#### **OUTPERFORM**

Reason for report:

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**COMPANY UPDATE** 

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## UNIQURE, N.V.

**Model Update** 

• **Bottom Line:** We are publishing our updated model and estimates for QURE. Our one-year price target is \$28/share and our rating is Outperform.

Key Stats: (NASDAQ:QURE)

S&P 600 Health Care Index: 1,312.22 Price: \$11.30 Price Target: \$28.00 Methodology: DCF analysis with 12% discount rate 52 Week High: \$18.75 52 Week Low: \$8.29 Shares Outstanding (mil): 17.6 Market Capitalization (mil): \$198.9 Book Value/Share: \$4.13 Cash Per Share: \$5.85 Dividend (ann): \$0.00 Dividend Yield: 0.0%



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2013A					€2.9					(€2.48)	NM
2014E	€1.2A	€1.2	€1.2	€1.2	€4.8	(€0.52)A	(€0.46)	(€0.46)	(€0.45)	(€1.88)	NM
2015E					€7.9					(€1.90)	NM

Source: Company Information and Leerink Partners LLC Research

Revenues in million EUROs



### **INVESTMENT THESIS**

We rate QURE Outperform with a \$28/share price target. QURE is a leader in the field of gene therapy and has developed the first and currently the only gene therapy product to receive regulatory approval in the Western World. Gene therapy offers the prospect of long-term and potentially curative benefit to patients. QURE's Glybera has been EMA-approved for treatment of patients with lipoprotein lipase deficiency (LPLD), a ultra-rare metabolic disease. Glybera is partnered with Chiesi Farmaceutici in Europe and QURE retains full commercial rights in the United States. QURE is developing a pipeline of additional gene therapies through multiple collaborations that are designed to accelerate the development and commercialization of these programs. QURE's gene therapies are delivered through an engineered non-replicating version of the adeno-associated virus (AAV) and therapies are being developed using an innovative. modular technology platform, which consists of a suite of components that may be applied to multiple gene therapies and includes QURE's proprietary cost effective commercial scale manufacturing process. We believe QURE shares are poised to appreciate primarily driven by progress of the Glybera launch in Europe, clinical progress toward approval in the U.S., and by advances of pipeline candidates targeting significantly larger indications than Glybera, such as Hemophilia-A and -B, congestive heart failure, Sanfilippo B, Acute Intermittent Porphyria, and Parkinson's Disease, among others. QURE has multiple potential meaningful catalysts over the next two years.

### **VALUATION**

We estimate a \$28 fair value for QURE shares in one year, based on a discounted multiple of sales analysis. We attribute \$5/share to Glybera EU royalties, \$4/share to the Glybera US franchise and assume a 70% probability of success, \$14 to AMO-060 in Hemophilia B, assuming a 30% probability of success, and the rest to net cash. We use a 12% WACC as the discount rate, similar to other small-cap biotech stocks in our coverage since our revenue assumptions are already probability-of-success weighted. We model 2025 US Glybera sales of 46M EURO, 2025 Glybera EU royalties of 22M EUROs, 2025 US AMF-060 sales of 233M EUROs, and 2025 EU AMT-060 royalties of 82M EUROs (all before probability adjustment).

### RISKS TO VALUATION

An investment in QURE is fundamentally a high-risk, high-reward investment, in our opinion. For risks associated with LPLD in EU, a poorer-than-expected launch, reimbursement, and inability to identify patients despite approval could harm the stock. In the US, Glybera has additional clinical, regulatory risks. On the hemophilia front, competition from Longer Acting Factors (e.g., BIIB), RNAi (e.g., ALNY) and other Gene Therapy companies could deem QURE's program as risky. Clinical and regulatory risks remain with QURE's early hemophilia program. Systemic impact from other Gene Therapy failure such as a new case of leukemia with competitor initiative could pose significant risk. Finally, financing risks also remain and we don't expect the company to be cash-flow positive for several years.

