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LEERINK SWANN

HEALTHCARE EQUITY RESEARCH

## HYPERION THERAPEUTICS, INC.

### 4Q Recap - Ravicti Commercial Launch to be Underway by April 30

• **Bottom Line:** HPTX reported net losses of \$8.3MM in 4Q12 vs. or estimate of \$5.2MM on incrementally higher spending. The lean commercial launch for Ravicti will be commencing by April 30. Meanwhile we expect HPTX to exercise its option to acquire Buphenyl upon completion of due diligence in 2Q13. Potential Ravicti label extension to treat hepatic encephalopathy (HE) remains a source of significant upside, in our view. **Reiterate OP and ~\$30 FVE.**

• **Lean commercial launch for Ravicti will be commencing by April 30.** HPTX is currently in the process of preparing the launch for Ravicti. Mgmt spent recent weeks with the sales force and initiated a training program. HPTX has hired seven field sales representatives, one senior director who manages the group, and also a payor specialist team of four. On the clinical side, HPTX has a medical science liaison team of four specialists, consisting of one director and three field-based specialists.

• **We expect HPTX to exercise its option to acquire Buphenyl upon completion of due diligence in 2Q13.** HPTX would market Buphenyl for use by urea cycle disorders (UCD) patients who do not transition to Ravicti or who otherwise may be ineligible to use Ravicti. Recall, HPTX has the option to purchase all of Ucylyd's (now VRX) WW rights in Buphenyl and Ammonul for an upfront payment of \$22MM until May 2, 2013. VRX has a time-limited option to retain Ammonul at a purchase price of \$32MM. If VRX exercises its option and retains Ammonul, the upfront purchase price for VRX's WW rights to Buphenyl will be \$19MM resulting in a net payment from VRX to HPTX of \$13MM.

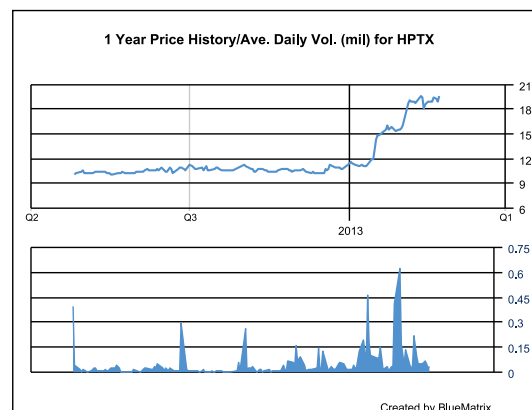
• **Ravicti label extension to treat HE remains a source of significant upside, in our view.** Based on an end-of-Phase II FDA meeting, HPTX is currently working on the final protocol including a validated endpoint measure and plans on obtaining a special protocol assessment (SPA) for Phase III likely to be launched in 2H14. Hepatic encephalopathy (HE) presents an upside market opportunity around \$500MM, in our estimation. We account for a 65% sNDA approval probability in our current valuation.

• **HPTX reported net losses of \$8.3MM in 4Q12** vs. or estimate of \$5.2MM on incrementally higher-than-expected spending. R&D expenses in 4Q12 were \$3.0MM vs. or estimate of \$2.5MM; SG&A expenses in 4Q were \$4.8MM vs. our estimated of \$2.5MM. At the end of 4Q, HPTX had a net cash position of \$37.8MM. We are adjusting our expense assumptions in our financial model to reflect spending in the last quarter as well as our expectations going forward based on the company's recently finalized commercial organization.

#### Key Stats:

(NASDAQ:HPTX)

<b>S&amp;P 600 Health Care Index:</b>	<b>945.84</b>
<b>Price:</b>	<b>\$19.56</b>
52 Week High:	\$23.47
52 Week Low:	\$9.95
Shares Outstanding (mil):	16.6
Market Capitalization (mil):	\$324.7
Book Value/Share:	\$0.00
Cash Per Share:	\$2.00
Dividend (ann):	\$0.00
Dividend Yield:	0.0%
Valuation:	~\$30 on DCF



Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2012A	0.0	0.0	0.0	0.0	0.0	(\$25.33)	(\$15.26)	(\$0.44)	(\$0.50)	(\$4.45)	NM
2013E - New	0.0	0.0	\$6.4	\$9.3	\$15.7	(\$0.80)	(\$0.04)	(\$0.53)	(\$0.44)	(\$1.81)	NM
2013E - Old	0.0	0.0	\$11.5	\$15.3	\$26.7	(\$0.79)	(\$0.06)	(\$0.30)	(\$0.16)	(\$1.31)	NM
2014E - New	--	--	--	--	\$99.1	--	--	--	--	\$1.17	16.7x
2014E - Old	--	--	--	--	\$99.1	--	--	--	--	\$1.36	NM

Source: Company Information and Leerink Swann LLC Research  
Revenues in millions. Diluted EPS. HPTX completed an IPO on 7/31/12.



## INVESTMENT THESIS

We believe that HPTX shares present an attractive opportunity to invest in the orphan drug business model and rate the stock Outperform. Lead agent Ravicti is in late-stage development for urea cycle disorders (UCD) and hepatic encephalopathy (HE), two rare diseases characterized by elevated levels of ammonia in the bloodstream, which can cause significant neurological complications. HPTX generated positive Phase III data for Ravicti in adult urea cycle disorder patients and obtained FDA approval pursuant to a special protocol assessment (SPA). HPTX has also completed Phase II trials for Ravicti in HE and had an end-of-Phase II meeting in 4Q:12. Ravicti has a similar mechanism of action to MRX's FDA-approved Buphenyl, the use of which is constrained by a large dose burden, frequent (3-6 times/day) administration, unpleasant taste and smell, tolerability issues, and high sodium content. Easier patient compliance to Ravicti therapy may enable better disease management ultimately translating into fewer hyperammonemic (HA) crises relative to what is currently available with Buphenyl. The rate of HA crises with Ravicti was 40% lower than that seen for Buphenyl in the 12-month safety extension study following HPTX's pivotal Phase III trial. HPTX is led by seasoned orphan drug company executives who have stayed close to key physicians and patient support organizations who are expected to influence Ravicti uptake. HPTX expects to launch Ravicti by April 30, 2013 with a lean team of experienced personnel including seven field sales representatives, one senior director who manages the group, and also a payor specialist team of four. On the clinical side, HPTX has a medical science liaison team of four specialists, consisting of one director and three field-based specialists running back-office operations. We project that HPTX achieves breakeven by 2014 and generates peak sales around \$150MM in UCD in 2030. HPTX may influence the conversion and expansion of the UCD market since the company has the option to purchase worldwide rights to Buphenyl and Ammonul from MRX for \$22MM, which may be funded by drawing on a loan commitment from MRX. HE presents an upside market opportunity of around \$500MM, in our estimation. In contrast to SLXP's Xifaxan, which blocks nitrogen absorption in the gut for HE patients, Ravicti lowers ammonia systemically by increasing its clearance. Ravicti could thus potentially be complementary to currently approved agents that limit the local production of ammonia. HPTX completed a Phase II clinical study of similar design to the pivotal trial used to evaluate Xifaxan, the only therapy approved by the FDA for episodic HE within the last 30 years. Phase II data indicate that Ravicti may have superior efficacy compared to Xifaxan and may improve outcomes when given in combination.

## VALUATION

Our 12-month fair value estimate for HPTX is \$30/share based on discounted cash flow (DCF) analysis. We assume a 12% discount rate and 5% terminal growth rate. We discount free cash flow until 2030E, when orphan drug exclusivity for Ravicti for treating UCD expires.

## RISKS TO VALUATION

The key risks to HPTX's valuation include the potential for disappointing clinical data, regulatory setbacks, and commercial and financial shortfalls. Since HPTX presently has only one late-stage product candidate, any of those possible setbacks may impact the stock significantly.

