

Revance Therapeutics

(RVNC-NASDAQ)

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

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On the Road With Revance: Update on Development Timelines

Event

Last week we hosted Revance for investor meetings in Boston and New York. Dan Browne (CEO) and Lauren Silvermail (CFO) from Revance discussed the recent timeline setback and the path forward.

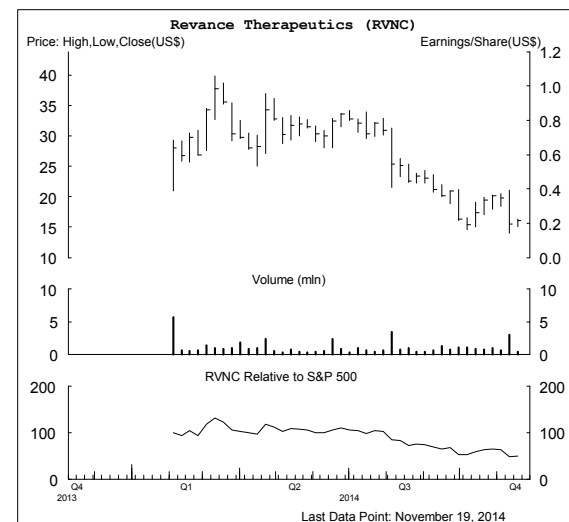
Impact & Analysis

Revance provided insight into the setback of delaying the Phase III trial for its topical product RT001 for lateral canthal (crow's feet) lines, and shed light on its plans and commitment to RT001. The company also discussed its view on the updated FDA draft guidelines on upper facial lines and said it believes it could get RT001 approved for crow's feet lines even if the draft guidance is finalized in its current form. Revance also emphasized its development programs for RT001 for hyperhidrosis (excessive sweating) and injectable RT002 for glabellar (frown) lines remain on track, and are unaffected by the delay to RT001 for crow's feet lines. The tone of investors ranged realistic optimism to skepticism. This note contains key takeaways and questions that had investors eager to meet with management.

Valuation & Recommendation

Overall we think our discussion with management and following investor meetings were timely and insightful. We also updated our model with 3Q earnings results, and have adjusted estimates accordingly. As we mentioned in previous notes, the reasons for the timeline delay carries with it real risks for RT001 for investors, so while we maintain our Outperform rating, investors should be cognizant of the risks.

Price (25-Nov) \$16.58 **52-Week High** \$39.86
Target Price \$31.00 **52-Week Low** \$14.02



(FY-Dec.)	2012A	2013A	2014E	2015E
EPS	na	na	-\$2.24↑	-\$3.75
P/E			na	na
CFPS	na	na	-\$3.35↑	-\$3.87↓
P/CFPS			na	na
Rev. (\$mm)	na	\$0	\$0	\$0
EV	na	\$512	\$883	\$883
EBITDA (\$mm)	na	na	-\$48	-\$76
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	-\$0.69a	-\$0.60a	-\$0.71
Dividend	\$0.00			0.0%
Book Value	-\$14.16			-1.2x
Shares O/S (mm)	23.5			\$389
Float O/S (mm)	6.7			\$111
Wkly Vol (000s)	1,081			\$28.8
Net Debt (\$mm)	\$4			na
Yield				0.0%
Price/Book				-1.2x
Mkt. Cap (mm)				\$389
Float Cap (mm)				\$111
Wkly \$ Vol (mm)				\$28.8
Next Rep. Date				na

Notes: All values in US\$

First Call Mean Estimates: REVANCE THERAPEUTICS INC (US\$)
2014E: -\$3.06; 2015E: -\$3.57

Changes

Annual EPS

2014E -\$2.38 to -\$2.24

Annual CFPS

2014E -\$3.55 to -\$3.35

2015E -\$3.84 to -\$3.87

Key Questions and Takeaways

In October, Revance Therapeutics announced it had initiated a study to confirm the successful transfer of production of the topical RT001 drug product to Revance's U.S. commercial manufacturing facility. On the company's earnings call in November, Revance announced the development timeline for RT001 for crow's feet lines has been further delayed due to inadequate preliminary results from the company's ongoing open-label. Revance also emphasized its development programs for RT001 for hyperhidrosis (excessive sweating) and injectable RT002 for glabellar (frown) lines remain on track, and are unaffected by the delay to RT001 for crow's feet lines. As such, we believe that it was good timing for management to be on the road meeting with investors.

