

Equity Research

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Price: \$21.00 (11/12/2014)

Price Target: \$55.00

OUTPERFORM (1)

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Key Data

Symbol **NASDAQ: RVNC**

Market Cap (MM) **\$493.4**

Company Quick Take

RT002 Is Where The Inherent Value Lies — Buy (Begrudgingly) Into The Weakness

The Cowen Insight

We – and the Street – continue to suffer from formulation and clinical development setbacks surrounding RT001. Since it is the most advanced clinical program, it has consumed (and understandably so) the vast majority of attention. However, we continue to be most focused on the prospects for RT002, which we believe could be a transformational product in the botulinum treatment paradigm.

Additional RT001 Open-Label Study To Be Conducted In Early 2015 Prior To Phase III Initiation; RT002 Head-To-Head Botox Study To Be Initiated By Year-End

Revance indicated on last night's call that its open-label confirmation study for RT001 (topical botulinum toxin) does not appear to be meeting the necessary efficacy to validate the formulation that was going to be used in the Phase III clinical program in lateral canthal lines (crow's feet). The explanation for what appears to be the inability to properly replicate the original formulation that was extensively studied in previous successful Phase II clinical trials is unclear. Specifically, the Company indicates that preliminary results in 32 out of 43 patients at this point are simply insufficient, with management indicating that although the grade 1 response data has been "very good," the grade 2 response data (which is the necessary regulatory threshold) has thus far been inadequate, and below what was previously observed with the original formulation. These preliminary results suggest that the manufacturing process needs to continued to be refined at Revance's commercial facility to replicate the efficacy of the original formulation and to increase the probability of success for the Phase III pivotal program. Therefore, the current ongoing open-label study will be completed, the data fully analyzed, and management (along with external consultants) will seek to make the necessary manufacturing adjustments in order to conduct another confirmatory open-label study (likely n=60) in early 2015 with an optimized product. When validated, Phase III studies can then begin. Although it is understandable that there will now be heightened cynicism around the viability of RT001, we do believe (hopefully not naively so) that this is simply a painful, but necessary, component of the topical botulinum toxin scale-up process.

With that tortured explanation of RT001 out of the way, we want to reiterate our ongoing enthusiasm for the long-duration, injectable RT002 product, which we believe has several orders of magnitude greater value. Importantly, management has confirmed plans to initiate a Phase II active comparator for RT002 – head-to-head with Botox – before the end of 2014 in frown lines. This study is designed enroll 250 patients and have three active arms of RT002 at different doses, versus Botox and placebo with interim duration results expected in late 2015. Given that the soon-to-be initiated Phase II study will be head-to-head, we believe this data could prove definitive. For background, recall, Revance has previously disclosed favorable proof-of-concept data for the injectable RT002 for the treatment of frown lines earlier this year (which is discussed again below). And this data was generated using drug product already produced at Revance's commercial facility. Stated more clearly, the RT002 drug

Please see addendum of this report for important disclosures.

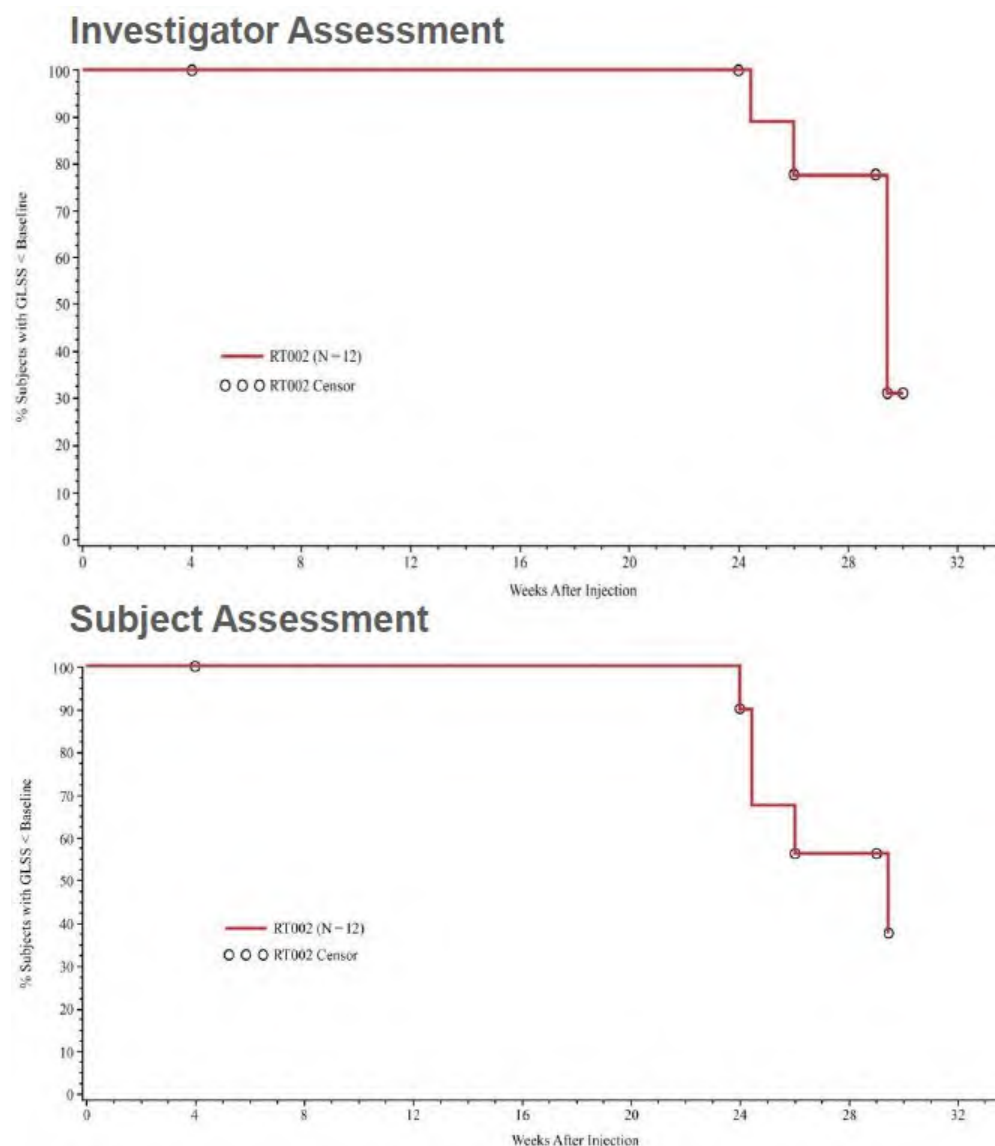
product that will be used in this Phase II head-to-head study does not need to be transferred or re-validated like RT001.

