in end-stage renal disease (ESRD) patients on hemodialysis, and low 30s percent range for Dalantercept in 2nd-line RCC.

## Quarter Update

**XLRN reported EPS of ($0.30) vs. our ($0.50) estimate primary driven by booking of some revenue and lower-than-anticipated expenses.** Revenue was $3.3M vs. our $0 estimate. Net loss was $9.1M vs. our $15.1M estimate. XLRN end 1Q14 with ~$214M in cash and equivalents or ~$7.06/share.

## ASCO 2014 Titles

| **Dalantercept:** | | | | |
|---|---|---|---|---|
| Abstract # | Title | Time/Session | Poster Board | Presenter |
| 5594 | Phase II evaluation of dalantercept, a soluble recombinant activin receptor-like kinase 1 (ALK1) receptor-fusion protein, for treatment of recurrent/persistent endometrial cancer: GOG-0229N. | 5/31(Sat) 8-11:45am<br>S Hall A2<br>General poster<br>Track(s): Gynecologic Cancer | 376 | Vicky Makker, MD |
| 6045 | Phase 2 study of dalantercept in recurrent or metastatic squamous cell carcinoma of the head and neck | 5/31 (Sat) 1:15-5pm<br>S Hall A2<br>General poster<br>Track(s): Head and Neck Cancer | 80 | Antonio Jimeno, MD, PhD |
| 4566 | A two-part phase 2 randomized study of dalantercept and axitinib versus placebo plus axitinib in advanced renal cell carcinoma: Results from the part 1 dose escalation cohorts. | 6/2 (Mon) 1:15-5pm<br>S Hall A2<br>General Poster<br>Track(s): Genitourinary Cancer | 134 | Michael B. Atkins, MD |

*Source: ASCO.org, Leerink Partners estimates*

Milestones

| Product | Partner | Indication | Phase | Timing | Milestone |
|---|---|---|---|---|---|
| **ACE-536** | CELG | MDS + β-Thal. | Ph. II | **2Q14** | **Phase II dose escalation data for MDS + β-Thal. at EHA-2014** |
| | | | | **4Q14** | **Final Phase II in MDS and β-Thal. data** |
| | | | | YE14/ early-15 | Initiate Phase III trial for MDS and/or β-Thal. |
| | | | | 2018 | Approval and launch |
| **Sotatercept (ACE-011)** | | | | **2Q14** | **Phase II dose escalation β-Thal. data at EHA-2014 +** Preclinical data in sickle cell anemia |
| | | | | **4Q14** | **Final Phase II in MDS + β-Thal. data** |
| | | | | 2018 | Approval and launch |
| | | | | YE14/early-15 | Initiate Phase III trial for MDS and/or β-Thal. |
| | CELG | ESRD | Ph. II | **11.11-16.14** | **Phase II Part-1 data (0.7mg/kg cohort+BMD/Vasc Calcificat)** |
| **Dalantercept (ACE-041)** | Proprietary | Oncology | Ph. II | **early-June -14** | **Interim Part-1 Phase II RCC combo data (ASCO-2014)** |
| | | | | 2Q14 | Initiate Phase II Dal-sorafenib combo trial in HCC |
| | | | | YE14 | Preliminary Phase II Dal-sorafenib combo RR data in HCC |
| | | | | **2H15** | **Phase II RCC Part-2 data** |
| | | | | 2014 | Phase II data in SCCHN |
| | | | | 2018 | Approval and launch in RCC |
| **ACE-083** | | Muscle | PC | 2H14 | Advance ACE-083 into clinic for Muscle Loss |
| **New TGF-β Candidates** | | Fibrosis | PC | 2015 | Advance Fibrosis (i.e., PAH) candidate into clinic |

