

## Revance Therapeutics, Inc.

### RT002 Publication Continues to Suggest Duration Benefit Over Botox, Which Bodes Well for BELMONT Trial

- After the close on Thursday, January 8, Revance announced publication of the company's Phase I/II study for RT002, the company's long-acting injectable botulinum toxin being tested for the treatment of moderate to severe glabellar (frown) lines. The peer-reviewed results were published in the journal *Dermatologic Surgery* and are largely in line with what the company has previously disclosed. Specifically, the median duration of benefit of seven months and the 60% response rate at month 6 both suggest a longer duration of effect over Dysport and Botox, which we illustrate in exhibit 1, on page 2.
- The peer-reviewed results from the study continue to suggest Revance's Phase II BELMONT trial, which was initiated earlier in year, may be the most significant catalyst for the company during 2015 given the Botox comparator arm and relatively large enrollment (n=250), five-arm trial, where efficacy will be measured at week 24 against the market leader. The company expects to report interim duration results in late 2015. We believe that if RT002 can show similar efficacy and safety profiles with double the duration (as shown in its previous trials), this product could become a blockbuster and would hold promise in several aesthetic and therapeutic indications. We believe the fact that poorly differentiated compounds such as Dysport and Xeomin have captured about 24% market share without any significant efficacy, safety, or duration benefits over Botox creates an opportunity for RT002, which holds potentially twice the duration of benefit over the currently marketed brands. On the safety side, RT002 continues to show no regional or systemic spread of toxin across all four dosage levels. There has been no eyelid ptosis in all 48 patients treated with RT002 in the study, while the Botox label shows a 3% rate in its label.
- RT002 does not hold the same regulatory risk as RT001, given the uncertainty surrounding efficacy endpoints and recent FDA guidance; an editorial published along with the Phase I/II study called into question the endpoints used by the FDA. Recent FDA guidance notes that clinical trials in upper-facial procedures should use endpoints measured at maximal muscle contraction; for LCL, this would be a measurement of efficacy at maximal smile versus at rest, which is the primary endpoint included in the current RT001 Phase III program. In the editorial, the authors, Drs. Alastair Caruthers and Shannon Humphrey, both disagree with terms used in the guidance (such as "paralytic effect") and note that patients seek differing aesthetic goals depending on the anatomical areas. We believe these comments are the latest support for Revance's view on the draft guidance documents. The company also received public support from three other leading physicians in the space who called into question the endpoints of assessment at maximal contraction and the required two-point benefit, again echoing Revance's view that patients are desiring a "more natural look," one that is likely provided by RT001 in LCL. While this debate likely will continue, we note that the next upcoming catalyst for RT001 is likely resolution to the company's manufacturing issues with RT001 as well as data from a hyperhidrosis trial, which again does not hold the same endpoint risk as LCL.

*Revance Therapeutics is a clinical-stage pharmaceutical company focused on development, manufacturing, and commercialization of novel botulinum toxin products using its proprietary TransMTS technology.*

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Stock Rating: **Outperform**  
Company Profile: **Aggressive Growth**  
Price Target: \$35.00

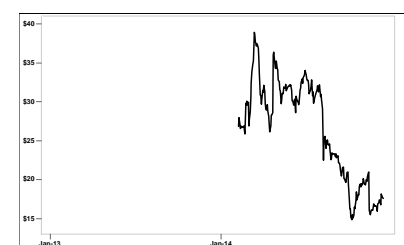
Symbol: RVNC (NASDAQ)  
Price: \$16.98 (52-Wk.: \$14-\$40)  
Market Value (mil.): \$403  
Fiscal Year End: December  
Long-Term EPS Growth Rate:  
Dividend/Yield: None

	2013A	2014E	2015E
<b>Estimates</b>			
EPS Q1	NA	A\$-1.93	NA
Q2	NA	A\$-0.69	NA
Q3	NA	A\$-0.60	NA
Q4	NA	-\$0.53	NA
FY	-\$2.69	-\$3.16	-\$2.49
CY		-\$3.16	-\$2.49
<b>Valuation</b>			
FY P/E	NM	NM	NM
CY P/E		NM	NM

<b>Trading Data (FactSet)</b>	
Shares Outstanding (mil.)	23
Float (mil.)	8
Average Daily Volume	214,260

<b>Financial Data (FactSet)</b>	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	7.9
Return on Equity (TTM)	0.0

