

Revance Therapeutics, Inc. (RVNC)

Overweight

New FDA Guidance Does Not Heighten Risk Surrounding RT001

CONCLUSION

With the issuance of FDA draft guidance on clinical endpoints for botulinum toxin products for the treatment of upper facial lines (e.g., lateral canthal lines (LCL), or wrinkles around the eyes), there is renewed concern that Revance's evaluation of LCL improvement "at rest" as opposed to "at smile" as a primary measure in its pivotal trials for RT001 will not be sufficient for FDA approval. We would not read the document that way, in part due to RVNC's dispute resolution with the FDA after Phase II work was completed (see below for more details) and given that in general, draft guidance documents can be fluid (and not to mention RT001's pristine safety profile to date). With that in mind, we would not conclude that the risk surrounding RT001 is now heightened. We reiterate our Overweight rating and \$44 PT on RVNC.

- **"At smile" or "at rest"? FDA draft guidance a source of renewed anxiety over RT001 endpoints.** The guidance document notes that *"Measurements at maximum contraction should be used to assess the efficacy... 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..."* In short, maximum contraction means "at smile." Recall that in the pivotal studies for RT001, the composite responder analysis looks at both investigator and patient assessments of LCL severity "at rest" (though RVNC has and will collect data on patients "at smile"). Treatment with RT001 has achieved superiority to placebo in terms of the portion of patients with a 1-point improvement in LCL severity "at smile," but not at the 2-point improvement that the guidance document wants. That said, RVNC has argued, with significant support from key opinion leaders, that a 2-point improvement "at smile" essentially produces the dreaded "frozen face" that is commonly stigmatized in the context of neuromodulator treatments.
- **RVNC's dispute resolution process at the end of Phase II is supportive of the current clinical endpoints, and that matters.** At the end of Phase II, the FDA's Division of Dermatology and Dental Products (DDDP) and RVNC were not in agreement on the "at smile" versus "at rest" question, and as a result, RVNC initiated a formal dispute resolution process whereby the FDA's Office of New Drugs (OND) essentially sided with the company on this issue. This is a formal ruling at a level within the agency that is administratively higher than the DDDP. Further, the document notes, as is standard practice, that a sponsor *"can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."* It is our understanding that "applicable statutes and regulations" would encompass the dispute resolution process.
- **What is important here? The data.** Our view here is that guidance documents are fluid, and that the agency assesses a drug's risk/benefit profile individually based on the totality of the data. Put another way, around 1,400 patients to date have been exposed to RT001, and the safety profile has been in keeping with commercially-available neuromodulators. Assuming the RT001 Phase III data are clean from an efficacy (i.e., meets its primary and secondary endpoints) and safety perspective, we find it hard to fathom how the product would not be approvable.

COMPANY DESCRIPTION

Revance is focused on next-generation neuromodulator treatments.

PRICE: US\$22.50

TARGET: US\$44.00

30x 2020E non-GAAP EPS of \$3.65, disc. by 20%

David Amsellem

Sr. Research Analyst, Piper Jaffray & Co.
212 284-9455, david.a.amsellem@pjc.com

Traver A. Davis

Research Analyst, Piper Jaffray & Co.
212 284-5031, traver.a.davis@pjc.com

Related Companies:

RVNC

Share Price:

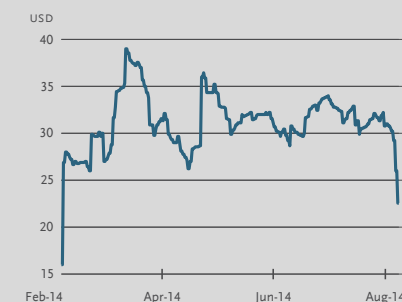
22.50

RISKS TO ACHIEVEMENT OF PRICE TARGET

Risks include clinical and regulatory setbacks for RT001 and RT002.

Note: price as of the close Aug. 7, 2014

Price Performance - 1 Year



Source: Bloomberg

Piper Jaffray does and seeks to do business with companies covered in its research reports. As a result, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decisions. This report should be read in conjunction with important disclosure information, including an attestation under Regulation Analyst certification, found on pages 2 - 3 of this report or at the following site: <http://www.piperjaffray.com/researchdisclosures>

Revance Therapeutics, Inc.

IMPORTANT RESEARCH DISCLOSURES



Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

Legend:

I: Initiating Coverage
 R: Resuming Coverage
 T: Transferring Coverage
 D: Discontinuing Coverage
 S: Suspending Coverage
 OW: Overweight
 N: Neutral
 UW: Underweight
 NA: Not Available
 UR: Under Review

Distribution of Ratings/IB Services Piper Jaffray				
Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [OW]	361	62.03	95	26.32
HOLD [N]	210	36.08	22	10.48
SELL [UW]	11	1.89	0	0.00

Note: Distribution of Ratings/IB Services shows the number of companies currently in each rating category from which Piper Jaffray and its affiliates received compensation for investment banking services within the past 12 months. FINRA rules require disclosure of which ratings most closely correspond with "buy," "hold," and "sell" recommendations. Piper Jaffray ratings are not the equivalent of buy, hold or sell, but instead represent recommended relative weightings. Nevertheless, Overweight corresponds most closely with buy, Neutral with hold and Underweight with sell. See Stock Rating definitions below.

