

Revance Therapeutics

(RVNC-NASDAQ)

Stock Rating: Outperform**Industry Rating:** Outperform

August 7, 2014

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Shares Under Pressure

Event

We believe that Revance shares were under selling pressure on Wednesday due to two factors: 1) the expiry of the IPO lock-up period, which occurred on Monday, August 4; and 2) the issuance of new FDA draft guidance on upper facial lines, which appears to have been issued on August 4 but circulated today. We spoke with the company late in the day.

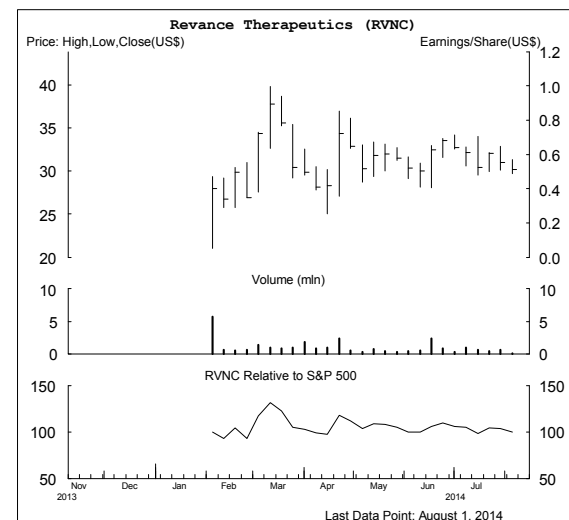
Impact & Analysis

On the expiry of the lock-up: The expiry of a lock-up on shares often has a negative impact on the shares for a short period, of time and we would not be surprised if this were a significant part of the recent price pressure. On the FDA guidance: The new draft guidance on facial line treatments took the market by surprise, as we believe investors and companies were unaware that the FDA was contemplating issuing draft guidance. Most problematic in new guidance is the statement that the “endpoint should be based on responder rates defined by an IA scale at maximum contraction and an SSA scale at maximum contraction.” Recall that Revance’s clinical program was designed after an official dispute resolution with the FDA and uses responder rates at rest, not at maximum contraction (or smile).

Valuation & Recommendation

We are making no changes to our model at this time. The new draft guidelines do represent an incremental negative risk for investors. We do not want to get overly concerned as a knee-jerk reaction, because final guidance can change dramatically. However, if the final FDA guidance were identical to the draft guidance, we believe that the guidelines would be contrary to Revance’s current clinical program. What then? Well, guidelines are just advice, and a company can either alter its clinical programs to be better aligned with the guidelines or convince the FDA, and perhaps a panel, that the studies it has conducted and the endpoints chosen are the right ones for its drug.

Price (6-Aug) \$25.95 **52-Week High** \$39.86
Target Price \$37.00 **52-Week Low** \$21.00



(FY-Dec.)	2012A	2013A	2014E	2015E
EPS	na	na	-\$2.54	-\$3.33
P/E			na	na
CFPS	na	na	-\$2.83	-\$3.53
P/CFPS			na	na
Rev. (\$mm)	na	\$0	\$0	\$0
EV	na	\$512	\$512	\$512
EBITDA (\$mm)	na	na	na	na
EV/EBITDA	na	na	na	na
Quarterly EPS	Q1	Q2	Q3	Q4
2012A	na	na	na	na
2013A	na	na	na	na
2014E	-\$1.93a	-\$0.73	-\$0.74	-\$0.74
Dividend	\$0.00			0.0%
Book Value	-\$14.16			-1.8x
Shares O/S (mm)	18.6			Mkt. Cap (mm)
Float O/S (mm)	6.7			\$483
Wkly Vol (000s)	1,058			Float Cap (mm)
Net Debt (\$mm)	\$11			\$174
				Wkly \$ Vol (mm)
				\$32.6
				Next Rep. Date
				na

Notes: All values in US\$

First Call Mean Estimates: REVANCE THERAPEUTICS INC (US\$)
2014E: -\$2.84; 2015E: -\$3.42

Details & Analysis

We believe that Revance shares were under selling pressure on Wednesday due to two factors:

- 1) The expiry of the IPO lock-up period, which occurred on Monday, August 4; and
- 2) The issuance of new FDA draft guidance on upper facial lines, which appears to have been issued on August 4 but circulated today. We spoke with the company late in the day.