*Source: Company reports, Leerink Partners estimates*

| Phase II Sotatercept Intravenous (IV)/Subcutaneous (SC) End-Stage Kidney Disease Patients on Hemodialysis | |
|---|---|
| **Purpose:** | Determine optimal administration route, dose level, and safety of IV or SC sotatercept for maintaining hemoglobin levels in ESRD hemodialysis subjects |
| **# Pts:** | **Part-1:** N=60<br>**Part-2:** N=230<br>19 international sites (as of 1.8.14) |
| **Design:** | Interventional, 2x Part, randomized, open label, treatment trial |
| **Trial Arms:** | **Note:** Patients in both parts of study must first be on stable dose of ESA to maintain Hg levels and switched to treatment with sotatercept after an ESA treatment free period of ~5 days<br><br>**Part-1:** Staggered dose group escalation<br>▪ **Arm-1 (IV):** ACE-011 IV starting at **0.1mg/kg (gp-1)**, then **0.2mg/kg (gp-2)** and **0.3mg/kg (gp-3)** every 14 days for total of 8 doses and followed for 4 months after last dose<br>▪ **Arm-2 (SC):** ACE-011 SC starting at **0.13mg/kg (gp-1)**, then **0.26mg/kg (gp-2)**, and **0.4mg/kg (gp-3)** every14 days for total of 8 doses and followed for 4 months after last dose<br><br>**Part-2:** Parallel group, randomized vs. active control (ESA) |
| **Primary Endpoint:** | **Part-1:**<br>▪ **Pharmacokinetics:** C-max, T-max, AUC 28days [Time Frame: 28 days] and T-1/2,z [211 days]<br>▪ **Adverse Events:** [Time Frame: 211 days] [Designated as safety issue], TEAEs<br>**Part-2:**<br>▪ **Change in mean hemoglobin concentration from baseline**<br>▪ **Ability of sotatercept to maintain hemoglobin levels within target range after switching from ESA to sotatercept** |
| **Secondary Endpoints:** | ▪ Efficacy [Time Frame: 113 days]<br>▪ Change in mean hemoglobin (Hg) concentration between baseline and day-113<br>▪ Bone Turnover biomarkers for remodeling and mineral metabolism for 211 days<br>▪ Change in serum bone biomarker concentrations between baseline and end of study (day-211) |
| **Start:** | October-2013 |
| **Data:** | October-2015 |
| **Status:** | Recruiting (as of 1.8.14) |
| **Sponsors:** | **CELG** |
| **Clin.Trial.ID:** | NCT01999582, **ACE-011-REN-002, 2012-003788-23** |

*Source: Company reports, Leerink Partners estimates*

## VALUATION

Our $52 12-month price target of XLRN shares reflects probability-adjusted royalty revenue at 20% from ESRD patients on hemodialysis. Our valuation is based on a discounted cash flow analysis. We believe XLRN shares are poised to appreciate near/longer term driven by progress with CELG-partnered compounds Sotatercept/ACE-536 and proprietary Dalantercept (ACE-041). We apply a discount rate of 10% and a terminal growth rate of 1%, which translates to an 11x terminal multiple, which we believe is comparable to biotechnology companies in a similar development stage.

## RISKS TO VALUATION

An investment in XLRN is fundamentally a high-risk, high-reward investment, in our opinion. XLRN may face significant clinical, regulatory, and commercial risks for pipeline products. Most important is clinical risk for Phase II Sotatercept and ACE-536 trials in MDS (myelodysplastic syndromes) and β-Thal. as well as Dalantercept/Axitinib in RCC. There is also competitive risk from emerging MDS, β-Thal., and RCC therapies. Finally, XLRN may face financing risk beyond 1H15.