RT002 Appears To Be A Best-In-Class Injectable Toxin

As for the Phase I/II data reported for the injectable RT002 in April of this year, the 12-patient study met all primary and secondary endpoints – and importantly – demonstrated a duration of action of 7.3 months, or approximately twice as long as Allergan's Botox (3-4 months). And these results are also supported by early animal data, which – via a Toxicon publication in 2011 (H.F. Stone et al. / Toxicon 58 (2011) 159-167) – demonstrated that mice treated with RT002 demonstrated a +58-100% longer duration of action (as compared to Botox). Moreover, when using “diffusion matched doses,” RT002 treatment resulted in a +100-126% increase in duration of drug effect as compared to Botox.

Stated as simply as possible, this profile of an almost 2-fold increase in duration could prove transformational for the neurotoxin treatment market and ultimately yield a \$1B+ product. While the initial study size was relatively small, our consultants note that given the nature/profile of the product, the efficacy/duration data from the Phase I study should be strongly predictive of future clinical results. Also while early, the previous Phase I/II data suggests that it could be a blockbuster product and could ultimately support Revance's valuation alone. If the initial duration data can be replicated, which would provide clear differentiation, our clinician consultants (both in the aesthetic and in the various therapeutic indications) indicate that the product could be transformational for the injectable Botulinum toxin market. Physicians at the Company's recent clinical advisory board at ASDS appear to agree after reviewing the RT002 data. We continue to believe this is likely – and yet it is still exceedingly underappreciated by the Street. Furthermore, we believe that there is almost no attribution of this program in the current RVNC valuation, which has been supported to date only by its RT001 topical botulinum toxin. Given the near-term initiation of the head-to-head studies, we expect visibility for the program will increase substantially over the next 6-12 months. And we would also note that given its disruptive potential, we continue to believe that it would be unwise for Allergan (or Valeant if they secure the Botox asset) to let such a head-to-head study read-out without owning the program. Interestingly, an asset like this could eventually have multiple suitors (any major large pharmaceutical player would also find such an asset attractive) as the market has been built and this product could ultimately be disruptive.

RT002 Phase I/II Data Demonstrates Duration Of 7.3 Months



Source: Revance Company Reports

As for tertiary developments with the Company's clinical programs, RT001 will be moving ahead in its second indication, hyperhidrosis, with a Phase II study expected to commence in early 2015. RT002 will also enter the clinic next year in therapeutic indications, which have yet to be disclosed. Lastly, management recently submitted a comprehensive response to the FDA draft guidance for botulinum toxin products and several of their points – which we and our consultants agree with – were also echoed in two separate responses by two clinician groups [here](#).

Specifics Of The RT001 Transfer And Clinical Study Verification

For background, we would note that RT001 drug product used in the early Phase I and Phase II studies was originally manufactured by List Biological Laboratories, a contract manufacturer in the San Francisco bay area. That product was then transferred

to Revance's facility where the additional successful confirmatory Phase IIb study product was manufactured. Revance is now performing the scale-up verification of the Phase III RT001 drug product via the studies discussed above. It appears that this is fairly normal drug development work, but was disclosed due to a delay in completing this validation work in time to initiate the Phase III studies to meet their previous target of Phase III data release by year-end. We would note that for any investors seeking to analyze the study protocol via clinicaltrials.gov, they will not find it since open-label studies are not required to be posted.

Valuation Methodology And Risks

Valuation Methodology

Pharmaceuticals/Specialty

For our valuation methodology, we arrive at fair value utilizing a discounted cash flow (DCF) approach to derive our 12-month price target.

Investment Risks

Pharmaceuticals/Specialty

Risks include: (1) growing competitive dynamics in the specialty pharmaceuticals space; (2) the ability of management to execute on external growth by successfully acquiring new strategic, accretive products; (3) the ability to grow organically and keep the product pipeline robust; (4) potential regulatory delays, rejections, or failures of pipeline products; (5) economic sensitivity of any self-pay products or weakening consumer demand; (6) domestic or international pricing pressures for marketed products; and (7) failure to execute on new product launches.

Risks To The Price Target

Revance is a development-stage specialty pharmaceutical company and with that carries risk. Failure to successfully develop RT001 could result in a significant decrease to our valuation.

Addendum

Stocks Mentioned in Important Disclosures

Ticker	Company Name
RVNC	Revance

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

Underperform (3): Stock expected to underperform the S&P 500

Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

Cowen Securities, formerly known as Dahlgren Rose & Company, Rating System until May 25, 2013

Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

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Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	440	59.95%	105	23.86%
Hold (b)	278	37.87%	10	3.60%
Sell (c)	16	2.18%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.

Revance Rating History as of 11/12/2014

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Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

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