On the expiry of the lock-up: The expiry of a lock-up on shares often has a negative impact on shares for a short period of time, and we would not be surprised if this were a significant part of the recent price pressure.

On the FDA guidance: The new draft guidance on facial line treatments took the market by surprise, as we believe investors and companies were unaware that the FDA was contemplating issuing draft guidance. Most problematic in new guidance is the statement that the “endpoint should be based on responder rates defined by an IA scale at maximum contraction and an SSA scale at maximum contraction.” Recall that Revance’s clinical program was designed after an official dispute resolution with the FDA and uses responder rates at rest, not at maximum contraction (or smile).

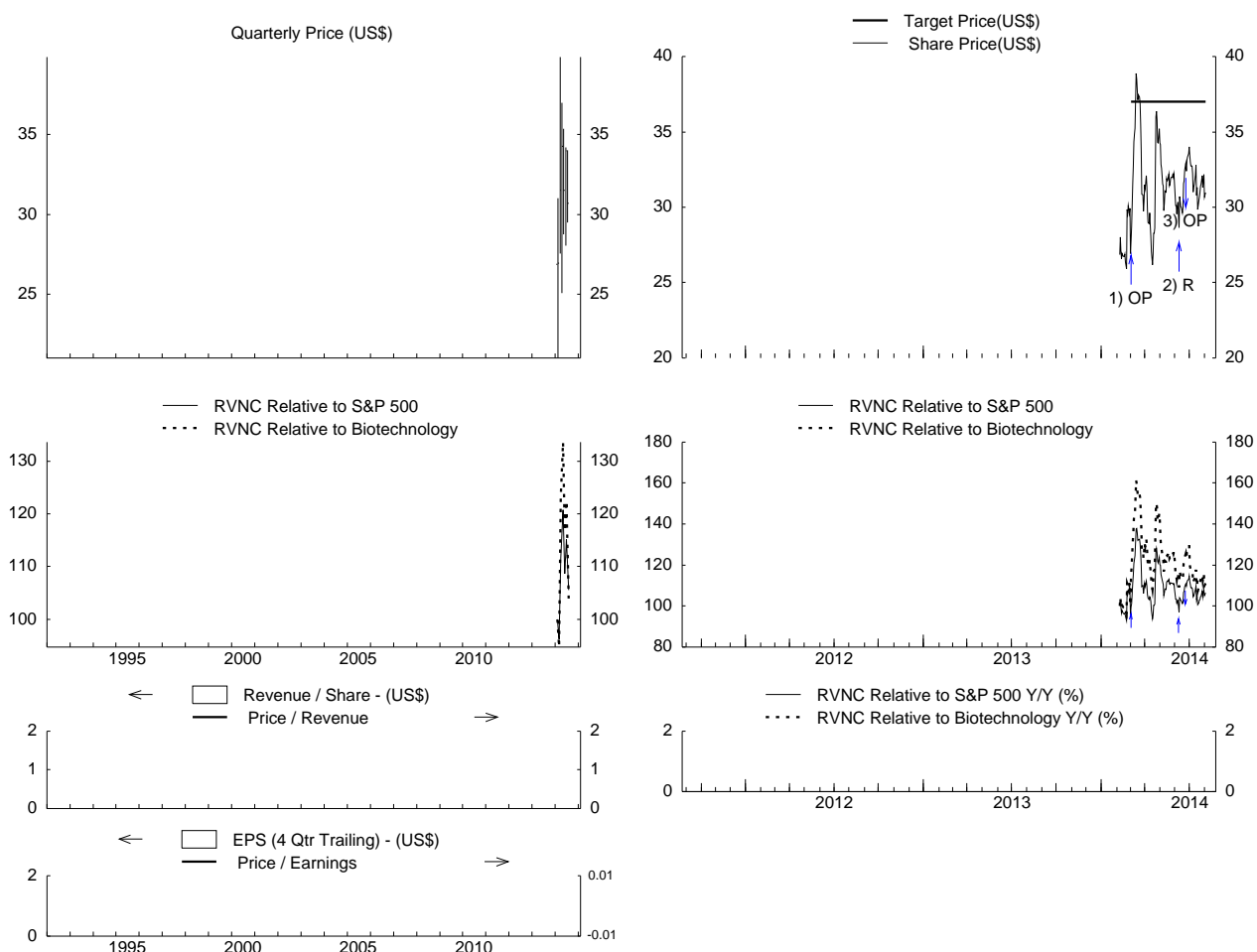
The FDA also noted, “Success should be defined as achievement of a score of 0 or 1 and a two-grade improvement from the baseline, on both the IA and the SSA scales concurrently, to ensure clinical significance.” We believe that Revance’s program may be better able to show a statistically significant response, but perhaps not a two-grade improvement.

