Revance

Equity Research

Company Quick Take

August 13, 2014

Price: $24.46 (08/12/2014)

Price Target: $55.00

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: RVNC
Market Cap (MM)	$554.1

RT001 Moving Forward As Expected; Rationale For The Approach Remains Sound

The Cowen Insight

During the Q2 earnings call, management reinforced that the development approach for RT001 is appropriate and will continue forward as planned. Management is exceedingly comfortable with the current protocol after its previous extensive Formal Dispute Resolution with senior members of the Agency, and still anticipates a straightforward regulatory pathway. RT002 also remain on track. Add here.

RT001 Will Continue To Move Forward As Planned

During the Revance Q2 earnings call, management provided its initial comments addressing the FDA's "Draft Guidance For Developing Botulinum Toxin Drug Products," that was published last week. Most importantly, Revance reiterated that the development program for RT001 remains on track and will move forward with its planned protocol. Specifically, management referenced the FDA Fact Sheet, which describes regulatory policy and indicates "Although guidances are not legally binding, they show stakeholders one way to reach their regulatory goal. However, stakeholders are free to use other approaches that satisfy the relevant law and regulations." Furthermore, management also referenced the FDA's Draft guidance itself which states "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations." Stated more clearly, even if the guidance document is finalized as is, it has merely been developed to serve as a roadmap for development programs and that Revance's extensive RT001-specific discussions with the FDA during the May 2012 Formal Dispute Resolution process should provide much greater specificity on how the Agency will likely seek to evaluate the product. In order for us to assume that the Draft guidance will determine RT001's final clinical outcome, the FDA would have to completely disregard the rigorous, formalized process that Revance already completed with the Agency. Discussions with management also clarified that the Formal Dispute Resolution meetings were with senior members of the FDA, specifically the Director and Deputy Director at the Office of New Drugs/Office of Drug Evaluation, and that the Director still continues to hold this position at the Agency. Moreover, Revance has been actively engaging with the FDA within the normal course of business and discussing all components of the RT001 development program, and there does not appear to be any significant concerns noted to date. Finally, management has also consulted with outside advisers which indicate that Revance should continue with the RT001 development protocol that has already been established and do not believe this Draft guidance alters the appropriate development pathway. Overall, yesterday's call further reinforces our belief that the clinical development approach for RT001 is sound, and that the recent concerns surrounding the Draft guidance are overdone, and that the program will continue to progress as planned.

As for the timing, data from the first U.S. Phase III trial for RT001 is still expected by year-end. Data from a second U.S. Phase III trial and a European Phase III are expected in 2015. Regarding RT002, management noted that the program is also progressing as planned and that Phase II Botox active comparator data is still expected in 2015. In terms of the financials, Revance has a cash balance of $203MM as of June 30, 2014. Management also reaffirmed guidance for 2014, with an expected cash burn of $75-85MM, including operating expenses of $55-60MM. The current cash balance is expected to fund operations through at least the next two years and should provide an extensive runway to move forward with both clinical programs.

Measuring Crow's Feet Lines At Rest (vs. At Smile) Makes More Sense For This Topical Approach

As we have discussed in previous notes and which we discuss here again, the FDA has posted its "Draft Guidance For Developing Botulinum Toxin Drug Products." 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. For the reasons we describe within this note, we continue to have significant confidence that Revance's protocols should and will be accepted. We would therefore be buying aggressively into the weakness.

Before we discuss the anatomy of the face and why an "at rest" measurement is appropriate for this topical administration, we find it exceedingly relevant to point out that the Draft guidance notes (on page 7) that "Measurements at maximum contraction should be used to assess the efficacy of botulinum toxin drug products to demonstrate the paralytic effect of the botulinum toxin. This is needed to justify the use of botulinum toxin in a drug product intended for aesthetic use (i.e., to show that the toxin has a paralytic effect on muscle and therefore is necessary for drug product effectiveness)." Essentially the Agency is trying to definitively establish that the active botulinum toxin has an effect on the muscle as opposed to how a normal cream or ointment treatment impacts and improves the skin (i.e. differentiate between a muscle effect and a skin effect). Therefore, stated more simply, the ultimate goal of the Agency is to prove that the botulinum toxin product has a paralytic muscle effect. Our understanding is that muscle paralysis was a primary focus of the Formal Dispute Resolution process in which Revance prevailed with the "at rest" measurement. Fundamentally, it is our belief that after speaking with clinicians, that muscle paralysis – the key focus here – can be measured and ultimately demonstrated "at rest," not

necessarily just "at smile" which Revance has successfully done in multiple Phase II studies. We – and our consultants – believe that this "at rest" measurement appears most appropriate for a topical product administration versus the current injectables – especially in light of the muscles that the topical is designed to primarily target versus the injectables –which we describe below. The Draft guidance does not make this distinction between the Revance topical and the other injectables and the subtle but real difference of targeting different muscles – and we believe that this will ultimately be communicated during the 90-day Draft guidance comment period, and eventually accepted by the FDA.