| XLRN P&L ($000s, except per share data) | 2013A | 1Q14A | 2Q14E | 3Q14E | 4Q14E | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Revenues** | | | | | | | | | | | | | | | | | | |
| Sotatercept/ACE-536 WW Revenue in MDS to CELG | | | | | | | | | | $66,089 | $141,589 | $227,505 | $324,937 | $435,091 | $559,283 | $698,955 | $855,680 | $1,031,180 |
| *Probability of Success* | | | | | | | | | | *32%* | *32%* | *32%* | *32%* | *32%* | *32%* | *32%* | *32%* | *32%* |
| Risk Adjusted Sotatercept/ACE-536 WW Revenue | | | | | | | | | | $21,148 | $45,308 | $72,801 | $103,980 | $139,229 | $178,971 | $223,666 | $273,818 | $329,978 |
| **Risk Adjusted Sotatercept/ACE-536 WW Royalties in MDS** | | | | | | | | | | **$4,230** | **$9,515** | **$16,016** | **$23,915** | **$32,023** | **$42,953** | **$55,916** | **$68,454** | **$82,494** |
| Sotatercept/ACE-536 WW Revenue in NTD β-Thal. to CELG | | | | | | | | | | $3,659 | $60,642 | $127,092 | $226,546 | $339,098 | $466,097 | $609,020 | $767,222 | $904,639 |
| *Probability of Success* | | | | | | | | | | *40%* | *40%* | *40%* | *40%* | *40%* | *40%* | *40%* | *40%* | *40%* |
| Risk Adjusted Sotatercept/ACE-536 WW Revenue in NTD β-Thal. | | | | | | | | | | $1,464 | $24,257 | $50,837 | $90,619 | $135,639 | $186,439 | $243,608 | $306,889 | $361,856 |
| **Risk Adjusted Sotatercept/ACE-536 WW Royalties in NTD β-Thal.** | | | | | | | | | | **$293** | **$4,851** | **$10,676** | **$19,936** | **$29,841** | **$42,881** | **$58,466** | **$73,653** | **$90,464** |
| Dalantercept WW Revenue in 2nd-line RCC | | | | | | | | | | $68,061 | $131,647 | $210,325 | $298,864 | $398,173 | $509,233 | $633,101 | $770,918 | $877,863 |
| *Probability of Success* | | | | | | | | | | *32%* | *32%* | *32%* | *32%* | *32%* | *32%* | *32%* | *32%* | *32%* |
| **Risk Adjusted Dalantercept WW Revenue in 2nd-line RCC** | | | | | | | | | | **$21,780** | **$42,127** | **$67,304** | **$95,637** | **$127,415** | **$162,954** | **$202,592** | **$246,694** | **$280,916** |
| Sotatercept US Revenue in ESRD Patients on Hemodialysis | | | | | | | | | | | | $301,866 | $819,107 | $1,418,781 | $1,915,379 | $2,064,199 | $2,220,226 | $2,383,756 |
| *Probability of Success* | | | | | | | | | | | | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* | *20%* |
| Risk Adjusted Sotatercept US Revenue in ESRD Patients on Hemodialysis | | | | | | | | | | | | $60,373 | $163,821 | $283,756 | $383,076 | $412,840 | $444,045 | $476,751 |
| **Risk Adjusted Sotatercept US Royalties in ESRD Patients on Hemodialysis** | | | | | | | | | | | | **$12,075** | **$36,041** | **$65,264** | **$91,938** | **$103,210** | **$111,011** | **$119,188** |
| Collaboration Revenue | $57,231 | $3,307 | - | $30,000 | - | $33,307 | - | $40,000 | $30,000 | $22,400 | $8,000 | - | $8,000 | - | $8,000 | $8,000 | $8,000 | $8,000 |
| **Total Revenue** | **$57,231** | **$3,307** | **-** | **$30,000** | **-** | **$33,307** | **-** | **$40,000** | **$30,000** | **$48,702** | **$64,493** | **$106,071** | **$183,529** | **$254,543** | **$348,727** | **$428,184** | **$507,813** | **$581,062** |
| **Costs and Expenses** | | | | | | | | | | | | | | | | | | |
| Probability Adjusted Dalantercept COGS | - | | | | | - | - | - | - | $3,267 | $6,319 | $10,096 | $9,564 | $12,742 | $16,295 | $20,259 | $24,669 | $28,092 |
| Research and Development | $36,051 | $11,765 | $12,200 | $12,500 | $13,280 | $49,745 | $55,217 | $61,291 | $68,033 | $34,016 | $35,717 | $37,503 | $39,378 | $41,347 | $43,415 | $45,585 | $47,864 | $50,258 |
| SG&A (Risk Adjusted from Time of Dalantercept Launch) | $14,227 | $3,750 | $4,500 | $5,100 | $5,200 | $18,550 | $20,405 | $22,446 | $24,690 | $31,090 | $34,199 | $36,935 | $38,782 | $40,721 | $42,757 | $44,895 | $47,139 | $49,496 |
| **Total Costs and Expenses** | **$50,278** | **$15,515** | **$16,700** | **$17,600** | **$18,480** | **$68,295** | **$75,622** | **$83,736** | **$92,723** | **$68,373** | **$76,235** | **$84,534** | **$87,724** | **$94,810** | **$102,467** | **$110,739** | **$119,673** | **$127,846** |
| **Operating Income (EBIT)** | **$6,952** | **($12,208)** | **($16,700)** | **$12,400** | **($18,480)** | **($34,988)** | **($75,622)** | **($43,736)** | **($62,723)** | **($19,671)** | **($11,742)** | **$21,537** | **$95,805** | **$159,733** | **$246,260** | **$317,445** | **$388,140** | **$453,217** |
| *Y/Y growth* | | | | | | | | | | | | | | | | | | |
| Other Income (Expenses) | ($27,710) | $3,088 | | | | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Interest Income | $20 | | | | | | | | | | | | | | | | | |
| Interest Expense | ($1,161) | | ($378) | ($298) | ($219) | ($895) | ($521) | - | - | - | - | - | - | - | - | - | - | - |
| **Income Before Taxes** | **($21,898)** | **($9,120)** | **($17,078)** | **$12,102** | **($18,699)** | **($32,795)** | **($76,143)** | **($43,736)** | **($62,723)** | **($19,671)** | **($11,742)** | **$21,537** | **$95,805** | **$159,733** | **$246,260** | **$317,445** | **$388,140** | **$453,217** |
| Provision for Taxes | | | | | | - | - | - | - | - | - | - | - | - | 29,317 | 107,931 | 131,967 | 154,094 |
| Tax Rate | | | | | | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 12% | 34% | 34% | 34% |
| **Net income** | **($21,898)** | **($9,120)** | **($17,078)** | **$12,102** | **($18,699)** | **($32,795)** | **($76,143)** | **($43,736)** | **($62,723)** | **($19,671)** | **($11,742)** | **$21,537** | **$95,805** | **$159,733** | **$216,942** | **$209,514** | **$256,172** | **$299,123** |
| **Net income (loss) applicable to common stockholders—diluted** | **($39,003)** | **($9,120)** | **($17,078)** | **$12,102** | **($18,699)** | **($32,795)** | **($76,143)** | **($43,736)** | **($62,723)** | **($19,671)** | **($11,742)** | **$21,537** | **$95,805** | **$159,733** | **$216,942** | **$209,514** | **$256,172** | **$299,123** |
| Change in fair value of warrants | $1,500 | | | | | | | | | | | | | | | | | |
| **EPS (LPS) Basic** | **($4.15)** | **($0.30)** | **($0.55)** | **$0.39** | **($0.60)** | **($1.06)** | **($2.29)** | **($1.30)** | **($1.85)** | **($0.57)** | **($0.34)** | **$0.62** | **$2.72** | **$4.48** | **$6.03** | **$5.76** | **$6.98** | **$8.07** |
| Basic Shares (000) | **9,407** | **30,321** | **31,140** | **31,171** | **31,202** | **30,931** | **33,241** | **33,573** | **33,909** | **34,248** | **34,590** | **34,936** | **35,286** | **35,639** | **35,995** | **36,355** | **36,719** | **37,086** |