As expected, investors in the meetings sought more detail surrounding the delay of topical RT001 for crow's feet lines and the draft FDA guidelines. Revance believes taking the extra time to complete the short duration clinical study, prior to enrolling patients in its pivotal studies to confirm successful manufacturing transfer of RT001, has the potential to benefit the pipeline of RT001 product candidates. Below are some key questions on the forefront of investors' minds and our summary of the company's answers to the most commonly asked questions during the roadshow.

Q: Why do you think the product didn't perform as well as it did in Phase II?

Revance explained that botulinum is a very complex molecule and while results proved to be statistically significant on the 1-point scale, the data for the composite endpoint was not in the 35-45% range of signal the company had outlined in its S-1. Given that the Phase IIb trial serves as a last chance to make changes before initiating a Phase III, Revance felt that it wanted to work to see data within that 35-45% range of signal and want to have the greatest probability of success before starting Phase III. Allergan (AGN; \$212.10; rated Outperform), Johnson & Johnson (JNJ; \$106.70; rated Outperform by Joanne Wuensch) and Merz Pharmaceuticals had issues at some point during the CMC process.

According to Revance, Allergan, who also used List Biological Laboratories, Inc. (List) for its initial batches, experienced problems during the CMC process, faced stability issues and almost ran out of product. JNJ experienced setbacks in the CMC process as well, which Revance believes likely happened later in the development stage, but notes that it is hard to tell from available information. Also, further speaking to the complexity of the molecule, Allergan at one point had tried to increase dose to get a longer duration, and adverse events rose significantly.

Q: Why wasn't RT002 (injectable product) also impacted by the transfer to the Revance facility and the commercial scale up?

Revance explained that the injectable product, RT002, has always been manufactured in house and there hasn't been the same complexity associated in dealing with transferring facilities and large scale ups. There will be scaling up of RT002, but Revance does not anticipate seeing similar issues. The difference in the delivery method (injection versus topical) changes the process and should alleviate any issues since the drug does not have to penetrate the skin.

Revance is doing a very early proof of concept in hyperhidrosis and will need to see how that goes before determining how to progress the development timeline. It is the same drug delivered to the skin but a completely different trial design and set of endpoints.

Q: Why didn't you just keep the manufacturing at List and work on the scale up within their facilities?

According to Revance, List is known for its work in the earlier stages of manufacturing and is not set up to handle the commercial scale quantity of Revance product, RT001, which would be required for commercialization. The company has been investing heavily in CMC capabilities and had previously planned on the transfer to its own facility. Looking back, competitor Allergan had followed this same plan of soliciting List for the initial batches and eventually moving the manufacturing away from List as larger scale was needed.

Q: Did the initial open label batch show statistical significance?

The initial batch was shown to be statistically significant; the variance, however, is in the endpoints. The regulatory endpoint is a 2-point improvement, whereas the clinical endpoint is a 1-point improvement. According to the company, it and doctors working with RT001, Botox and other Botox-like products feel that the 2-point scale is not the result or look patients are seeking. What Revance is finding is that patients want to avoid the "frozen look" and are opting for a result more along the lines of a 1-point improvement. As a result, many doctors are using smaller dosing to achieve this optimal look along the lines of a 1-point improvement. At the commercial scale, the 2-point improvement was a little less than the results seen in the Phase II trial.

Q: What are the next steps?

Management will be looking into the product, studying execution and scale. Following successful confirmation of the transfer, Revance plans to initiate its first U.S. Phase III RT001 pivotal study for the treatment of crow's feet lines, with results now anticipated during 1Q of 2015. Previously, Revance expected to report results from the first U.S. Phase III pivotal study by the end of 2014.

There will be two pivotal Phase III trials about the same size (170-200 patients) and the trials are expected to enroll quickly, in approximately one month, with an entire expected initiation to data timeline of six to nine months.

Q: What is the latest on the FDA draft guidance?