Discussing The Anatomy Of Crow's Feet Lines And Why A Topical Approach Is More Targeted, Thereby Limiting The Ability To Get A "Frozen Face" Look – This Is What Clinicians And Patients Want

One of the discussions that we did not fully flesh out yesterday was some of the anatomical background and rationale on why Revance is seeking to study and eventually commercialize RT001 measured "at rest" versus "at smile," which we believe will shed further light on why there will ultimately be final agreement with the Agency on the current protocol. From an anatomical perspective, crow's feet lines "at rest" are primarily produced by the muscle orbicularis oculi, while the zygomaticus major and other muscles – which run vertically down the cheek – have little effect on crow's feet lines "at rest", but a larger impact "at smile". RT001 specifically targets orbicularis oculi – the superficial circular muscle positioned around the eye and primarily responsible for crow's feet lines "at rest" – while injectables target much deeper muscles such as the zygomaticus major muscle. In essence, the injectables hit all the muscles involved in crows feet both "at rest" and "at smile". But because injectables target multiple and deeper muscles – not necessarily involved in creating wrinkles in the target area – it is possible to achieve an overeffect commonly known as "frozen face," especially in unskilled hands. Thus, even at smile, when injectable patients should show some "crinkles" to appear natural, often times they do not and frankly appear unnatural. This can result in dissatisfaction or apprehension to treatment for some patients, which clinicians ultimately want to avoid. Put simply, we – and our consultants – believe that botulinum toxin treatment is headed away from the "frozen face" look and towards a more natural look. RT001 achieves that precisely by mainly targeting the "at rest" muscles, yet still subtly hitting the muscles responsible for "at smile", just not as meaningfully as the injectables.

This topic of an unnatural look has received much public scrutiny in the media. In the past few years, there has been increased media attention and focus on the negative aspects of neurotoxin use, particularly “frozen face.” The “frozen face” look often lacks expression and appears “done”. As noted above, RT001’s delivery mechanism (transport across the skin to target superficial muscles), as opposed to injectable neurotoxins (injected deep into the dermis, potentially affecting multiple, off-target muscles), lends itself towards preventing this “frozen face” look. RT001 therefore may provide for a more natural appearance, while reducing/removing the observed crow’s feet lines "at rest". In fact, RT001 has demonstrated that it maintains the patients' natural expression in clinical studies and allows for a more natural look, not an age-inappropriate complete disabling of "crinkles" and smile lines (i.e. unnatural at a certain age). We believe that this could be a distinct marketing advantage and be favorable for women increasingly concerned of the “frozen face.” For the reasons mentioned above, physicians have stated that this is an increasingly relevant clinical effect and an "at rest" measurement is an appropriate method for looking at efficacy. The bottom line is that we – and our clinician consultants – believe that the RT001 approach underscores this very evolution in the way patients want to be treated.

The Facial Anatomy "At Rest" Versus "At Smile:" One Muscle – Not Many – Is Primary Responsible For Crow's Feet Lines

Source: Company Information

The FDA Draft Guidance Was Surprising

Although the Draft Guidance was surprising, we believe that Revance's extensive formal Dispute Resolution will ultimately prevail and be the agreed upon finalized trial design. 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

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

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.

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

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Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	417	58.57%	94	22.54%
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Sell (c)	16	2.25%	0	0.00%

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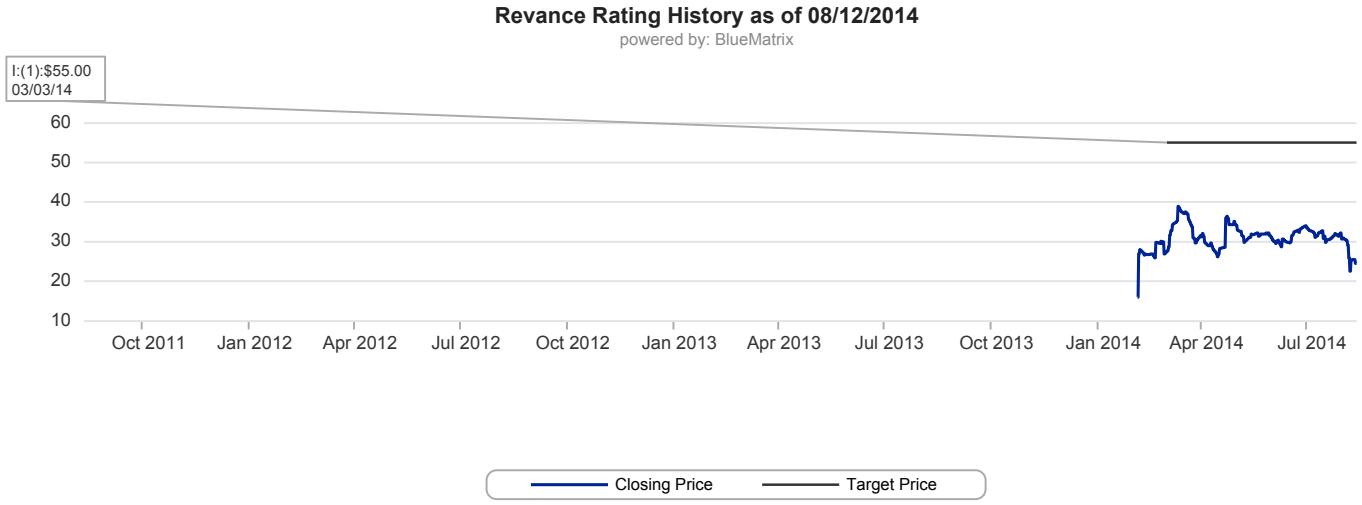

Legend for Price Chart:

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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