*Source: Leerink Partners estimates and company reports.*
*NTD=non-transfusion dependent.*

**DCF Calcuation**

| | |
|---|---|
| *Discount rate* | *10%* |
| *Terminal Growth Rate* | *1%* |
| Valuation ($M) | $1,668 |
| **Valuation / Share** | **$52** |

*Source: Leerink Partners estimates.*

**XLRN DCF Valuation/Share Sensitivity Analysis**

| Terminal Growth Rate \ Discount Rate | 8.0% | 9.0% | 10.0% | 11.0% | 12.0% |
|---|---|---|---|---|---|
| 0.0% | $69 | $57 | $48 | $41 | $36 |
| 1.0% | $76 | $62 | **$52** | $44 | $38 |
| 2.0% | $86 | $69 | $57 | $47 | $40 |
| 3.0% | $99 | $78 | $62 | $51 | $43 |
| 4.0% | $120 | $90 | $70 | $57 | $47 |

*Source: Leerink Partners estimates.*

# Disclosures Appendix

## Analyst Certification

I, Marko Kozul, M.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

## Valuation

Our $52 12-month price target of XLRN shares reflects probability-adjusted royalty revenue at 20% from ESRD patients on hemodialysis. Our valuation is based on a discounted cash flow analysis. We believe XLRN shares are poised to appreciate near/longer term driven by progress with CELG-partnered compounds Sotatercept/ACE-536 and proprietary Dalantercept (ACE-041). We apply a discount rate of 10% and a terminal growth rate of 1%, which translates to an 11x terminal multiple, which we believe is comparable to biotechnology companies in a similar development stage.

