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HEALTHCARE EQUITY RESEARCH

## ACCELERON

## Innovative Science, Large Markets, Mgmt &amp; Catalysts Drive an OP Rating &amp; \$33PT

• **Bottom Line:** Positive MEDACorp KOL feedback for its 3 lead pipeline compounds, and our analysis suggests XLRN is pushing innovation boundaries with lead compounds for anemia (Sotatercept, ACE-536) and oncology (Dalantercept). Sotatercept and ACE-536 have potential to compete directly with Erythropoiesis-Stimulating Agents (ESAs) through a distinct mechanism of action (MOA) but are initially being evaluated in MDS ESA refractory patients and  $\beta$ -Thalassemia. Dalantercept (ACE-041) could be used synergistically with any VEGF-inhibitor but is initially being pursued in 2nd-line Renal Cell Carcinoma (RCC). Based on probabilities of success (POS) in the low 30s% and modeling revenue only for these initial orphan disease indications, we derive a base case 12-month NPV calculation ~\$1B. Additionally, XLRN has important catalysts for almost every quarter through YE14. We initiate coverage with an Outperform (OP) rating & \$33 price target (PT).

• **Positive MEDACorp feedback leads us to believe the risk for XLRN compounds is not whether they have any efficacy but rather whether they have too much efficacy, which we view as an unusual risk profile.** For Sotatercept and ACE-536 we expect future dose escalation cohorts will start to demonstrate meaningful responses in terms of improving anemia. For Sotatercept, KOLs anticipate early signs of activity at 0.5mg/kg in MDS non-del 5q ESA resistant patients with improving activity in the next cohort likely to be at 1g/kg. In  $\beta$ -Thal., at 0.3mg/kg, the drug is already demonstrating dose-dependent activity with the ability to increase hemoglobin (Hgb) by ~1g. KOLs are optimistic the  $\geq 0.5$ mg/kg cohort will increase Hgb by  $\geq 1.5$ g. Assuming a low 30s% approval POS for Sotatercept/ACE-536 in ~11K MDS and ~20K  $\beta$ -Thal. initial target patient population, we arrive at peak risk-adjusted revenues of ~\$619M (or \$1.9B non-risk adjusted), leading to ~\$155M in total Sotatercept/ACE-536 royalty revenue. For Dalantercept we model use in ~24K WW patients in 2nd-line RCC for peak risk-adjusted revenue of ~\$281M (~\$878M non-risk adjusted).

• **XLRN has multiple significant pipeline catalysts through YE14 that could drive shares higher.** On a scale of 1-10 (with 10 being most important) these include; 1) interim Sotatercept Phase II (ongoing)  $\beta$ -Thal. 0.5mg/kg cohort data at ASH in 4Q13 (4/10); 2) preliminary Dalantercept Phase II RCC data in 1Q14 (5/10); top-line Sotatercept and ACE-536 Phase II MDS and  $\beta$ -Thal. (4 trials) data at EHA in 2Q14 (6/10); 4) final Sotatercept and ACE-536 Phase II MDS and  $\beta$ -Thal. (4 trials) data at ASH in 4Q14 (8/10); initiate pivotal MDS/ $\beta$ -Thal. trials by YE14 (5/10).

• **We calculate a 12 month \$33 PT for XLRN based on a discounted cash flow (DCF) analysis that assumes risk adjusted (32%) US/EU revenue, a 10% discount rate and 1% long-term growth rate.**

We do not currently ascribe any value to pipeline market expansion or combination opportunities or its earlier stage pipeline.

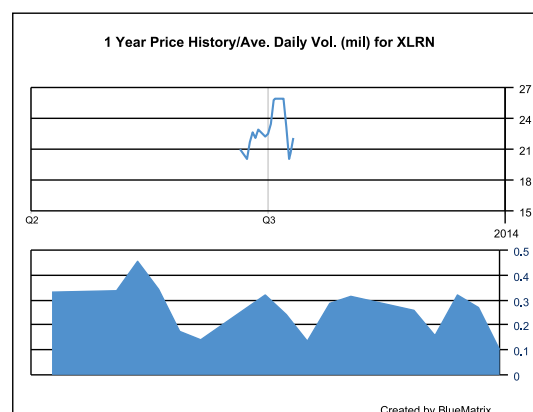
Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	--	--	--	--	\$15.3	--	--	--	--	(\$1.44)	NM
2013E	\$15.0A	\$26.4A	\$8.0	\$18.0	\$67.4	\$0.13A	\$0.64A	(\$0.21)	\$0.12	\$0.68	32.5x
2014E	--	--	--	--	\$40.0	--	--	--	--	(\$0.59)	NM

Source: Company Information and Leerink Swann LLC Research  
Revenue in MM, GAAP EPS presented

## Key Stats:

(NASDAQ:XLRN)

S&P 600 Health Care Index:	1,155.56
Price:	\$22.12
Price Target:	\$33.00
Methodology:	NPV with 10% discount rate, 1% LT growth rate, risk adjusted revenues at 32%
52 Week High:	\$26.73
52 Week Low:	\$15.00
Shares Outstanding (mil):	28.0
Market Capitalization (mil):	\$619.4
Book Value/Share:	\$1.43
Cash Per Share:	\$16.29
Dividend (ann):	\$0.00
Dividend Yield:	0.0%



Please refer to Pages 26 - 28 for Analyst Certification and important disclosures. Price charts and disclosures specific to covered companies and statements of valuation and risk are available at <https://leerink2.bluematrix.com/bluematrix/Disclosure2> or by contacting Leerink Swann LLC Publishing Department, One Federal Street, 37th Floor, Boston, MA 02110.