According to Revance, there have been three responses to the FDA's draft guidance. The likely next steps would be for the FDA to incorporate feedback and revise the draft in the coming years. Revance believes that it does not make sense to wait for final draft guidance, as the timing is not clear and points out that the guidance does not impact its injectable product. To shed further light on the impact of the draft guidance, management provides several examples where draft guidance has remained in draft form for an extended period of time and to this date has not been resolved into final guidance. The company feels confident that it will be able to get its topical product approved given its previous interactions with the FDA and the fact that the draft guidance does not explicitly say that the company's endpoints are insufficient to receive approval.

Q: Looking across your pipeline, would you consider cutting the RT001 topical program and moving forward with RT002?

Revance is committed to making a go at RT001 and believes the data is very close to where it needs to be to move forward, so this is encouraging. Revance also believes that the topical product, if approved, is the gateway and would likely expand the market, but the long-acting injectable product (RT002) would directly attack the \$3 billion Botox market. RT002 is a few years behind RT001's timeline, but based on the company's analysis it doesn't move the needle significantly in a discounted model. That being said, Revance believes it had undervalued its RT002 product at the start and that it could end up being bigger than RT001 largely due to the price differential. However, management reiterated it remains confident that it can obtain approval for RT001 and that as of now it plans to stay the course with commitment to RT001.

Do you expect RT001 for hyperhidrosis or RT002 for frown lines to be affected by the delay to RT001 for crow's feet lines?

Revance emphasized its development programs for RT001 for hyperhidrosis (excessive sweating) and injectable RT002 for glabellar (frown) lines remain on track, and are unaffected by the delay to RT001 for crow's feet lines. The company expects to initiate a Phase II open label study for RT001 to treat hyperhidrosis in early 2015. Revance will be using the same RT001 product it is currently using in the ongoing RT001 for CFL trial for its hyperhidrosis Phase II study, and made sure to point out the difference in anatomy and end points in these indications. Revance expects to begin a Phase II active comparator trial of RT002 before the end of the year. The five-arm, dose-ranging study will have three active arms, a placebo arm and a Botox arm, and will include 300 subjects. Revance expects interim results in late 2015.

What are the upcoming milestones?

- 1Q2015- Select RT002 therapeutic indication
- 1H2015- Results from RT001 hyperhidrosis Phase II POC
- 1H2015- Conclude RT001 open label trial, assuming success, move into phase III
- 2H2015 – RT002 interim active comparator data by end 2015
- YE 2015/Early 2016- Data from first Phase III RT001 for crow's feet lines.

Overall, the meetings were exactly as we expected – somewhat challenging and direct, but the company was forthright with the answers it has and the answers it doesn't. There are a lot of unanswered questions that should be answered in the coming months, and with them, the path forward will be clearer.

3Q Model Update

With this note we are also updating our model for 3Q results. Revance reported a loss in the third quarter of \$13.8 million vs. our expectation of a loss of \$13.7 million and consensus of a loss of \$15.4 million. The company reported a loss per share of \$0.60, beating our \$0.71 loss per share estimate and consensus \$0.69 loss per share. Revance adjusted its 2014 full-year guidance of operating expenses excluding amortization, depreciation, and stock-based compensation to be in the range of \$45-50 million (from \$55-60 million) and 2014 cash burn to be in the range of \$65-75 million (from \$75-85 million).

We have adjusted our model for 3Q earnings and our new EPS estimates are detailed below in Exhibit 1.

Exhibit 1: BMO Estimates vs. Consensus

	3Q14A	FY2014E	FY2015E	FY2016E	FY2017E
BMO EPS (New)	(\$0.60)A	(\$2.24)	(\$3.75)	(\$3.68)	(\$3.87)
BMO EPS (Previous)	(\$0.71)	(\$2.38)	(\$3.75)	(\$3.68)	(\$3.87)
Consensus	(\$1.00)	(\$3.06)	(\$3.57)	(\$3.48)	(\$3.62)

Source: Company Reports, Thomson Reuters, BMO Capital Markets.

