Revance

Equity Research

Company Quick Take

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Price: $29.12 (08/5/2014)
Price Target: $55.00

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: RVNC
Market Cap (MM)	$659.7

New Botox Draft Guidance Has Been Released

The Cowen Insight

The FDA has posted "Draft Guidance For Developing Botulinum Toxin Drug Products" which indicates that the agency would like to see a primary endpoint different than Revance's RT001 planned Phase III protocol. This does create some uncertainty. Nonetheless, given management's previous formal interaction with the Agency, we believe their program/protocol will be found acceptable. We would add.

The FDA Draft Guidance Is Surprising

The FDA has posted its "Draft Guidance For Developing Botulinum Toxin Drug Products" that can be found here. This Draft guidance (and we stress that at this point it is only *Draft* and not *Final*) is exceedingly relevant to Revance's RT001 – its topical botulinum toxin candidate – which is about to enter Phase III studies. The current RT001 protocol is to have the primary efficacy measurement analyzed "at rest" versus the currently approved injectable botulinum toxins which were studied and approved "at smile". There had previously been controversy surrounding Revance's decision to analyze the efficacy "at rest", but we had long thought that this controversy had passed with management's favorable receipt of a Formal Dispute Resolution with the FDA, which had provided them with comfort that their Phase III program could proceed utilizing an "at rest" measurement as the primary endpoint, and "at smile" as a secondary. Unfortunately, within the Draft guidance, the Agency noted that "For each anatomic region, the primary efficacy endpoint should be based on responder rates defined by an IA (investigator assessment) scale at maximum contraction and an SSA (subject self-assessment) scale at maximum contraction. Maximum contraction should be defined based on the targeted area (e.g., maximum frown for glabellar lines, maximum smile for LCLs)." For clarity, "LCLs" is lateral canthal lines (crows feet) and is the indication that RT001 is being studied. Therefore, this Draft guidance seems to suggest that the primary efficacy endpoints for LCL studies – such as for Revance's RT001 – should be taken "at smile", as opposed to "at rest". But as we noted above, Revance's decision to proceed with "at rest" came during an exhaustive Formal Dispute Resolution process where the Company seemingly prevailed with their viewpoint. Per page 99 of the Revance Form S-1, it states: "After our Phase 2 clinical trials, we used the FDA's Formal Dispute Resolution process and obtained written confirmation in May 2012 from the FDA that we had achieved End-of-Phase 2 and that our proposed indication, primary endpoint assessment and primary endpoint measurement were acceptable for Phase 3 clinical trials. We have incorporated the FDA's comments during this process into our Phase 3 program. Specifically, the primary efficacy assessments are being conducted at rest and additional assessments are being obtained at smile." Therefore, this new Draft document clearly seems to be in contradiction with the FDA's previous correspondence that was provided to Revance. We would note – however – that the Agency clearly can initially agree, and then disagree, but we are comforted with Revance's earlier Dispute Resolution findings.

Given that this is Draft guidance, the Agency will now solicit feedback from industry (including obviously Revance) for up to 90 days before Final guidance is issued. Therefore, the Company will have a chance to comment on this initial guidance with respect to the previous extensive discussion and formal Dispute Resolution. Also, management indicates that at this point they are anticipating no changes with respect to the initiation of their upcoming Phase III trial utilizing "at rest" – and that data should be disclosed by year-end. However, to fully understand the eventual impact of the guidance in relation to the RT001 development program, we will – unfortunately – have to wait to see the final guidance and any interaction the Company may have with the Agency. As for the initial data-set of RT001 "at smile" there is currently no data that we are aware of that would meet the FDA's 2-point improvement criteria, so clearly having this issue resolved "at rest" is critical.