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## **Acceleron (XLRN): Initiation of Coverage with OP & \$33 Price Target**

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# Acceleron (NASDAQ: XLRN) Company Overview



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- Mid-stage biopharma company focused on developing/commercializing novel protein therapeutics for cancer and rare diseases.
- Lead candidates Sotatercept (ACE-011) and ACE-536 in Phase II for anemia associated with Myelodysplastic Syndrome (MDS) and  $\beta$ -Thalassemia ( $\beta$ -Thal.)
- All clinical stage programs are receptor fusion ligand traps (similar to REGN's (OP) platform) that inhibit TGF- $\beta$  family of ligands
- Compared to previous TGF- $\beta$  initiatives, MEDACorp KOLs believe XLRN is likely to succeed based on integration of in-vivo pharmacology, protein engineering, internal good manufacturing practice (GMP) capabilities, cell biology and an experienced management team
- Sotatercept and ACE-536 key ongoing Phase II trials (4 total) in both MDS and  $\beta$ -Thal. will have top-line readouts in 2Q14 (European Hematology Association, EHA-2014), final data in 4Q14 (American Society of Hematology, ASH-2014) and potential pivotal Phase III trials starting YE14
- Dalantercept (proprietary) Phase II Renal Cell Carcinoma (RCC) combo program with PFE's (MP) VEGF-inhibitor Axitinib (approved in 2<sup>nd</sup>-line RCC) demonstrating very encouraging preliminary Part-1 data with next formal update in 1Q14 and Part-2 starting in 1H14
- Based on strong/differentiated Phase I data coupled with positive MEDACorp KOL calls (~10 docs), we estimate ~32% likelihood of FDA approval and model first sales in 2018E

# Acceleron (XLRN): Investment Thesis



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- Shares poised to appreciate near/longer term driven by progress with CELG (OP) partnered compounds Sotatercept/ACE-536 and proprietary Dalantercept (ACE-041), in our view
- XLRN has multiple significant data read-out catalysts during almost every quarter until YE14
- **Pivotal Catalysts through 2014:**
  - 1) Interim Sotatercept Phase II (ongoing)  $\beta$ -Thal. 0.5mg/kg cohort data at ASH in 4Q13
  - 2) Preliminary Dalantercept Phase II RCC data in 1Q14
  - 3) Top-line Sotatercept and ACE-536 Phase II MDS and  $\beta$ -Thal. (4 trials) data at EHA in 2Q14
  - 4) Final Sotatercept and ACE-536 Phase II MDS and  $\beta$ -Thal. (4 trials) data at ASH in 4Q14
  - 5) Initiate pivotal MDS and/or  $\beta$ -Thal. trials by YE14
- **MEDACorp KOLs are very bullish and encouraged by emerging pipeline data and science**
- We assume **32%** probability of approval for Sotatercept/ACE-536 in MDS,  $\beta$ -Thal. and Dalantercept in 2<sup>nd</sup>-line RCC
- Strong pipeline Intellectual Property (IP) coverage to **2026-2029** without extensions
- We model peak risk adjusted pipeline revenues of **~\$900M (or \$2.8B non-risk adjusted)**, leading to ~\$436M in total Sotatercept/ACE-536 royalty revenue and Dalantercept revenue
- Our base case 12-month NPV calculation of **~\$1B (including cash)** is based on Sotatercept or ACE-536 approval in MDS and  $\beta$ -Thal.; and Dalantercept approval in RCC

# Upcoming Milestones



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Product	Partner	Indication	Timing	Milestone
Sotatercept (ACE-011)	CELG	MDS + $\beta$ -Thal	Dec-2013	Interim Phase II ACE-011 $\beta$ -Thal. (incl 0.5mg/kg dose) at ASH-2013
			1Q14	Initiate Phase II Expansion Cohort for Sotatercept $\beta$ -Thal.
			2Q14	Phase II Sotatercept MDS + $\beta$ -Thal. data at EHA-2014
			4Q14	Final Phase II Sotatercept in MDS + $\beta$ -Thal. data
			2018	Approval and launch
			YE14	Initiate Phase III trial for MDS or $\beta$ -Thal.
ACE-536			1Q14	Initiate Phase II Expansion Cohort for II ACE-536 $\beta$ -Thal.
			2Q14	Phase II data for ACE-536 MDS at EHA-2014
				Phase II data for ACE-536 $\beta$ -Thal. at EHA-2014
			4Q14	Final Phase II ACE-536 in MDS and $\beta$ -Thal. data
			YE14	Initiate Phase III trial for MDS or $\beta$ -Thal.
			2018	Approval and launch
	Dalantercept (ACE-041)	Proprietary	Oncology	1Q14
1H14				Initiate Phase II (Part-2, N=112) RCC randomized trial (progression free survival [PFS] endpoint)
3Q14				Initiate Phase II combo trials in other indications (i.e., HCC, CRC, NSCLC)
2018				Approval and launch
New TGF- $\beta$ Candidates	Muscle Loss		YE14	Advance Muscle Loss candidate into clinic (ACE-083)
	Fibrosis		2015	Advance Fibrosis (i.e., PAH) candidate into clinic

# Sotatercept and ACE-536 Product Profiles



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- Both are TGF- $\beta$  ligand traps, subcutaneously (SC) administered, with similar methods of action (MOA) but differing affinities for ligand receptors
- To date, Sotatercept evaluated in >160 patients, ACE-536 in 32 patients (completed trials) that demonstrated robust/dose dependent efficacy across tumor types. Ongoing Phase II trials include another 100-200 treated patients.
- Sotatercept Phase I healthy volunteer data show treatment with 1g/kg resulted in ~3g/dL hemoglobin (Hgb) increase (similar to 3 units of blood transfusion)
- In ongoing Sotatercept  $\beta$ -Thal. Phase II dose escalation trial, 100% (5/5) of patients treated at 0.3mg/kg achieved  $\geq 1$ g/dL increase in Hgb. Data for 0.5mg/kg dose will be presented at ASH-2013
- Goal is to find doses of Sotatercept/ACE-536 that increase Hgb  $\geq 1.5$ g/dL