HPTX P&L (\$MM)	2010	2011	1Q12	2Q12	3Q12	4Q12	2012	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E
Revenue	-	-	-	-	-	-	-	-	-	6.4	9.3	15.7	99.1	115.7
COGS	-	-	-	-	-	-	-	-	-	1.0	1.4	2.4	14.9	17.4
R&D	23.1	17.2	8.9	2.7	2.4	3.0	17.0	5.0	5.0	5.0	5.0	20.0	24.8	25.5
SG&A	3.5	8.9	2.3	2.0	2.4	4.8	11.5	8.0	8.5	9.0	10.0	35.5	39.1	41.0
Operating expenses	26.6	26.2	11.2	4.8	4.8	7.8	28.5	13.0	13.5	15.0	16.4	57.9	78.7	83.8
Operating income	(26.6)	(26.2)	(11.2)	(4.8)	(4.8)	(7.8)	(28.5)	(13.0)	(13.5)	(8.5)	(7.1)	(42.1)	20.4	31.9
Total other income (expense)	1.1	(3.3)	(0.7)	(2.4)	(0.2)	(0.5)	(3.7)	(0.2)	12.8	(0.2)	(0.2)	12.1	(0.8)	(0.1)
EBT	(25.5)	(29.4)	(11.9)	(7.2)	(4.9)	(8.3)	(32.3)	(13.2)	(0.7)	(8.8)	(7.3)	(30.0)	19.6	31.8
Tax expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(25.5)	(29.4)	(11.9)	(7.2)	(4.9)	(8.3)	(32.3)	(13.2)	(0.7)	(8.8)	(7.3)	(30.0)	19.6	31.8
<b>Diluted EPS</b>	<b>(61.70)</b>	<b>(62.68)</b>	<b>(25.33)</b>	<b>(15.26)</b>	<b>(0.44)</b>	<b>(0.50)</b>	<b>(4.45)</b>	<b>(0.80)</b>	<b>(0.04)</b>	<b>(0.53)</b>	<b>(0.44)</b>	<b>(1.81)</b>	<b>1.17</b>	<b>1.89</b>
Basic shares outstanding	0.4	0.5	0.5	0.5	11.3	16.6	7.3	16.6	16.6	16.6	16.6	16.6	16.7	16.8
Dilutive securities					2.9	2.0		2.0	2.0	2.0	2.0	2.0	2.0	2.0
Diluted shares outstanding					14.2	18.6		18.6	18.6	18.6	18.6	18.6	18.7	18.8

Source: SEC filings and Leerink Swann Estimates

HPTX BS	2010	2011	1Q12	2Q12	3Q12	4Q12	2012	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E
Cash	6.6	7.0	3.7	7.3	56.5	49.9	49.9	37.7	38.0	30.4	24.3	24.3	50.3	76.6
Debt	-	23.4	30.7	40.5	12.0	12.1	12.1	12.0	12.0	12.0	12.0	12.0	12.0	-
Convertible notes	-	23.4	30.7	31.2	-	-	-	-	-	-	-	-	-	-
Venture debt	-	-	-	9.4	12.0	12.1	12.1	12.0	12.0	12.0	12.0	12.0	12.0	-
Ucyclyd loan	-	-	-	-	-	-	-	-	-	-	-	-	-	-

HPTX CFS	2010	2011	1Q12	2Q12	3Q12	4Q12	2012	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E
Change in cash	(3.5)	0.4	(3.3)	3.6	49.2	(6.7)	42.8	(12.2)	0.4	(7.6)	(6.1)	(25.6)	26.0	26.4
Cash from operations	(25.9)	(24.5)	(10.7)	(5.8)	(5.7)	(6.3)	(28.5)	(12.2)	0.4	(7.6)	(6.1)	(25.6)	26.0	38.4
Net Income	(25.5)	(29.4)	(11.9)	(7.2)	(4.9)	(8.3)	(32.3)	(13.2)	(0.7)	(8.8)	(7.3)	(30.0)	19.6	31.8
SOE	0.2	0.3	0.1	0.2	0.3	0.4	1.0	1.0	1.1	1.1	1.2	4.4	6.4	6.6
Other	(0.6)	4.5	1.1	1.1	(1.1)	1.6	2.7	-	-	-	-	-	-	-
Cash from investing	(0.0)	(0.0)	(0.1)	0.2	(0.0)	(0.0)	0.0	-	-	-	-	-	-	-
Option to purchase Buphenyl	-	-	(0.3)	-	-	-	(0.3)	-	-	-	-	-	-	-
Other	(0.0)	(0.0)	0.2	0.2	(0.0)	(0.0)	0.3	-	-	-	-	-	-	-
Cash from financing	22.4	25.0	7.6	9.2	55.0	(0.4)	71.4	-	-	-	-	-	-	(12.0)
Issuance (buyback) shares	22.5	-	(0.0)	0.1	53.4	-	53.5	-	-	-	-	-	-	-
Issuance (repay) debt	-	25.0	7.5	10.0	2.5	-	20.0	-	-	-	-	-	-	(12.0)