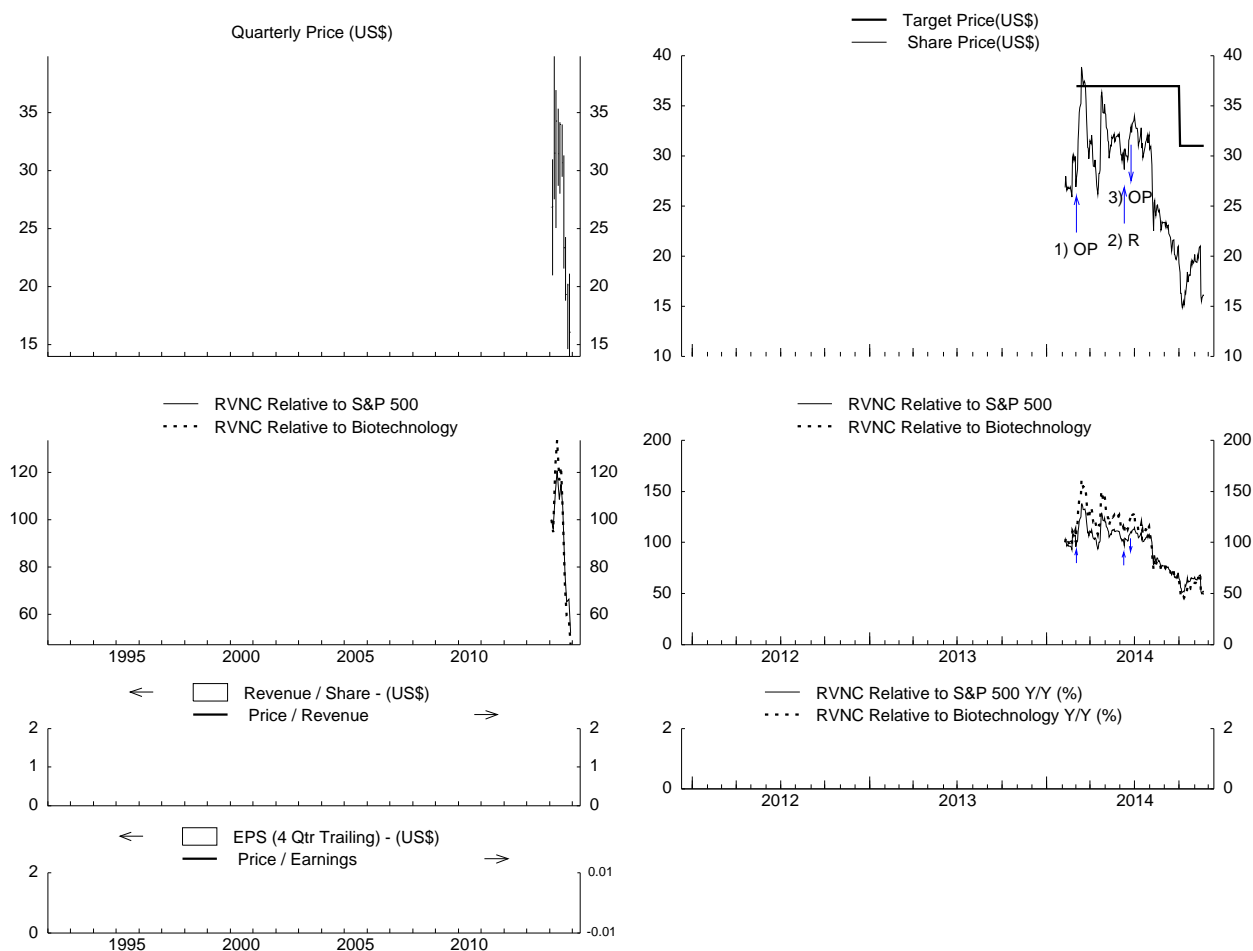
Exhibit 2: Revance Income Statement

\$ thousands, except per-share data

Revance Income Statement	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E
US Cosmetic Neurotoxin Market (est.)									
Total	\$507	\$596	\$664	\$772	\$838	\$921	\$1,059	\$1,218	\$1,309
Y/Y % Growth		17.6%	11.5%	16.2%	8.5%	10.0%	15.0%	15.0%	10.0%
EU Cosmetic Neurotoxin Market (est)	\$253.3	\$263.4	\$274.0	\$284.9	\$296.3	\$308.2	\$320.5	\$333.3	\$346.6
Y/Y % Growth			4.0%	4.0%	4.0%	4.0%	4.0%	4.0%	4.0%
RT001 (Topical Cosmetic Use) - US						\$0.0	\$85.4	\$131.3	\$167.0
Market Share						0.0%	8.1%	10.8%	12.8%
RT001 (Topical Cosmetic Use) - EU							\$0.0	\$16.7	\$22.5
Market Share							0.0%	5.0%	6.5%
RT002 (Long-Acting Injectable)								\$57.3	\$92.4
RT001 (Topical for Hyperhidrosis)								\$30.9	\$75.2
Total revenues	\$0.7	\$0.6	\$0.3	\$0.0	\$0.0	\$0.0	\$85.4	\$236.2	\$357.2
									51%
COGS	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$64.6	\$15.4	\$35.4	\$53.6
as % of product revenues							18.0%	15.0%	15.0%
Gross profit	\$0.7	\$0.6	\$0.3	\$0.0	\$0.0	\$0.0	\$70.1	\$200.7	\$303.6
Gross margin							82.0%	85.0%	85.0%
R&D	\$32.7	\$27.8	\$33.4	\$55.0	\$60.0	\$50.0	\$50.0	\$50.0	\$60.7
as % of revenues							58.5%	21.2%	17.0%
SG&A	\$11.2	\$11.0	\$19.1	\$25.0	\$25.0	\$47.0	\$60.0	\$85.0	\$126.7
as % of revenues							36.0%	35.5%	35.5%
Operating profit	(\$43.2)	(\$38.2)	(\$52.1)	(\$80.0)	(\$85.0)	(\$97.0)	(\$39.9)	\$65.7	\$116.2
Operating margin							27.8%	32.5%	32.5%
Financial Income	\$0.0	\$0.0	\$0.9	\$1.0	\$1.0	\$1.0	\$1.0	\$0.4	\$1.2
Financial Expense	\$0.0	\$0.0	(\$10.3)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Change in fair value of derivative liabilities (conv. notes)		\$1.8	\$4.0						
Changes in fair value of derivative liabilities (Medicis)		(\$0.3)	(\$0.4)						