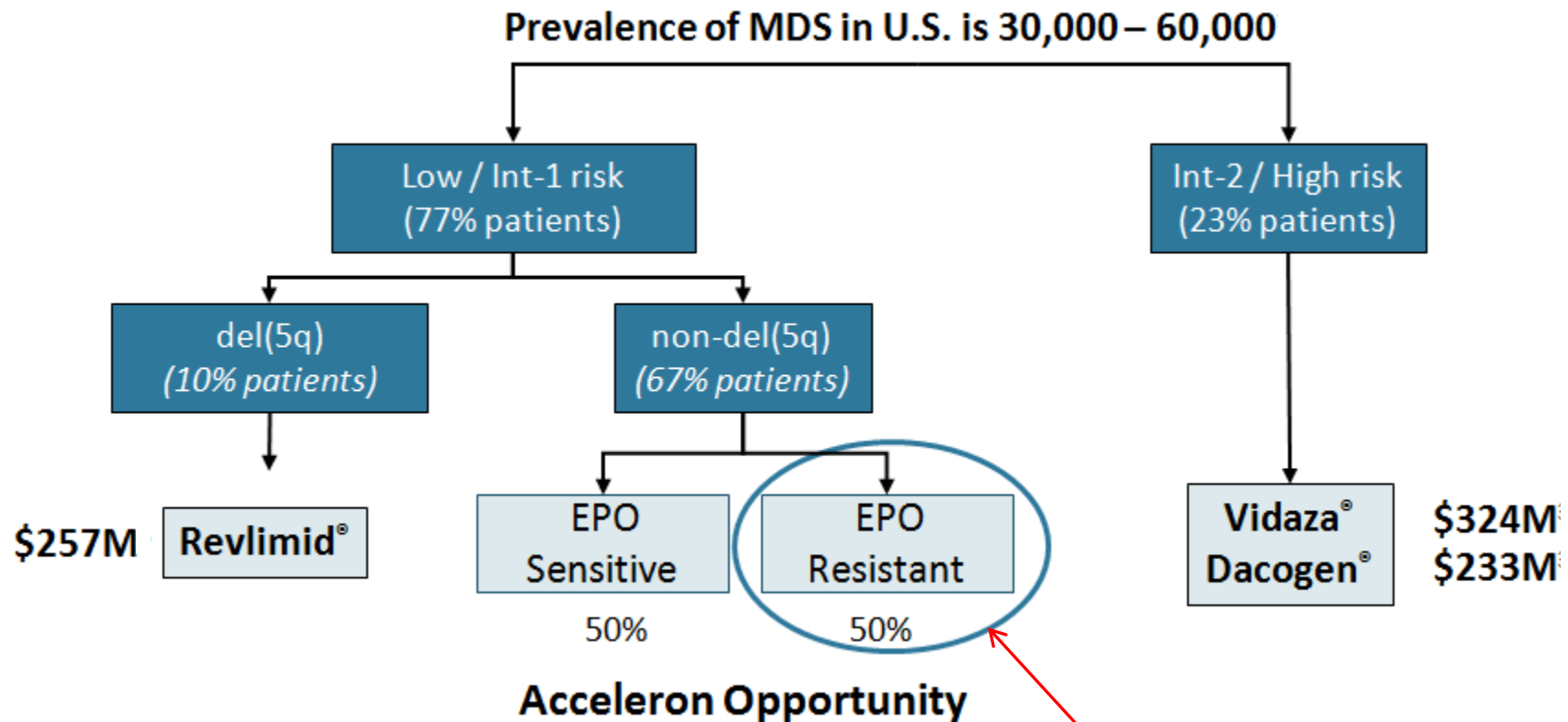


# Sotatercept/ACE-536 Key Differentiation

- Both compounds work by MOA independent of Erythropoietin (EPO) which is how current Erythropoiesis-Stimulating Agents (ESAs) function. This may provide for:
  - 1) Use for indications resistant to ESAs (i.e., MDS ESA resistant patients)**
  - 2) Alternative to ESAs with better side effect profile**
  - 3) Combination with ESAs for better outcomes**
- Both compounds may initially have utility across multiple orphan diseases or longer term compete directly with ESAs for large markets
- ACE-536 may have additional beneficial impact by preventing bone loss



# Sotatercept/ACE-536 Positioning in MDS Market



We est. this represents ~11K US patients

Source: Company Reports, Leerink Swann Estimates.



# MEDACorp KOL Feedback for Sotatercept/ACE-536



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- Positive Phase II results could be defined by as little as a 30% response rate (RR) that is also durable (i.e., 6 or 12 months)
- Doses needed for efficacy in MDS are likely higher than what showed efficacy in Phase I healthy volunteer patients (i.e., women enrolled in Phase I were administered 1g of Sotatercept)
- Believe Sotatercept 0.5mg might be minimally effective dose and they have greater expectations for 1g cohort (planned to start in 4Q13)
- **Biomarkers** could be very important with low hanging fruit being correlation of Hgb changes to phos-SMAD-2/3 levels which should become evident from current Phase IIs
- **Time to measuring a response** should be feasible after 16-24 weeks and initial biomarker analysis would occur after this
- **ASH-2014** should include response rates (dose escalation and expansion patients), data on duration of response, initial biomarker analysis