#### Two-Year Price Performance Chart

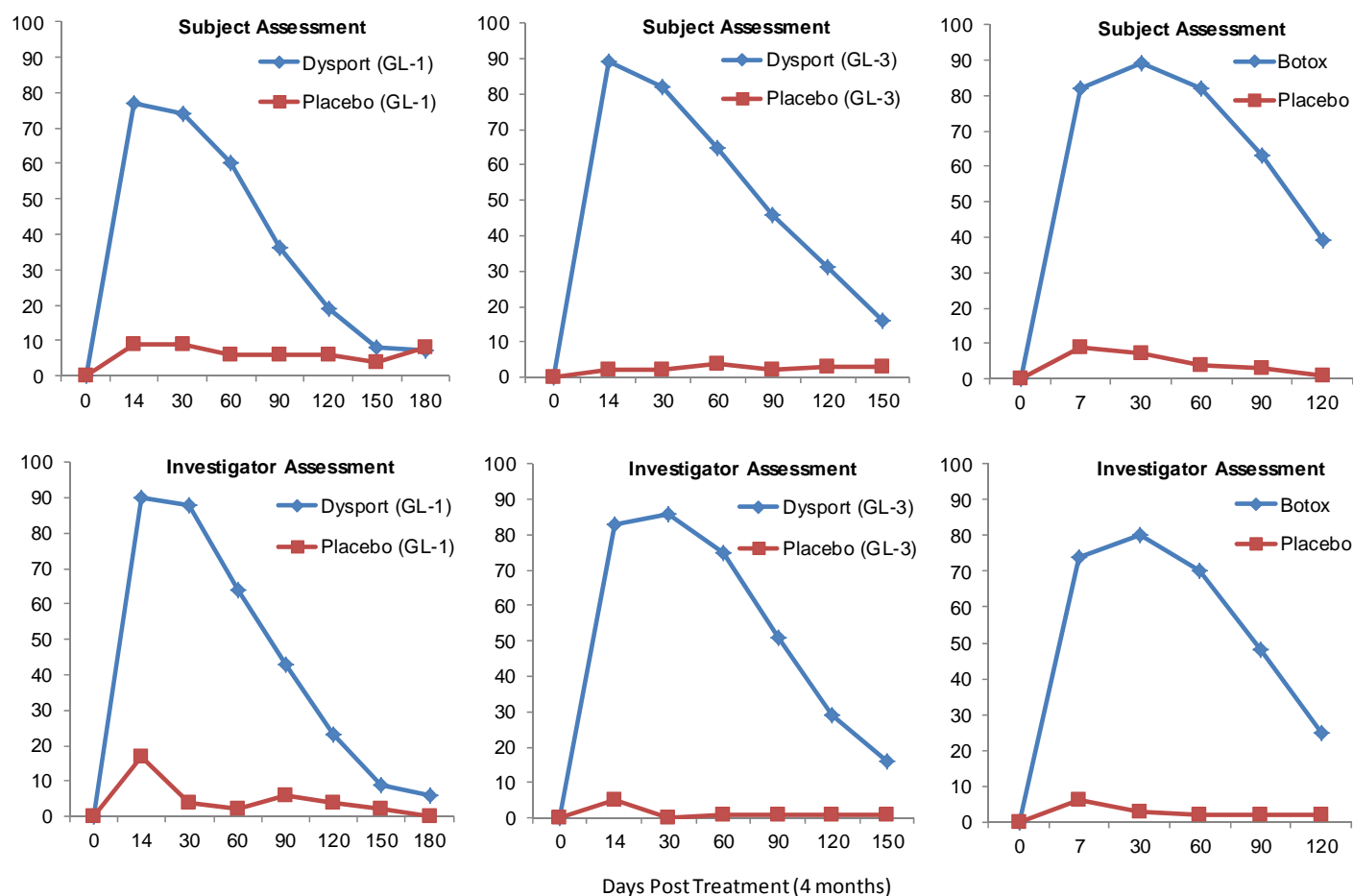


Sources: FactSet, William Blair & Company estimates

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- We continue to rate shares with an Outperform rating despite the significant uncertainty surrounding the regulatory pathway for RT001 in lateral canthal lines (LCL). While we understand investor hesitation over RT001 given the recent FDA guidelines (although we believe concerns are overdone), we believe that the potential for a topical botulinum toxin product that fits perfectly in physicians' need for a "more natural" effect is worth the risk; in addition, RT002 does not hold the same risk profile surrounding its endpoints and could also prove transformational in the large therapeutic market. We view Revance as an attractive longer-term investment given the large potential for RT002 in the therapeutic neuromodulator indications.
- We maintain our price target of \$35, based on a net present value (NPV) of the company's lead development program, RT001, which we assume in our NPV has a 25% likelihood for success; however, while we believe this to be a conservative view in terms of the efficacy and safety of the product, we believe this also conservatively handicaps the risk surrounding the recent FDA aesthetic guidelines and manufacturing capabilities. Upon a successful Phase II open-label study using the RT001 manufacturing facilities in early 2015, we would expect to increase this probability of success as the company details its plans for the Phase III program and new timelines for potential NDA and MAA submission and approval. We also place a higher value on RT002 than RT001, accounting for \$26 within our NPV calculation. While RT002 does not have exposure to the discussions surrounding the appropriate endpoints for facial aesthetic procedures, the product is in an earlier stage of development, which we believe is accounted for in our 40% risk adjustment.