QURE P&L (in million EUROs, except EPS)	2012A	2013A	1Q14A	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E
License revenues	-	0.4	0.2	0.2	0.2	0.2	0.9	0.9	0.9	0.9
Collaboration revenues	-	2.5	1.0	1.0	1.0	1.0	4.0	4.0	4.0	4.0
Milestones	-	-	-	-	-	-	-	-	5.0	10.0
Product sales	-	-	-	-	-	-	-	-	-	-
Royalty revenue	-	-	-	-	-	-	-	3.0	7.5	15.0
Total revenue	-	2.9	1.2	1.2	1.2	1.2	4.8	7.9	17.4	29.9
COGS	-	(0.8)	-	-	-	-	-	1.5	1.9	3.8
Other income	0.6	0.6	0.2	0.2	0.2	0.2	1.0	-	-	-
R&D expense	(10.2)	(13.2)	(6.2)	(7.0)	(7.0)	(7.0)	(27.2)	(32.0)	(35.0)	(40.0)
SG&A expense	(4.6)	(11.6)	(2.3)	(2.3)	(2.3)	(2.3)	(9.1)	(10.0)	(10.2)	(15.2)
Other gains/losses, net	(0.0)	(0.5)	(0.5)	-	-	-	(0.5)	-	-	-
Total operating expenses	(14.2)	(25.5)	(8.8)	(9.0)	(9.0)	(9.0)	(35.9)	(40.5)	(43.3)	(51.5)
Operating income (loss)	(14.2)	(22.5)	(7.6)	(7.8)	(7.8)	(7.8)	(31.0)	(32.6)	(25.9)	(21.6)
Finance income	0.0	0.1	0.0	-	-	-	0.0	-	-	-
Finance expense	(0.5)	(4.4)	(0.3)	(0.2)	(0.2)	(0.2)	(0.9)	(1.1)	(0.9)	(0.0)
Finance income/expense, net	(0.5)	(4.3)	(0.2)	(0.2)	(0.2)	(0.2)	(0.9)	(1.1)	(0.9)	(0.0)
EBT	(14.7)	(26.8)	(7.8)	(8.0)	(8.0)	(8.0)	(31.9)	(33.7)	(26.9)	(21.6)
Income Tax expense	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(14.7)	(26.8)	(7.8)	(8.0)	(8.0)	(8.0)	(31.9)	(33.7)	(26.9)	(21.6)
Other comprehensive income		0.0	0.0	-	-	-	0.0	-	-	-
Total comprehensive income (loss)	(14.7)	(26.8)	(7.8)	(8.0)	(8.0)	(8.0)	(31.9)	(33.7)	(26.9)	(21.6)
Common shares outstanding (basic)	8.6	12.2	15.1	17.6	17.6	17.7	17.0	17.7	20.9	20.9
Common shares outstanding (diluted)	8.6	12.2	15.1	17.6	17.6	17.7	17.0	17.7	20.9	20.9
EPS (basic)	(1.70)	(2.48)	(0.52)	(0.46)	(0.46)	(0.45)	(1.88)	(1.90)	(1.28)	(1.03)
EPS (diluted))	(1.70)	(2.48)	(0.52)	(0.46)	(0.46)	(0.45)	(1.88)	(1.90)	(1.28)	(1.03)
QURE BS & CFS (in million EUROs, except EPS)	2012A	2013A	1Q14A	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E
Cash & equivalents	0.3	23.8	77.5	67.8	64.1	53.8	53.8	22.9	75.6	50.1
Debt	1.5	7.9	7.5	7.5	15.0	14.4	14.4	11.3	4.4	-
Change in Cash	(0.8)	23.5	53.7	(9.7)	(3.7)	(10.3)	29.9	(30.8)	52.7	(25.5)
Cash from operations	(11.3)	(4.1)	(5.1)	(6.7)	(6.7)	(6.7)	(25.2)	(27.7)	(20.4)	(13.6)
Net income (loss)	(14.7)	(26.8)	(7.8)	(8.0)	(8.0)	(8.0)	(31.9)	(33.7)	(26.9)	(21.6)
Share based comp	1.8	2.0	2.3	1.4	1.4	1.4	6.5	6.3	6.8	8.3
D&A	0.5	0.5	0.1	0.1	0.1	0.1	0.6	0.6	0.6	0.6
Other (Change in WC)	1.1	20.1	0.3	(0.2)	(0.2)	(0.2)	(0.4)	(0.9)	(0.9)	(0.9)
Cash from investing	(0.8)	(6.0)	(3.1)	(3.0)	(6.0)	(3.0)	(15.1)	-	-	(7.5)
CapEx	(0.4)	(1.3)	(2.0)	(3.0)	(3.0)	(3.0)	(11.0)	-	-	(7.5)
Acquisitions	-	(1.5)	(2.0)	-	(3.0)	(5.0)	(3.0)	-		-
Other	(0.4)	(4.6)	(1.1)	_	-	-	(1.1)	-	-	_
Cash from financing	11.3	33.6	61.9	-	9.0	(0.6)	70.3	(3.1)	73.1	(4.4)
Equity issue (buyback)	9.8	14.3	62.0	-	1.5	- (0.0)	63.5	- (3.1)	80.0	(-1/)
Debt issue (principal payment)	1.5	19.5	-		7.5	(0.6)	6.9	(3.1)	(6.9)	(4.4)
Other	-	(0.1)	(0.0)		7.5	(0.0)	(0.0)	(3.1)	(0.5)	(4.4)
Source: SEC Filings and Legrink Partners Estimates		(0.1)	(0.0)				(0.0)			