Other	(0.0)	-	0.1	(0.9)	(0.9)	(0.4)	(2.1)	-	-	-	-	-	-	-
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Source: SEC filings and Leerink Swann Estimates

UCD Scenario 1: Ravicti approved in UCD only	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total US pts diagnosed	1,000	1,002	1,004	1,006	1,009	1,005	1,014	1,022	1,031	1,040	1,049	1,058	1,067
Total untreated pts	575	576	577	579	580	578	583	588	593	598	603	608	613
patients < age 6	161	161	162	162	162	162	163	165	166	167	169	170	172
patients age 6-17	184	184	185	185	186	185	187	188	190	191	193	195	196
adults	230	230	231	231	232	231	233	235	237	239	241	243	245
Total Buphenyl treated pts	425	426	427	428	429	427	431	435	438	442	446	450	453
patients < age 6	119	119	120	120	120	120	121	122	123	124	125	126	127
patients age 6-17	136	136	137	137	137	137	138	139	140	141	143	144	145
adults	170	170	171	171	171	171	172	174	175	177	178	180	181
Untreated pts on Ravicti	-	-	-	-	12	3	58	88	119	120	121	122	123
penetration, patients < age 6	0%	0%	0%	0%	2%	1%	10%	15%	20%	20%	20%	20%	20%
penetration, patients age 6-17	0%	0%	0%	0%	2%	1%	10%	15%	20%	20%	20%	20%	20%
penetration, adults	0%	0%	0%	0%	2%	1%	10%	15%	20%	20%	20%	20%	20%
Prior Buphenyl treated pts on Ravicti	-	-	-	21	43	16	302	391	438	442	446	450	453
penetration, patients < age 6	0%	0%	0%	5%	10%	4%	70%	90%	100%	100%	100%	100%	100%
penetration, patients age 6-17	0%	0%	0%	5%	10%	4%	70%	90%	100%	100%	100%	100%	100%
penetration, adults	0%	0%	0%	5%	10%	4%	70%	90%	100%	100%	100%	100%	100%
Total Ravicti pts	-	-	-	21	54	19	360	479	557	562	566	571	576
Avg cost/pt(\$mm)	-	0.058	0.058	0.058	0.058	0.230	0.230	0.230	0.230	0.230	0.230	0.230	0.230
<b>Ravicti US sales in UCD (\$MM)</b>	-	-	-	1	3	4	83	110	128	129	130	131	132

Buphenyl Model Private Payors	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Patients on Buphenyl	425	426	427	406	386	411	129	43	-	-	-	-	-
Branded Buphenyl market private payor	40%	40%	40%	40%	40%	40%	40%	40%	40%	10%	0%	0%	0%
Avg cost/pt	0.056	0.019	0.019	0.019	0.019	0.075	0.230	0.230	0.230	0.230	0.230	0.230	0.230
<b>Buphenyl US sales in UCD (\$MM)</b>	10	3	3	3	3	12	12	4	-	-	-	-	-

Buphenyl Model Medicare/Medicaid	2012E	1Q13E	2Q13E	3Q13E	4Q13E	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Patients on Buphenyl	425	426	427	406	386	411	129	43	-	-	-	-	-
Branded Buphenyl market public payor	60%	60%	60%	60%	60%	60%	60%	60%	60%	10%	0%	0%	0%
Avg cost/pt	0.056	0.014	0.014	0.014	0.014	0.056	0.056	0.056	0.056	0.056	0.056	0.056	0.056
<b>Buphenyl US sales in UCD (\$MM)</b>	14	4	4	3	3	14	4	1	-	-	-	-	-

<b>Total Buphenyl US sales (\$MM)</b>	24	7	7	6	6	26	16	5	-	-	-	-	-
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<b>Total sales Ravicti + Buphenyl</b>	33	-	-	6	9	16	99	116	128	129	130	131	132
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Source: SEC filings and Leerink Swann Estimates