# MEDACorp KOLs on Sotatercept/ACE-536 Next-Steps



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- **Next Steps:** Depend on amount of activity (RR and duration) and biomarker availability
- **Registration Pathway:** Depends on predictive value of biomarker + RR/duration + amount of clinically significant increase in Hgb
  - Example: 30% RR + 6-12 month duration + biomarker → KOLs recommend advancing drugs into ESA failures either in a large Phase II or Phase III
  - Example: If biomarker is highly predictive → keep Phase IIs open and continue evaluating patients and validating the biomarker with enrollment of another 15-20 → KOLs recommend advancing drugs directly against ESAs (i.e., in non-del-5q ESA sensitive MDS patients vs. Procrit)

# Sotatercept/ACE-536 Market Opportunity



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- Both compounds have potential in MDS and  $\beta$ -Thal. but we assume XLRN/CELG will select only one for MDS and the other for  $\beta$ -Thal.
- For initial target MDS population (non-del 5q EPO resistant low-int-1 risk MDS pts), there are no effective therapies so blood transfusions with marginal efficacy are provided, given there is no alternative
- We estimate ~11K U.S. patients represent the initial target MDS population leading to our **peak WW sales estimate in MDS of \$1B (or probability-adjusted royalty of \$82M)**
- For non-transfusion dependent (NTD)  $\beta$ -Thal., we estimate ~800 patients in U.S. and ~19K in EU represent the initial target population leading to our **peak WW sales estimate of \$905M (or probability adjusted royalty of \$72M)**
- Other Sotatercept clinic trial indications include Chronic Kidney Disease (CKD), Investigator Sponsored Trials (ISTs) for Multiple Myeloma, Diamond Blackfan Anemia and Myelofibrosis (MF)

# Dalantercept Product Profile



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- Is a novel anti-angiogenic activin receptor-like kinase-1 (ALK-1) therapeutic that is subcutaneously (SC) administered
- To date, Dalantercept evaluated in 37 patients (completed trials). Ongoing Phase II trials include additional patients.
- In ongoing Dalantercept Phase II dose escalation 2<sup>nd</sup>-line RCC trial, powerful dose response (measured by tumor regression) is emerging with a significantly improved response rate (RR)
- PFE's Axitinib (Inlyta) approved for 2<sup>nd</sup>-line RCC based on **RR of 20%**
- Phase II Dalantercept shows emerging **RR of 25-50% with impressive responses in other organs with metastases (lung, liver)**



# Dalantercept+Axitinib Phase II RCC Early Data

Dalantercept 0.6 mg/kg cohort - 4 patients treated	
One partial response (PR) (-31%, -42%, -50%)	<ul style="list-style-type: none"> <li>• Previous best response of stable disease (SD) with sunitinib</li> <li>• Cycle 3 target lesions in lung decreased by 31%; cycle 5 decreased by 42% and cycle 7 decreased by 50%</li> </ul>
One stable disease (SD) (-15%, -29%)	<ul style="list-style-type: none"> <li>• Patient received three prior lines of therapy with a best response of SD. Most recently received <u>everolimus</u> with SD for 5 months</li> <li>• Cycle 3 target lesions in liver decreased by 15% and cycle 5 decreased by 29%</li> </ul>
Two progressive disease (PD)	
Dalantercept 0.9 mg/kg cohort - 4 patients treated	
One partial response (PR) (-46%)	<ul style="list-style-type: none"> <li>• Patient had received three prior lines of therapy. Previous best response of SD for 9 months with sunitinib, PD with <u>temsirolimus</u> for 2 months and PD with <u>bevacizumab</u> for 1 month</li> <li>• Cycle 3 target lesions in liver decreased by 46%</li> </ul>
One stable disease (SD) (-26%)	<ul style="list-style-type: none"> <li>• Patient had received one year of adjuvant pazopanib</li> <li>• Cycle 3 target lesions in liver decreased by 26%</li> </ul>
2 remaining patients will be restaged at cycle 3 by the end of August	

Source: Company Reports.



# Dalantercept Market Opportunity

- In general, we are skeptical of add-on therapies that do not have differentiated monotherapy activity better than standards of care (SOC)
- Emerging Dalantercept Phase II RCC data appear to be the “real deal” by demonstrating real and impressive synergistic activity with current SOC drugs and potential across multiple tumor types
- We estimate ~7K U.S. patients and 17K ROW patients in 2<sup>nd</sup>-line RCC as the initial target market
- **We estimate peak sales in refractory (2<sup>nd</sup>-line ) RCC of \$878M (or probability adjusted revenue of \$281M)**
- Dalantercept is already clearly demonstrating significant promise in additional tumor types by its reduction of liver and lung metastases in the ongoing 2nd-line RCC trial, possibly providing significant upside.



# Pipeline Intellectual Property (IP)



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Drug	Expiration Date
Sotatercept (ACE-011)	2026 (composition of matter)
ACE-536	2029 (composition of matter)
Dalantercept (ACE-041)	2029 (composition of matter)

Source: Company reports

Note: Hatch Waxman could add 3-5 years of IP extension



# Model Assumptions

## ➤ **Sotatercept or ACE-536 Pricing:**

- About the same as Revlimid in 2018 and beyond
- Year-over-year price increase of 4% from 2018 and beyond

## ➤ **Dalantercept Pricing:**

- Higher than Nexavar (est. annual cost of \$40K for Dalantercept vs. \$31K for Nexavar in 2013)
- Year-over-year price increase of 4% from 2018 and beyond

## ➤ **Probability of Success (At Current Stage)**

- Assumes 32% probability of success on WW Sotatercept MDS, non-transfusion-dependent  $\beta$ -Thal., and Dalantercept refractory RCC revenues. Based on our experience with orphan disease development stage product, we see this as an in-line probability of success.
- **Discount Rate** of 10% and **Terminal Growth Rate** of 1% (translates to a ~11x terminal multiple)