Source: SEC Filings and Leerink Partners Estimates

US Glybera Model	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
US population (M)	303	306	309	312	315	318	322	325	328	331	335	338	341	345	348	352	355
% adult	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%
Adult US population (M)	230	233	235	237	240	242	244	247	249	252	254	257	259	262	265	267	270
% with SHTG (>2000mg/dL)	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%
Adult pts with SHTG	41,450	41,865	42,284	42,706	43,133	43,565	44,000	44,440	44,885	45,334	45,787	46,245	46,707	47,174	47,646	48,123	48,604
% with LPLD	2.55%	2.57%	2.59%	2.62%	2.59%	2.52%	2.40%	2.25%	2.12%	1.99%	1.87%	1.77%	1.67%	1.58%	1.49%	1.41%	1.34%
LPLD patients	1,057	1,077	1,097	1,117	1,117	1,097	1,057	1,002	951	903	858	817	779	743	710	679	650
LPLD incidence	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
% with severe pancreatitis	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
LPLD Patients with severe pancreatitis	528	538	548	558	558	548	528	501	475	451	429	409	389	372	355	339	325
Patients treated with Glybera					20	40	60	75	71	68	64	61	58	56	53	51	49
Cost per course (€ MM)					0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
US sales (€ MM)					15	30	45	56	53	51	48	46	44	42	40	38	37

Source: Leerink Partners Estimates

EU Glybera Model	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EU population (M)	505	510	515	520	526	531	536	541	547	552	558	563	569	575	580	586	592
% adult	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%	76%
Adult EU population (M)	384	388	392	395	399	403	407	411	416	420	424	428	432	437	441	446	450
% with SHTG (>2000mg/dL)	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%	0.02%
Adult pts with SHTG	69,084	69,775	70,473	71,177	71,889	72,608	73,334	74,067	74,808	75,556	76,312	77,075	77,846	78,624	79,410	80,204	81,006
% with LPLD	2.58%	2.60%	2.60%	2.56%	2.47%	2.39%	2.28%	2.15%	2.03%	1.92%	1.82%	1.72%	1.63%	1.55%	1.48%	1.41%	1.34%
LPLD patients	1,784	1,814	1,829	1,819	1,779	1,733	1,672	1,593	1,519	1,450	1,386	1,327	1,271	1,220	1,172	1,127	1,086
LPLD incidence	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
% with severe pancreatitis	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
LPLD Patients with severe pancreatitis	892	907	915	910	890	866	836	796	759	725	693	663	636	610	586	564	543
Patients treated with Glybera		10	25	50	80	87	100	119	114	109	104	99	95	91	88	85	81
Cost per course (€ MM)		0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75	0.75
Chiesi EU sales (€ MM)		8	19	38	60	65	75	90	85	82	78	75	72	69	66	63	61
% royalties to QURE		40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
EU royalties to QURE (€ MM)		3	8	15	24	26	30	36	34	33	31	30	29	27	26	25	24
% COGS incurred by QURE on EU sales		20%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%	10%
COGS incurred by QURE on EU sales		2	2	4	6	6	8	9	9	8	8	7	7	7	7	6	6
QURE EU royalties net of COGS (€ MM)		2	6	11	18	19	23	27	26	24	23	22	21	21	20	19	18
QURE EU royalties net of COGS as % of sales		20%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%