HPTX DCF (Scenario 1)	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	TV
FCF	(26)	26	38	52	38	40	40	41	50	50	51	51	52	52	52	53	53	54	11	
Discount periods	-	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0	12.0	13.0	14.0	15.0	16.0	17.0	18.0	
NPV	(26)	23	31	37	24	23	20	18	20	18	16	15	13	12	11	10	9	8	1	21
Valuation	305																			

Discount Rate	12%
Terminal Growth	5%

Valuation	Valuation	per shr	Probability	P/W
Scenario 1, Ravicti approved for UCD only	305	\$ 16	35%	107
Scenario 2, Ravicti approved for UCD and HE	640	\$ 34	65%	416
Blended Valuation				522
Net cash				37.8
Diluted Shares Outstanding				18.6
Per share valuation				\$ 30

Source: SEC filings and Leerink Swann Estimates

<b>Hyperion Therapeutics, Inc. (HPTX) Expected Milestones</b>			<b>Timing</b>
Ravicti	UCD	Data presentations at ACMC	Mar-13
Buphenyl		Expiration Ammunol/Buphenyl licensing option period	5/2/2013
Ammunol		Expiration MRX/VRX right to retain Ammunol	5/2/2013
Ravicti		2 addl. patent allowances	2013
Ravicti	HE	Phase III initiation	2014
Ravicti	HE	Phase III data	2015
Ravicti	HE	sNDA filing	2016
Ravicti	HE	sNDA approval	2017

*Source: Company reports, Leerink Swann LLC estimates*



## Disclosures Appendix

### Analyst Certification

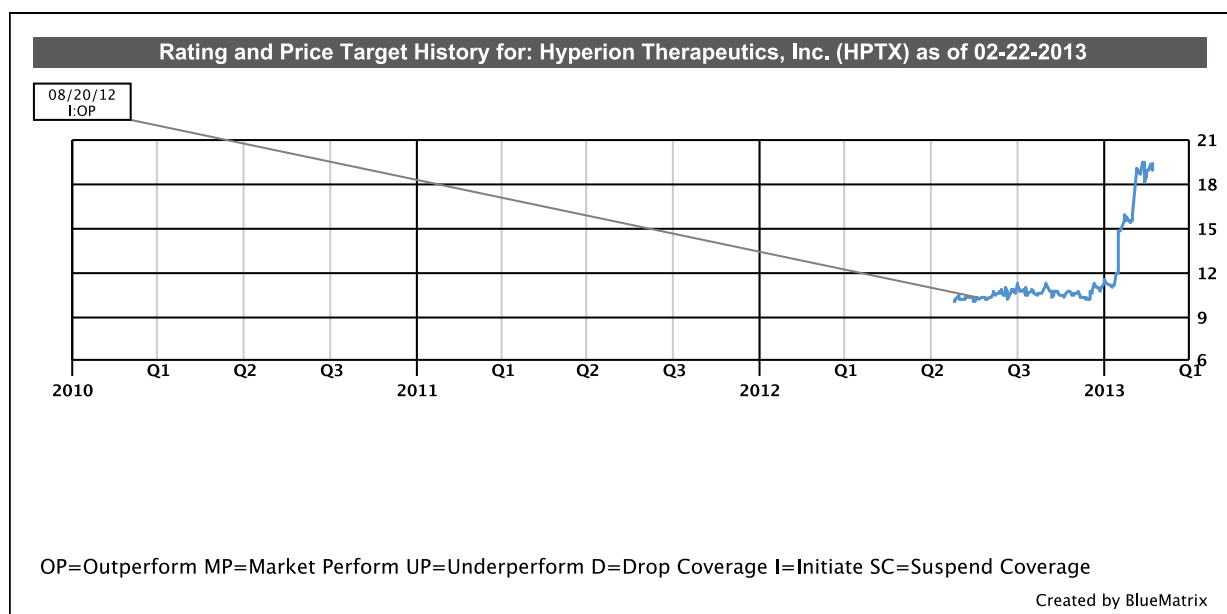
I, Joseph P. Schwartz, certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