# Key Sources of Potential Future Upside

- Phase II Sotatercept/ACE-536 MDS or  $\beta$ -Thal. results suggesting it could compete directly with current ESAs
- Successful Sotatercept/ACE-536 clinical trial results in tumor types or anemia patients beyond MDS or  $\beta$ -Thal.
- Dalantercept positive data in tumor types beyond RCC including NSCLC, Hepatocellular Cancer (HCC), Colorectal Cancer (CRC)
- Leerink Swann estimates for PFE's Axitinib growing to ~\$1B in 2019 clearly assumes successful approvals/use in addition tumor types beyond RCC
- Advancement of other pipeline candidates such as muscle loss and fibrosis candidates

# XLRN DCF Valuation



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XLRN Cash Flow (\$000s, except per share data)																			
	2012A	1Q13A	2Q13A	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Cash Flow from Operating Activities																			
Net Loss	(\$32,582)	\$1,647	\$13,078	(\$5,982)	\$3,468	\$12,211	(\$16,830)	(\$61,628)	(\$27,218)	(\$48,940)	(\$8,323)	(\$2,134)	\$20,247	\$67,743	\$102,746	\$149,386	\$142,987	\$183,010	\$218,889
Adj to Reconcile losses to net cash in Op Act																			
Depreciation and amortization	\$1,293	\$224	\$225	\$250	\$250	\$949	\$1,200	\$1,400	\$1,800	\$2,000	\$2,000	\$2,000	\$2,000	\$2,000	\$2,000	\$2,000	\$2,000	\$2,000	\$2,000
Stock-based compensation	1,206	428	520	400	400	1,748	1,700	1,800	2,000	2,500	2,500	2,500	2,500	2,500	2,500	2,500	2,500	2,500	2,500
Amortization of debt discount	51	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Accretion of deferred interest	335	86	85	-	-	171	-	-	-	-	-	-	-	-	-	-	-	-	-
Amortization of deferred debt issuance costs	84	18	159	-	-	177	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of warrants	2,258	1,067	433	-	-	1,500	-	-	-	-	-	-	-	-	-	-	-	-	-
Gain on retirement of warrants	-	(76)	-	-	-	(76)	-	-	-	-	-	-	-	-	-	-	-	-	-
Forgiveness of related party receivable	-	-	237	-	-	237	-	-	-	-	-	-	-	-	-	-	-	-	-
Net cash used in operating activities	(38,884)	(735)	(10,012)	(5,332)	4,118	(11,961)	(13,930)	(58,428)	(23,418)	(44,440)	(3,823)	2,366	24,747	72,243	107,246	153,886	147,487	187,510	223,389
Cash flows from investing activities																			
Purchases of property and equipment	(\$441)	(\$80)	(\$45)	(\$110)	(\$110)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)
Net cash used in investing activities	(\$441)	(\$80)	(\$45)	(\$110)	(\$110)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)	(\$346)
Free Cash Flow	(\$39,325)	(\$815)	(\$10,057)	(\$5,442)	\$4,008	(\$12,307)	(\$14,276)	(\$58,774)	(\$23,764)	(\$44,785)	(\$4,169)	\$2,020	\$24,402	\$71,898	\$106,900	\$153,541	\$147,141	\$187,164	\$223,044

Source: Leerink Swann estimates and company reports.

## DCF Calculation

Discount rate	10%
Terminal Growth Rate	1%
Valuation (\$M)	\$1,058
<b>Valuation / Share</b>	<b>\$33</b>

Source: Leerink Swann estimates.

## XLRN DCF Valuation/Share Sensitivity Analysis

		Discount Rate				
		8.0%	9.0%	10.0%	11.0%	12.0%
Terminal Growth Rate	0.0%	\$44	\$37	\$31	\$26	\$22
	1.0%	\$49	\$40	<b>\$33</b>	\$28	\$23
	2.0%	\$56	\$44	\$36	\$30	\$25
	3.0%	\$65	\$50	\$40	\$32	\$27
	4.0%	\$78	\$58	\$45	\$36	\$29

Source: Leerink Swann estimates.