Change in fair value of common stock warrant liability		\$0.0	(\$2.2)						
Change in fair value of convertible preferred stock warrant liability		(\$1.1)	(\$0.2)						
Loss on settlement of preferred stock warrant		\$0.0	(\$1.4)						
Other	(\$15.1)	(\$1.2)	(\$0.1)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Pretax income	(\$58.3)	(\$52.5)	(\$40.9)	(\$79.0)	(\$84.0)	(\$96.0)	(\$38.9)	\$66.1	\$117.4
Pretax margin									
Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$6.3	\$17.6
Tax rate	0%	0%	0%	0%	0%	0%	0%	10%	15%
Net income	(\$58.3)	(\$52.5)	(\$40.9)	(\$79.00)	(\$84.0)	(\$96.0)	(\$38.9)	\$59.8	\$99.8
Net margin								25.3%	27.9%
Shares out (diluted)			18.3	21.0	22.8	24.8	27.3	28.6	29.8
Earnings per share GAAP			(\$2.24)	(\$3.75)	(\$3.68)	(\$3.87)	(\$1.43)	\$2.09	\$3.34

Source: Company reports, BMO Capital Markets.

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	-1.4	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 Q2/2014.
 * Valuation metrics are based on high and low for the fiscal year.
 * Range indicates the valuation range for the period presented above.

Last Price (November 19, 2014): \$16.07
 Sources: IHS Global Insight, Thomson Reuters, BMO Capital Markets.

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Methodology: We arrive at our target price using a discounted cash flow analysis, as well as a sector multiple applied to discounted earnings.

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 (September 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	44.3%	18.0%	60.3%	43.9%	56.5%	56.0%
Hold	Market Perform	52.5%	9.7%	38.5%	51.6%	42.1%	39.1%
Sell	Underperform	3.2%	5.3%	1.3%	4.5%	1.4%	4.9%

* Reflects rating distribution of all companies covered by BMO Capital Markets Corp. equity research analysts.

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