### Valuation

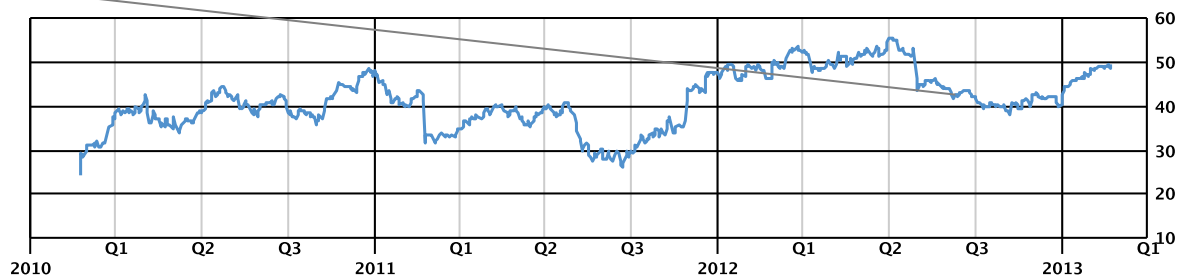
Our 12-month fair value estimate for HPTX is \$30/share based on discounted cash flow (DCF) analysis. We assume a 12% discount rate and 5% terminal growth rate. We discount free cash flow until 2030E, when orphan drug exclusivity for Ravicti for treating UCD expires.

### Risks to Valuation

The key risks to HPTX's valuation include the potential for disappointing clinical data, regulatory setbacks, and commercial and financial shortfalls. Since HPTX presently has only one late-stage product candidate, any of those possible setbacks may impact the stock significantly.





**Rating and Price Target History for: Salix Pharmaceuticals, Ltd. (SLXP) as of 02-22-2013**09/10/12  
I:MP

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 03/31/13				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OP]	107	61.14	32	29.91
HOLD [MP]	68	38.86	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.

From October 1, 2006 through January 8, 2009, the relevant benchmarks for the above definitions were the Russell 2000® 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.

Definitions of Leerink Swann Ratings prior to October 1, 2006 are shown below:

**Outperform (Buy):** We expect this stock to outperform its benchmark by more than 10 percentage points over the next 12 months.

**Market Perform (Hold/Neutral):** We expect this stock to perform within a range of plus or minus 10 percentage points of its benchmark over the next 12 months.

**Underperform (Sell):** We expect this stock to underperform its benchmark by more than 10 percentage points over the next 12 months.

For the purposes of these definitions, the relevant benchmark were the Russell 2000® Health Care Index for issuers with a market capitalization of less than \$2 billion and the S&P 500® Index for issuers with a market capitalization over \$2 billion.



## Important Disclosures

This information (including, but not limited to, prices, quotes and statistics) has been obtained from sources that we believe reliable, but we do not represent that it is accurate or complete and it should not be relied upon as such. All information is subject to change without notice. This is provided for information purposes only and should not be regarded as an offer to sell or as a solicitation of an offer to buy any product to which this information relates. The Firm, its officers, directors, employees, proprietary accounts and affiliates may have a position, long or short, in the securities referred to in this report, and/or other related securities, and from time to time may increase or decrease the position or express a view that is contrary to that contained in this report. The Firm's salespeople, traders and other professionals may provide oral or written market commentary or trading strategies that are contrary to opinions expressed in this report. The Firm's asset management group and proprietary accounts may make investment decisions that are inconsistent with the opinions expressed in this report. The past performance of securities does not guarantee or predict future performance. Transaction strategies described herein may not be suitable for all investors. Additional information is available upon request by contacting the Publishing Department at One Federal Street, 37th Floor, Boston, MA 02110.

Like all Firm employees, analysts receive compensation that is impacted by, among other factors, overall firm profitability, which includes revenues from, among other business units, the Private Client Division, Institutional Equities, and Investment Banking. Analysts, however, are not compensated for a specific investment banking services transaction.

Leerink Swann Consulting LLC, an affiliate of Leerink Swann LLC, is a provider of evidence-based strategy and consulting to the healthcare industry.

In the past 12 months, the Firm has received compensation for providing investment banking services to Hyperion Therapeutics, Inc.

Leerink Swann LLC makes a market in Hyperion Therapeutics, Inc. and Salix Pharmaceuticals, Ltd.

Leerink Swann LLC has acted as the manager for a public offering of Hyperion Therapeutics, Inc. in the past 12 months.

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Leerink Swann LLC Equity Research			
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