# XLRN Income Statement



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	XLRN P&L (\$000s, except per share data)																		
	2012A	1Q13A	2Q13A	3Q13E	4Q13E	2013E	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											32%	32%	32%	32%	32%	32%	32%	32%	32%
Risk Adjusted Sotatercept/ACE-536 WW Revenue in NTD β- Thal.											\$1,171	\$19,405	\$40,669	\$72,495	\$108,511	\$149,151	\$194,886	\$245,511	\$289,485
Risk Adjusted Sotatercept/ACE-536 WW Royalties in NTD β- Thal.											\$234	\$3,881	\$8,541	\$15,949	\$23,873	\$34,305	\$46,773	\$58,923	\$72,371
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
Collaboration Revenue						-	-	-	-	-									
License and milestone (Risk Adjusted beyond approval)	\$9,696	\$12,515	\$22,891	\$5,000	\$15,000	\$55,406	\$40,000	-	\$40,000	\$25,000	\$22,400	\$6,400	-	\$6,400	-	\$6,400	\$6,400	\$6,400	\$6,400
Cost-Sharing, Net	\$5,558	\$2,497	\$3,537	\$3,000	\$3,000	\$12,034	-	-	-	-	-	-	-	-	-	-	-	-	-
Contract Manufacturing																			
Total Revenue	\$15,254	\$15,012	\$26,428	\$8,000	\$18,000	\$67,440	\$40,000	-	\$40,000	\$25,000	\$48,643	\$61,923	\$91,861	\$141,901	\$183,311	\$246,612	\$311,681	\$380,471	\$442,182
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	\$35,319	\$8,780	\$8,911	\$9,200	\$9,500	\$36,391	\$40,030	\$44,033	\$48,436	\$53,280	\$26,640	\$27,972	\$29,371	\$30,839	\$32,381	\$34,000	\$35,700	\$37,485	\$39,359
SG&A (Risk Adjusted from Time of Dalantercept Launch)	\$8,824	\$3,096	\$3,365	\$3,700	\$3,950	\$14,111	\$15,522	\$17,074	\$18,782	\$20,660	\$27,060	\$29,766	\$32,147	\$33,755	\$35,442	\$37,214	\$39,075	\$41,029	\$43,080
Total Costs and Expenses	\$44,143	\$11,876	\$12,276	\$12,900	\$13,450	\$50,502	\$55,552	\$61,107	\$67,218	\$73,940	\$56,967	\$64,057	\$71,613	\$74,157	\$80,565	\$87,510	\$95,035	\$103,183	\$110,531
Operating Income (EBIT)	(\$28,889)	\$3,136	\$14,152	(\$4,900)	\$4,550	\$16,938	(\$15,552)	(\$61,107)	(\$27,218)	(\$48,940)	(\$8,323)	(\$2,134)	\$20,247	\$67,743	\$102,746	\$159,102	\$216,647	\$277,287	\$331,650
Y/Y growth																			
Income Before Taxes	(\$32,582)	\$1,647	\$13,078	(\$5,982)	\$3,468	\$12,211	(\$16,830)	(\$61,628)	(\$27,218)	(\$48,940)	(\$8,323)	(\$2,134)	\$20,247	\$67,743	\$102,746	\$159,102	\$216,647	\$277,287	\$331,650
Provision for Taxes							-	-	-	-	-	-	-	-	-	9,716	73,660	94,278	112,761
Tax Rate							0%	0%	0%	0%	0%	0%	0%	0%	0%	6%	34%	34%	34%
Net income	(\$32,582)	\$1,647	\$13,078	(\$5,982)	\$3,468	\$12,211	(\$16,830)	(\$61,628)	(\$27,218)	(\$48,940)	(\$8,323)	(\$2,134)	\$20,247	\$67,743	\$102,746	\$149,386	\$142,987	\$183,010	\$218,889
Change in fair value of warrants	\$2,258	\$1,067	\$433			\$1,500													
EPS (LPS) Basic	(\$1.44)	\$0.13	\$0.64	(\$0.21)	\$0.12	\$0.68	(\$0.59)	(\$1.94)	(\$0.85)	(\$1.51)	(\$0.25)	(\$0.06)	\$0.61	\$2.01	\$3.02	\$4.34	\$4.12	\$5.22	\$6.18
EPS (LPS) Diluted	(\$1.44)	\$0.12	\$0.59	(\$0.19)	\$0.11	\$0.63	(\$0.52)	(\$1.72)	(\$0.75)	(\$1.34)	(\$0.23)	(\$0.06)	\$0.54	\$1.80	\$2.70	\$3.89	\$3.69	\$4.68	\$5.55
Basic Shares (000)	21,062	20,954	20,954	28,048	28,328	20,061	28,612	31,755	32,072	32,393	32,717	33,044	33,375	33,708	34,046	34,386	34,730	35,077	35,428
Diluted Shares (000)	21,062	22,971	22,971	32,072	32,353	21,868	32,636	35,779	36,097	36,417	36,741	37,069	37,399	37,733	38,070	38,410	38,754	39,101	39,452

Source: Leerink Swann estimates and company reports.

Note: NTD=non-transfusion dependent.

# MDS Revenue Build for Sotatercept/ACE-536



LEERINK SWANN

U.S. Sotatercept/ACE-536 Revenue Build in MDS														
	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
MDS Patients	32,911	33,898	34,915	35,963	37,042	38,153	39,297	40,476	41,691	42,941	44,230	45,557	46,923	48,331
% Growth in MDS Patients		3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
% Low/Int-1 Patients	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%	77.0%
Low /Int-1 MDS Patients Diagnosed	25,341	26,102	26,885	27,691	28,522	29,378	30,259	31,167	32,102	33,065	34,057	35,079	36,131	37,215
% non-Del(5q)	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%	67.0%
Non-Del (5q) MDS Patients Diagnosed	22,050	22,712	23,393	24,095	24,818	25,562	26,329	27,119	27,933	28,771	29,634	30,523	31,439	32,382
% EPO Sensitive	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
Non-Del (5q) MDS Patients who are EPO Sensitive	11,025	11,356	11,697	12,048	12,409	12,781	13,165	13,560	13,966	14,385	14,817	15,261	15,719	16,191
% EPO Resistant	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
Non-Del (5q) MDS Patients who are EPO Resistant	11,025	11,356	11,697	12,048	12,409	12,781	13,165	13,560	13,966	14,385	14,817	15,261	15,719	16,191
% Sotatercept Penetration into Non-Del (5q) EPO Resistant Pts	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	10.0%	15.0%	20.0%	25.0%	30.0%	35.0%	40.0%	45.0%
# Non-Del (5q) EPO Resistant Pts on Sotatercept	-	-	-	-	-	639	1,316	2,034	2,793	3,596	4,445	5,342	6,288	7,286
YoY % Increase of Pts on Sotatercept							106.0%	54.5%	37.3%	28.8%	23.6%	20.2%	17.7%	15.9%
Sotatercept/ACE-536 Annual Cost per Patient	\$50,000	\$52,000	\$54,080	\$56,243	\$58,493	\$60,833	\$63,266	\$65,797	\$68,428	\$71,166	\$74,012	\$76,973	\$80,052	\$83,254
Sotatercept/ACE-536 US MDS Revenue (\$000s)	-	-	-	-	-	\$38,876	\$83,287	\$133,826	\$191,139	\$255,936	\$328,990	\$411,150	\$503,341	\$606,577

Source: Leerink Swann Estimates.