Source: Leerink Partners Estimates

US AMT-060 Model	2013	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Hemophilia prevalence	20,750	21,000	21,250	21,500	21,750	22,000	22,250	22,500	22,750	23,000	23,250	23,500	23,750	24,000	24,250	24,500	24,750	25,000
% Hemophilia B	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
Hemophilia B patients	3,113	3,150	3,188	3,225	3,263	3,300	3,338	3,375	3,413	3,450	3,488	3,525	3,563	3,600	3,638	3,675	3,713	3,750
% mild (FIX >5%)	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
% moderate (FIX 1-5%)	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%	15%
% severe (FIX <1%)	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Moderate/severe Hemophilia B patients	2,334	2,363	2,391	2,419	2,447	2,475	2,503	2,531	2,559	2,588	2,616	2,644	2,672	2,700	2,728	2,756	2,784	2,813
Patients treated	1,928	2,008	2,052	2,097	2,143	2,189	2,225	2,261	2,298	2,335	2,372	2,409	2,447	2,485	2,524	2,563	2,602	2,641
% patients treated	83%	85%	86%	87%	88%	88%	89%	89%	90%	90%	91%	91%	92%	92%	93%	93%	93%	94%
% treated w/ plasma FIX producs	12%	11%	8%	3%	0%	0%	0%	0%	0%	<b>0</b> %	0%	0%	0%	0%	<b>0</b> %	0%	0%	0%
% treated w/ recombinant FIX producs	71%	74%	<b>77%</b>	<b>83</b> %	88%	88%	84%	77%	65%	53%	41%	31%	31%	31%	31%	30%	30%	30%
% treated w/ gene Tx							5%	10%	20%	30%	40%	<i>50%</i>	51%	51%	<b>52%</b>	<b>52%</b>	<i>53%</i>	<i>53%</i>
% treated w/ AMT-060 (QURE)							5%	8%	14%	20%	26%	35%	35%	35%	36%	36%	37%	37%
% treated w/ other FIX gene Tx								2%	6%	11%	14%	16%	16%	16%	16%	16%	16%	16%
% treated w/ RNAi Tx								2%	5%	7%	10%	10%	10%	10%	10%	11%	11%	11%
Patients treated w/AMT-060							125	203	358	505	680	912	933	955	976	998	1,021	1,044
Annualized cost/patient (in € M)							0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
US Sales (€M)							31	51	90	126	170	228	233	239	244	250	255	261
EU sales as % of US sales							20%	50%	70%	90%	100%	100%	100%	100%	100%	100%	100%	100%
EU Sales (€M)							6	25	63	114	170	228	233	239	244	250	255	261
% royalties to QURE							40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%	40%
EU royalties to QURE (€M)							3	10	25	45	68	91	93	95	98	100	102	104
% COGS incurred by QURE on EU sales							5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%	5%
COGS incurred by QURE on EU sales							0	1	3	6	9	11	12	12	12	12	13	13
QURE EU royalties net of COGS (€ MM)							2	9	22	40	60	80	82	84	85	87	89	91
QURE EU royalties net of COGS as % of sales							35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%

Source: Leerink Partners Estimates

Proprietary pip	eline					
Agent	Partner	Vector - Gene	Indication	Status	n=	Next Events
Glybera - EU	Chiesi (EU)	AAV1-LPL	Lipopritein lipase deficiency	Approved in EU		Chiesi launch in 4Q14/1Q15
Glybera - US	Proprietary	AAV1-LPL	Lipopritein lipase deficiency	Phase III		IND in 1H14
						File BLA in 2017
						US approval in 2018
AMT-060	Chiesi (EU)	AAV5-Factor IX	Hemophilia B	Phase I/II	13-16	Initiate Phase I/II in 4Q14/1Q15
						Phase I/II interim data in mid-2015
	St. Jude	AAV8-Factor IX	Hemophilia B	IST Phase I/II	8	Interim data published
	n/a	AAV5-Factor VIII	Hemophilia A	Preclinical		Initiate Phase I/II in 1H16
	n/a	AAV9-S100A1	Congestive Heart Failure	Preclinical		Initiate Phase I/II in 1H16
Collaborator-s	ponsored programs					
Agent	Partner	Vector - Gene	Indication	Status	n=	Next Events
AMT-021	Digna Biotech	AAV5-PBGD	Acute Intermittent Porphyria	Phase I	8	Data in 2H14
AMT-110	Institut Pasteur	AAV5-NaGLU	Sanfilippo B	Phase I/II	4	Data in 2H15
AAV2/GDNF	UCSF/NIH	AAV2-GDNF	Parkinson's Disease	Phase I	24	Data in 2015
			Huntington's Diseases miRNA	Preclinical		
Source: Leerink Pa	rtners estimates, clinical t	rials.gov; company update	9S			