Confirmatory Phase IIb Data Post Reversion To Original RT001 Formulation

ENDPOINT		Cohort 1 (n=42)		Total Study (n=82)	
	Group	Response (%)	p value	Response (%)	p value
Composite	RT001	23.8	p=0.017	**22.0**	**p=0.024**
	placebo	0		**4.9**	
IGA (Rest) 2-point	RT001	52.4	p=0.009	**41.5**	**p=0.0003**
	placebo	14.3		**12.2**	
IGA (Rest) 1-point	RT001	57.1	p=ns	**63.4**	**p=0.047**
	placebo	47.6		**41.5**	
PSA 2-point	RT001	38.1	p=0.17	**39.0**	**p=0.15**
	placebo	19.0		**24.4**	
IGA (Smile) 1-point	RT001	57.1	p=0.36	**68.3**	**p=0.0002**
	placebo	38.1		**34.1**	
IGA (Smile) 2-point	RT001	4.8	p=ns	**4.9**	**p=ns**
	placebo	0		**4.9**	

Source: Company Information; Cowen And Company

We would remind investors that in addition to the RT001 program, Revance also has recently disclosed favorable data for RT002 (which is discussed again below). While still early the 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. We continue to believe this is likely – and yet it is still exceedingly underappreciated by the Street.

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

With the successful Phase I/II long-acting injectable RT002 study complete, management is continuing to plan for a head-to-head Phase II study with a market-leading neurotoxin (Botox) that should provide data in H2:2015. As for the specifics, with the successful Phase I/II study results for RT002 (7.3 months in duration vs. the typical 3-4 months for Botox; 1.5-2.0x longer duration), we now await further details around the timing of the Phase II head-to-head initiation. While the design of the study has still not been finalized/disclosed, management did indicate that it would likely involve at least two RT002 doses, an active comparator arm (i.e. Botox), and will be focused on duration. Furthermore, given the multiple doses to be tested in the Phase II study, we believe that there may be potential to achieve an even longer duration of action than the original Phase I results. Importantly, given that it will be head-to-head we believe this data could prove definitive. 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. 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. 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, which is in Phase III development (which itself we believe is a $300-500MM product). 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. Stated more clearly: this product could simply take the market.

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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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

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

Cowen Securities, formerly known as Dahlman 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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Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	417	58.57%	94	22.54%
Hold (b)	279	39.19%	7	2.51%
Sell (c)	16	2.25%	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.

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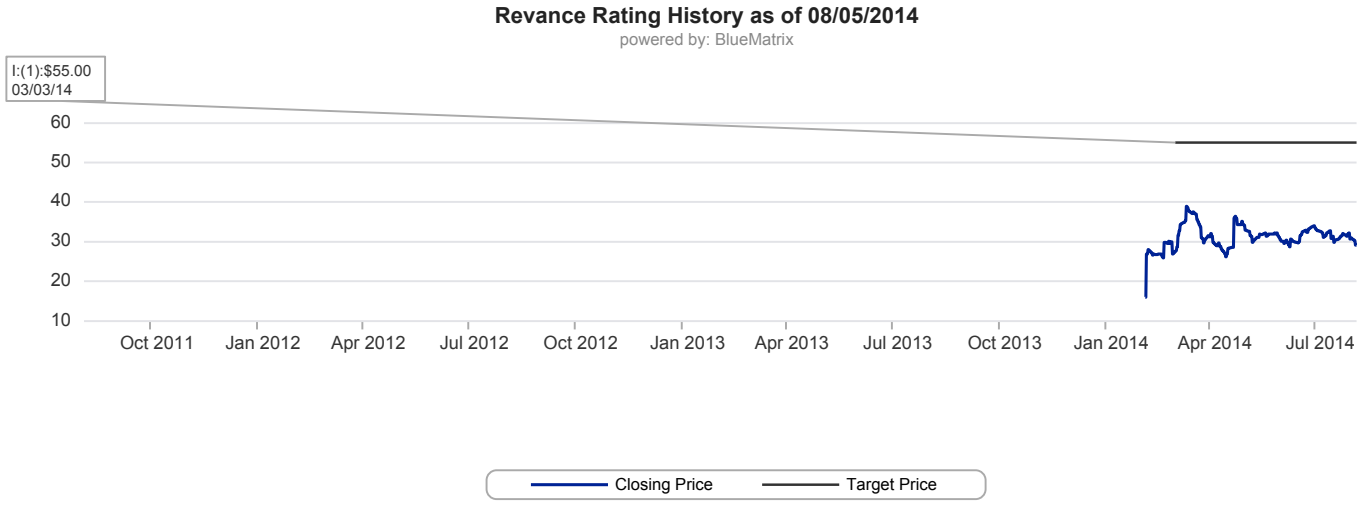

Legend for Price Chart:

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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