One of our questions is why did the FDA not include Revance’s approach in its draft guidance? Is this the FDA reasserting its position despite the dispute resolution win by Revance or is this simply draft guidance that is trying to be broad and will be refined in final form? Final guidance may take a year or longer to be issued.

Revance says: 1) Revance intends to provide robust input into the guidance process including data, feedback from key opinion leaders, and the rationale that led to its phase III study design; 2) none of the information in the draft guidance causes it to change its clinical development plan and it still intends to file the BLA for RT001 in 2016; and 3) Revance is pleased that the dialog with the FDA and industry is taking place now, rather than after filing, and remains hopeful that the clinical plan it is pursuing will be acceptable.

Our View: We are making no changes to our model at this time. The new draft guidelines do represent an incremental negative risk for investors. We do not want to get overly concerned as a knee-jerk reaction, because final guidance can change dramatically. However, if the final FDA guidance were identical to the draft guidance, we believe that the guidelines would be contrary to Revance’s current clinical program. What then? Well, guidelines are just advice, and a company can either alter its clinical programs to be better aligned with the guidelines or convince the FDA, and perhaps a panel, that the studies it has conducted and the endpoints chosen are the right ones for its drug.

Revance Therapeutics (RVNC)



FYE (Dec.)	EPS US\$	P/E Hi - Lo	DPS US\$	Yield% Hi - Lo	Payout %	BV US\$	P/B Hi - Lo	ROE %
Range*		na na		NC			>15 >15	
Current*	ND	na	0.00	0.0	na	-14.2	-2.2	na

RVNC - Rating as of 5-Feb-14 = NR

Date	Rating Change	Share Price
1 3-Mar-14	NR to OP	\$27.78
2 9-Jun-14	OP to R	\$28.65
3 23-Jun-14	R to OP	\$32.93

* Current EPS is the 4 Quarter Trailing to Q1/2014.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (August 1, 2014): \$30.99
 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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Risks: In addition to the normal risks inherent in pharmaceutical companies, such as regulatory, reimbursement, and competitive risks, our valuation of RVNC carries several other risks. Among the risks to our valuation is RVNC's dependence on approval of their lead product and anticipated sales and profitability to drive the value of RVNC.

Unseen side effects, safety issues, and competitive threats have not been taken into account in our valuation and if any of these were to emerge, it is likely RVNC shares would be significantly and negatively impacted. RVNC is currently running at a substantial loss, and with this fact comes several other risks, including the potential need for financing. One cannot be certain that RVNC would be able to secure additional financing and at what cost. Our valuation includes a value for the current pipeline of additional products RVNC is investigating. We have estimated a public market value for these assets based on what a similar company might be valued in a public market. Less is known about these programs relative to RVNC's lead program and given their early nature, they carry substantial development risk.

Distribution of Ratings (June 30, 2014)

Rating Category	BMO Rating	BMOCM US Universe*	BMOCM US IB Clients**	BMOCM US IB Clients***	BMOCM Universe****	BMOCM IB Clients*****	Starmine Universe
Buy	Outperform	44.1%	21.1%	67.5%	43.3%	58.6%	55.4%
Hold	Market Perform	50.9%	8.4%	31.3%	51.2%	39.9%	39.5%
Sell	Underperform	5.0%	3.4%	1.3%	5.5%	1.5%	5.1%

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