Analyst Certification — David Amsellem, Sr. Research Analyst
— Traver A. Davis, Research Analyst

The views expressed in this report accurately reflect my personal views about the subject company and the subject security. In addition, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this report.

Research Disclosures

Piper Jaffray was making a market in the securities of Revance Therapeutics, Inc. at the time this research report was published. Piper Jaffray will buy and sell Revance Therapeutics, Inc. securities on a principal basis.

Piper Jaffray expects to receive or intends to seek compensation for investment banking services from Revance Therapeutics, Inc. in the next 3 months.

Piper Jaffray has received compensation for investment banking services from or has had a client relationship with Revance Therapeutics, Inc. within the past 12 months.

Within the past 12 months Piper Jaffray was a managing underwriter of a public offering of, or dealer manager of a tender offer for, the securities of Revance Therapeutics, Inc. or the securities of an affiliate.

Within the past 3 years Piper Jaffray participated in a public offering of, or acted as a dealer manager for, Revance Therapeutics, Inc. securities.

Piper Jaffray research analysts receive compensation that is based, in part, on overall firm revenues, which include investment banking revenues.

Rating Definitions

Stock Ratings: Piper Jaffray ratings are indicators of expected total return (price appreciation plus dividend) within the next 12 months. At times analysts may specify a different investment horizon or may include additional investment time horizons for specific stocks. Stock performance is measured relative to the group of stocks covered by each analyst. Lists of the stocks covered by each are available at www.piperjaffray.com/researchdisclosures. Stock ratings and/or stock coverage may be suspended from time to time in the event that there is no active analyst opinion or analyst coverage, but the opinion or coverage is expected to resume. Research reports and ratings should not be relied upon as individual investment advice. As always, an investor's decision to buy or sell a security must depend on individual circumstances, including existing holdings, time horizons and risk tolerance. Piper Jaffray sales and trading personnel may provide written or oral commentary, trade ideas, or other information about a particular stock to clients or internal trading desks reflecting different opinions than those expressed by the research analyst. In addition, Piper Jaffray technical research products are based on different methodologies and may contradict the opinions contained in fundamental research reports.

- **Overweight (OW):** Anticipated to outperform relative to the median of the group of stocks covered by the analyst.
- **Neutral (N):** Anticipated to perform in line relative to the median of the group of stocks covered by the analyst.
- **Underweight (UW):** Anticipated to underperform relative to the median of the group of stocks covered by the analyst.

Other Important Information

The material regarding the subject company is based on data obtained from sources we deem to be reliable; it is not guaranteed as to accuracy and does not purport to be complete. This report is solely for informational purposes and is not intended to be used as the primary basis of investment decisions. Piper Jaffray has not assessed the suitability of the subject company for any person. Because of individual client requirements, it is not, and it should not be construed as, advice designed to meet the particular investment needs of any investor. This report is not an offer or the solicitation of an offer to sell or buy any security. Unless otherwise noted, the price of a security mentioned in this report is the market closing price as of the end of the prior business day. Piper Jaffray does not maintain a predetermined schedule for publication of research and will not necessarily update this report. Piper Jaffray policy generally prohibits research analysts from sending draft research reports to subject companies; however, it should be presumed that the analyst(s) who authored this report has had discussions with the subject company to ensure factual accuracy prior to publication, and has had assistance from the company in conducting diligence, including visits to company sites and meetings with company management and other representatives.

Notice to customers: This material is not directed to, or intended for distribution to or use by, any person or entity if Piper Jaffray is prohibited or restricted by any legislation or regulation in any jurisdiction from making it available to such person or entity. Customers in any of the jurisdictions where Piper Jaffray and its affiliates do business who wish to effect a transaction in the securities discussed in this report should contact their local Piper Jaffray representative. **Europe:** This material is for the use of intended recipients only and only for distribution to professional and institutional investors, i.e. persons who are authorised persons or exempted persons within the meaning of the Financial Services and Markets Act 2000 of the United Kingdom, or persons who have been categorised by Piper Jaffray Ltd. as professional clients under the rules of the Financial Conduct Authority. **United States:** This report is distributed in the United States by Piper Jaffray & Co., member SIPC, FINRA and NYSE, Inc., which accepts responsibility for its contents. The securities described in this report may not have been registered under the U.S. Securities Act of 1933 and, in such case, may not be offered or sold in the United States or to U.S. persons unless they have been so registered, or an exemption from the registration requirements is available.

This report is produced for the use of Piper Jaffray customers and may not be reproduced, re-distributed or passed to any other person or published in whole or in part for any purpose without the prior consent of Piper Jaffray & Co. Additional information is available upon request.

Copyright 2014 Piper Jaffray. All rights reserved.