## Risks to Valuation

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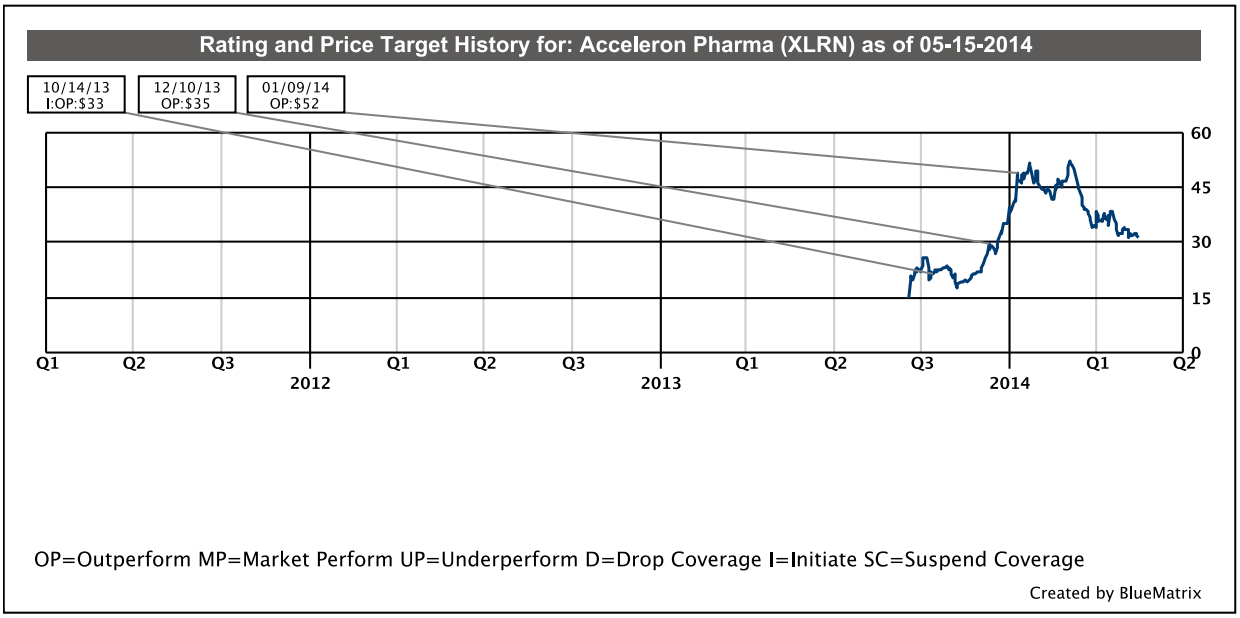

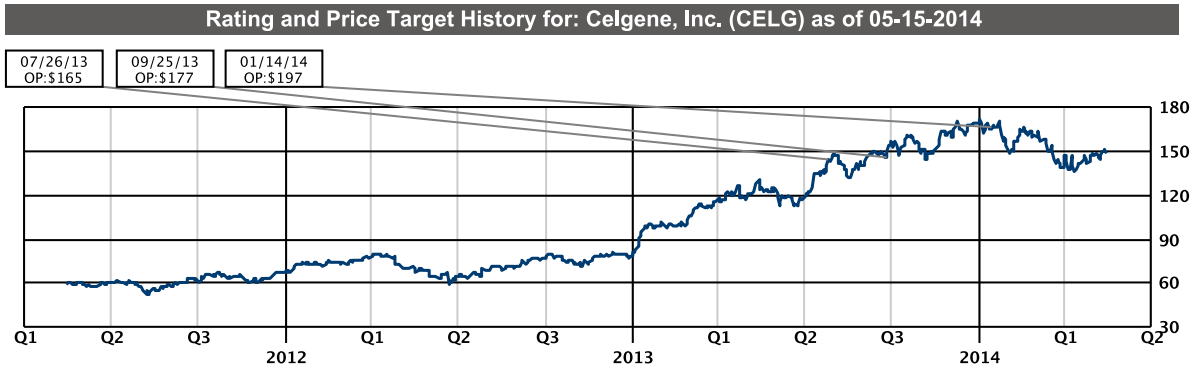


Leerink Swann initiated coverage of CELG with an Outperform rating on February 7, 2003. On June 11, 2013, Leerink Swann began a transition to specific price targets for the stocks under its coverage, replacing valuation ranges.

OP=Outperform MP=Market Perform UP=Underperform D=Drop Coverage I=Initiate SC=Suspend Coverage

Created by BlueMatrix

| Distribution of Ratings/Investment Banking Services (IB) as of 03/31/14 | | | | |
|---|---|---|---|---|
| | | | IB Serv./Past 12 Mos. | |
| 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.

**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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**Leerink Partners LLC has acted as the manager for a public offering of Acceleron Pharma in the past 12 months.**

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