ROW Sotatercept/ACE-536 Revenue in MDS														
	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Sotatercept/ACE-536 ROW Revenue (\$000s)	-	-	-	-	-	\$27,213	\$58,301	\$93,678	\$133,798	\$179,155	\$230,293	\$287,805	\$352,339	\$424,604

Source: Leerink Swann Estimates.



# β-Thal. Revenue Build for Sotatercept/ACE-536



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U.S. Sotatercept/ACE-536 Revenue Build in Non-transfusion dependent (NTD) β-Thal. Patients														
	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Living NTD β-Thal. Patients in U.S.	779	802	826	851	877	903	930	958	987	1,016	1,047	1,078	1,111	1,144
% Growth in NTD β-Thal. Patients		3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Incidence of NTD β-Thal. Patients in U.S.	300	300	300	300	300	300	300	300	300	300	300	300	300	300
Total NTD β-Thal. Patients in U.S.	1,079	1,102	1,126	1,151	1,177	1,203	1,230	1,258	1,287	1,316	1,347	1,378	1,411	1,444
% Sotatercept Penetration into U.S. NTD β-Thal. Patients	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	10.0%	17.0%	24.0%	31.0%	38.0%	45.0%	50.0%	50.0%
# U.S. NTD β-Thal. Patients on Sotatercept	-	-	-	-	-	60	123	214	309	408	512	620	705	722
YoY % Increase in NTD β-Thal. Patients on Sotatercept							104.5%	73.9%	44.4%	32.1%	25.4%	21.2%	13.7%	2.4%
Sotatercept/ACE-536 Annual Cost per Patient	\$50,000	\$52,000	\$54,080	\$56,243	\$58,493	\$60,833	\$63,266	\$65,797	\$68,428	\$71,166	\$74,012	\$76,973	\$80,052	\$83,254
<b>Sotatercept/ACE-536 U.S. Revenue in NTD β-Thal. (\$000s)</b>	-	-	-	-	-	\$3,659	\$7,783	\$14,072	\$21,133	\$29,042	\$37,881	\$47,742	\$56,463	\$60,109

Source: Company Reports and Leerink Swann Estimates.

EU Sotatercept/ACE-536 Revenue Build in Non-transfusion dependent (NTD) β-Thal. Patients														
	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Living NTD β-Thal. Patients in EU	18,622	19,181	19,756	20,349	20,959	21,588	22,236	22,903	23,590	24,297	25,026	25,777	26,551	27,347
% Growth in NTD β-Thal. Patients		3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%	3.0%
Incidence of NTD β-Thal. Patients in EU	1,636	1,636	1,636	1,636	1,636	1,636	1,636	1,636	1,636	1,636	1,636	1,636	1,636	1,636
Total NTD β-Thal. Patients in EU	20,258	20,817	21,392	21,985	22,595	23,224	23,872	24,539	25,226	25,933	26,662	27,413	28,187	28,983
% Sotatercept Penetration into EU NTD β-Thal. Patients	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	5.0%	10.0%	17.0%	24.0%	31.0%	38.0%	45.0%	50.0%
# EU NTD β-Thal. Patients on Sotatercept	-	-	-	-	-	-	1,194	2,454	4,288	6,224	8,265	10,417	12,684	14,492
YoY % Increase of NTD β-Thal. Patients on Sotatercept								105.6%	74.8%	45.1%	32.8%	26.0%	21.8%	14.3%
Sotatercept/ACE-536 Annual Cost per Patient	\$35,000	\$36,400	\$37,856	\$39,370	\$40,945	\$42,583	\$44,286	\$46,058	\$47,900	\$49,816	\$51,809	\$53,881	\$56,036	\$58,278
<b>Sotatercept/ACE-536 EU Revenue in NTD β-Thal. (\$000s)</b>	-	-	-	-	-	-	\$52,859	\$113,019	\$205,413	\$310,056	\$428,216	\$561,278	\$710,759	\$844,530

Source: Company reports and Leerink Swann Estimates.

# RCC Revenue Build for Dalantercept



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U.S. Dalantercept Revenue Build in Refractory RCC (Renal Cell Carcinoma)														
	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Patient with renal cell carcinoma	34,998	35,348	35,701	36,058	36,419	36,783	37,151	37,523	37,898	38,277	38,659	39,046	39,437	39,831
% Growth in RCC Patients		1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
% patient treated with systemic therapy in first-line	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%
Number of RCC patients treated in first-line	11,899	12,018	12,138	12,260	12,382	12,506	12,631	12,758	12,885	13,014	13,144	13,276	13,408	13,543
% patients progress and treated in refractory setting	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%	65.0%
Number of refractory RCC patients treated	7,735	7,812	7,890	7,969	8,049	8,129	8,210	8,292	8,375	8,459	8,544	8,629	8,715	8,803
% refractory patients receiving targeted agents	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%
Number of refractory patients on targeted agents	6,961	7,031	7,101	7,172	7,244	7,316	7,389	7,463	7,538	7,613	7,689	7,766	7,844	7,922
% Penetration of Dalantercept	0.0%	0.0%	0.0%	0.0%	0.0%	8.0%	15.0%	20.0%	25.0%	30.0%	35.0%	40.0%	45.0%	50.0%
Refractory patients on Dalantercept	-	-	-	-	-	585	1,108	1,493	1,884	2,284	2,691	3,107	3,530	3,961
Annual Cost per patient	\$40,000	\$41,600	\$43,264	\$44,995	\$46,794	\$48,666	\$50,613	\$52,637	\$54,743	\$56,932	\$59,210	\$61,578	\$64,041	\$66,603
U.S. Sales of Dalantercept in Refractory RCC (\$000s)	-	-	-	-	-	\$28,484	\$56,099	\$78,569	\$103,161	\$130,032	\$159,350	\$191,293	\$226,051	\$263,826

Source: Leerink Swann Estimates.