**Exhibit 1**  
**Dysport and Botox: Duration of Efficacy in Investigator and Subject Assessments**



Sources: Dysport and Botox labels

## Valuation

Shares of Revance have been weak following the release of FDA guidelines for the endpoints to be used in facial aesthetic clinical trials and the company's decision to delay the initiation of its pivotal Phase III trial. The weakness in shares, however,

allows for an attractive entry point in a company that we believe holds two unencumbered assets where the reward pending an approval of either outweighs the regulatory risks.

We outline our risk-adjusted net-present-value for shares of Revance below in exhibit 2. We assume peak-year sales of RT001 will approximate \$300 million, and we project RT002 peak-year sales approaching \$700 million, both of which may be conservative given their highly differentiated profiles and the 12% growth in the worldwide neuromodulator market in recent years.

**Exhibit 2**  
**Revance Therapeutics, Inc.**  
**Risk-Adjusted Sum-of-the-Parts Valuation**

Program	Peak Sales (\$M)	Discount Rate	Probability of Success	Value per share
RT-001	\$300	11%	25%	\$ 5.45
RT-002	\$650+	11%	40%	\$ 26.09
Cash Per Share				\$ 8.04
Discounted value of future net loss				\$ (4.54)
Sum-of-the-parts NPV Valuation				\$ 35.03

Source: William Blair & Company L.L.C. estimates

## Risks

Revance faces several risks to the development and commercialization of both RT001 and RT002. Risks include those that are common among the company's development-stage peers: clinical risk, manufacturing risk, and regulatory risk.

Both pipeline candidates, RT001 and RT002, face clinical risks. The development of compounds through clinical trials has inherent risks. The company experienced a clinical setback in a prior failed Phase III trial that exhibited placebo-like efficacy. The company was able to determine that the failed results were because of new additives in the formulation and has reverted to the same formulation used in the successful Phase II program. Another Phase II study also had some trial mistakes that were identified and corrected in a subsequent cohort. The latest confirmatory Phase II trial using the company's own manufacturing facility of RT001 yielded encouraging but inconsistent results. These are examples of errors that can occur in clinical development, and while we believe that there is a significant amount of data suggesting RT001's safety and effectiveness, significant clinical risk also remains in the Phase III program with RT001 for LCL until the company can confirm it can achieve its prior efficacy results with its current formulation/manufacturing capabilities.

The manufacturing of botulinum toxin type A is a complicated process with inherent risks. The company has one manufacturing facility to support both RT001 and RT002. While we believe that controlling manufacturing is a significant strategic asset, the process is relatively complex versus small-molecule drug development. While Revance is scaling manufacturing internally, there is always a risk when young companies bring complicated manufacturing processes to scale. We are seeing this play out currently in the Phase II open-label studies that are in progress for RT001. It should be noted that botulinum toxin type A is a known toxin and regulatory scrutiny will likely be strict.

Given the recent FDA guidance, regulatory risk remains, but we believe that RT002 is shielded from the controversy and holds less regulatory risk. As was reflected in the recent share price weakness following the release of FDA draft guidance on the development of aesthetic products, the FDA may again raise issues with the "at rest" endpoint used in the development of RT001 for LCL. While Revance prevailed in a prior dispute resolution with the division, the recent guidance document suggests that we have not seen the last of this issue.

The company is entering an established market with a leader that has significant market share, so there is competitive risk and the potential for lower-than-expected market penetration. RT001 and RT002 are both botulinum toxin type A products, where Botox is the market leader, with a 76% share; the second product, Dysport, has about 15% share. While we view both RT001 and RT002 as differentiated products, when brought to market they will likely compete with entrenched brands for several indications, such as LCL, glabellar lines, and movement disorders.

William Blair & Company, L.L.C.

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William Blair was a manager or co-manager of a public offering of equity securities for Revance Therapeutics, Inc. within the prior 12 months.

William Blair is a market maker in the security of Revance Therapeutics, Inc.

William Blair intends to seek investment banking compensation in the next three months from Revance Therapeutics, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Revance Therapeutics, Inc.

Additional information is available upon request.

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DOW JONES: 17,907.87

S&P 500: 2,062.14

NASDAQ: 4,736.19



### **Current Rating Distribution (as of 12/31/14)**

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	64	Outperform (Buy)	15
Market Perform (Hold)	31	Market Perform (Hold)	2
Underperform (Sell)	2	Underperform (Sell)	0

\*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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