							EU	RO	U:	SD
		2025E	POS	Multiple	Periods		NPV	per share	NPV	per share
Glybera US sales	€	46	70%	5	10.5	€	49	3	\$ 65	4
Glybera EU net royalty	€	22	100%	10	10.5	€	68	4	\$ 90	5
AMT-060 US sales	€	233	30%	5	10.5	€	106	6	\$ 141	8
AMT-060 EU net royalty	€	82	30%	10	10.5	€	75	4	\$ 99	6
Cash						€	78	4	\$ 103	6
Total						\$	376	\$ 21	\$ 499	\$ 28
US-EURO Fx	\$	1.33	08/20/2014	1						
Discout rate		12%								
Shares Outstanding		17.6								
Source: Leerink Partners Estimates										



# Disclosures Appendix Analyst Certification

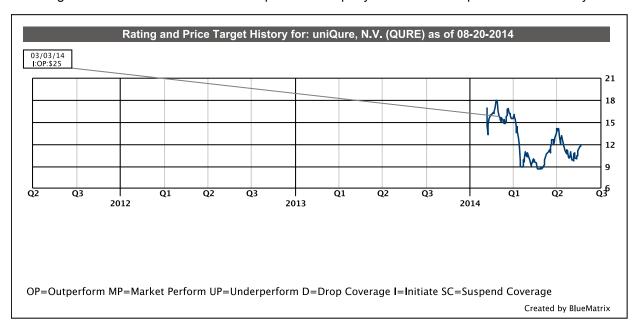
I, Michael Schmidt, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### **Valuation**

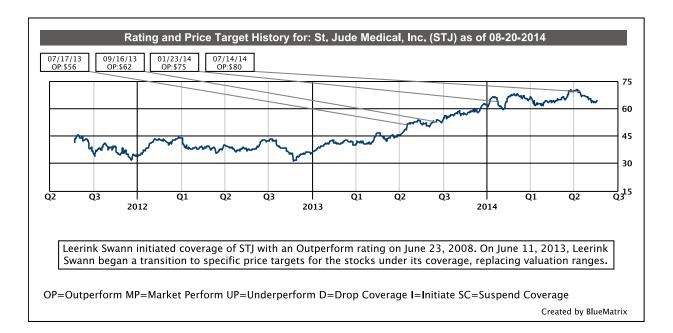
We estimate a \$28 fair value for QURE shares in one year, based on a discounted multiple of sales analysis. We attribute \$5/share to Glybera EU royalties, \$4/share to the Glybera US franchise and assume a 70% probability of success, \$14 to AMO-060 in Hemophilia B, assuming a 30% probability of success, and the rest to net cash. We use a 12% WACC as the discount rate, similar to other small-cap biotech stocks in our coverage since our revenue assumptions are already probability-of-success weighted. We model 2025 US Glybera sales of 46M EURO, 2025 Glybera EU royalties of 22M EUROs, 2025 US AMF-060 sales of 233M EUROs, and 2025 EU AMT-060 royalties of 82M EUROs (all before probability adjustment).

### **Risks to Valuation**

An investment in QURE is fundamentally a high-risk, high-reward investment, in our opinion. For risks associated with LPLD in EU, a poorer-than-expected launch, reimbursement, and inability to identify patients despite approval could harm the stock. In the US, Glybera has additional clinical, regulatory risks. On the hemophilia front, competition from Longer Acting Factors (e.g., BIIB), RNAi (e.g., ALNY) and other Gene Therapy companies could deem QURE's program as risky. Clinical and regulatory risks remain with QURE's early hemophilia program. Systemic impact from other Gene Therapy failure such as a new case of leukemia with competitor initiative could pose significant risk. Finally, financing risks also remain and we don't expect the company to be cash-flow positive for several years.









Distribution of Ratings/Investment Banking Services (IB) as of 06/30/14 IB Serv./P								
Rating	Count	Percent	Count	Percent				
BUY [OP] HOLD [MP]	138 62	69.00 31.00	50 2	36.20 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.

## **Important Disclosures**

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MEDACorp is a network of healthcare professionals, attorneys, physicians, key opinion leaders and other specialists accessed by Leerink and it provides information used by its analysts in preparing research.



In the past 12 months, the Firm has received compensation for providing investment banking services to uniQure, N.V. .

Leerink Partners LLC makes a market in uniQure, N.V.

Leerink Partners LLC is willing to sell to, or buy from, clients the common stock of St. Jude Medical, Inc. on a principal basis.

Leerink Partners LLC has acted as the manager for a public offering of uniQure, N.V. in the past 12 months.

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