ROW Dalantercept Revenue Build in Refractory RCC (Renal Cell Carcinoma)														
	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
Patient with renal cell carcinoma	70,761	71,469	72,183	72,905	73,634	74,370	75,114	75,865	76,624	77,390	78,164	78,946	79,735	80,533
% Growth in RCC Patients		1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
% patient treated with systemic therapy in first-line	40.0%	41.0%	42.0%	43.0%	44.0%	45.0%	46.0%	47.0%	48.0%	49.0%	50.0%	51.0%	52.0%	53.0%
% patients progress and treated in refractory setting	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%	60.0%
Number of refractory RCC patients treated	16,983	17,581	18,190	18,810	19,439	20,080	20,732	21,394	22,068	22,753	23,449	24,157	24,877	25,609
% Penetration of Dalantercept	0.0%	0.0%	0.0%	0.0%	0.0%	4.5%	8.0%	13.0%	18.0%	23.0%	28.0%	33.0%	38.0%	40.0%
Refractory patients on Dalantercept	-	-	-	-	-	904	1,659	2,781	3,972	5,233	6,566	7,972	9,453	10,244
Annual Cost per patient						\$43,800	\$45,551	\$47,374	\$49,268	\$51,239	\$53,289	\$55,420	\$57,637	\$59,943
EU Sales of Dalantercept in Refractory RCC (\$000s)	-	-	-	-	-	\$39,577	\$75,548	\$131,756	\$195,704	\$268,141	\$349,883	\$441,808	\$544,867	\$614,037

Source: Leerink Swann Estimates.

# Management



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- **JOHN KNOFF, PH.D. - CEO AND FOUNDER:** Dr. Knopf cofounded the company in 2003 and served on the BOD 2003-2004 and 2007 to present. Prior to founding Acceleron, he served as Site Head of the WYE Research facilities in Cambridge, MA and VP of Metabolic and Respiratory Disease. He was also an early key scientist at Genetics Institute from 1982-1998, participating in development biopharmaceutical products for hemophilia, recombinant factor VIII Recombinate, which helped establish GI as a premier biopharmaceutical company. Dr. Knopf is author of several key scientific manuscripts in areas of signal transduction. He received a BS in biology from SUNY Stonybrook and a Ph.D. in biology at SUNY Buffalo.
- **KEVIN MCLAUGHLIN - CFO:** Mr. McLaughlin joined Acceleron in Nov-2010 as CFO and Treasurer. Previously he served as CFO of Qteros, Inc., a cellulosic biofuels company. He co-founded Aptius Education, Inc. and from 2007-2009 he worked as its CFO and director. From 1996-2007, he held several executive positions with PRAECIS Pharmaceuticals, Inc. He was responsible for negotiating sale of the company to GSK. He began his career in senior financial roles at Prime Computer and Computervision Corporation. He received a BS in business from Northeastern University and an MBA from Babson College.
- **MATTHEW L. SHERMAN, M.D. – CMO:** Dr. Sherman joined Acceleron in May-2006 and is CMO. He previously served as CMO at SNTA with responsibilities for clinical research, clinical operations, biostatistics, data management, regulatory affairs, quality assurance and program management. He also worked at the Genetics Institute and WYE in various capacities including Therapeutic Area Director for Oncology. He is board certified in Medical Oncology and Internal Medicine and has held clinical positions at Harvard Medical School. He received an SB in chemistry from MIT and MD from Dartmouth Medical School.
- **STEVEN ERTEL – CBO:** Mr. Ertel joined Acceleron in Jan-2006 and is CBO and has established its business development function and he leads business development, commercial strategy and program management functions. He has >20 years of experience in biotechnology industry at VVUS, Genentech, BIIB, and SNTA. He began his career in venture capital at Oxford Bioscience Partners. He received a BSE in biomedical engineering from Duke University and an MBA from the Wharton School at the University of Pennsylvania.

# Pipeline Competition



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## ➤ Sotatercept and/or ACE-536:

- **MDS:** No apparent competition. CELG has Revlimid/Prednisone trials in target MDS setting but KOL expectations are low
- **β-Thal:** Multiple candidates ranging from BLUE's LentiGlobin BB305 (gene therapy) to National Heart Lung and Blood Institute's (NHLBI) Hydroxyurea

## ➤ Dalantercept:

- **RCC:** Multiple candidates but Dalantercept being evaluated with PFE's Axitinib already approved for 2<sup>nd</sup>-line RCC

# Valuation and Risks to Valuation



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## **Valuation:**

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 arrive at a 12-month price target of XLRN shares of ~\$33 a share based on a discounted cash flow analysis. We apply a discount rate of 10% and a terminal growth rate of 1% which translates to a 11x terminal multiple, which we believe is comparable to biotechnology companies in a similar development stage.

## **Risk 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 and  $\beta$ -Thal as well as Dalantercept/Axitinib in RCC. There is also competitive risk from emerging MDS,  $\beta$ -Thal and RCC therapies. Finally, XLRN may face financing risk beyond 1H15.



## 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.





Distribution of Ratings/Investment Banking Services (IB) as of 09/30/13				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	111	64.90	27	24.00
HOLD [MP]	60	35.10	0	0.00
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.

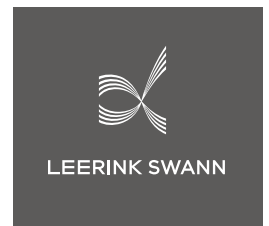
## Important Disclosures

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