

# Revance

# **Equity Research**

October 2, 2014

Price: \$18.37 (10/1/2014)
Price Target: \$55.00

### **OUTPERFORM (1)**

#### **Ken Cacciatore**

646.562.1305 ken.cacciatore@cowen.com

#### Tyler Van Buren, M.Sc.

646.562.1338 tyler.vanburen@cowen.com

#### **Key Data**

Symbol NASDAQ: RVNC Market Cap (MM) \$431.6

# Company Quick Take

# Delay Is Frustrating, But We Should Get Another Confirmation Of Efficacy Soon

# The Cowen Insight

Clearly this delay is frustrating. However, the 60-patient study is being run to confirm the successful verification/scale-up of the RT001 product for the Phase III studies. Importantly, the likely decision to move into Phase III in mid-November would be another de facto confirmation of this product's efficacy. We believe this could further de-risk the program prior to data readout in Q1:2015.

# Small Scale Study Should Provide Another Confirmation Of Efficacy Ahead Of Phase III

Revance announced that the data from the first Phase III – which we were previously expecting in the fourth quarter of this year – will be delayed one quarter. Clearly, a delay – albeit minor – is disappointing and we share investors' frustration. And this delay is compounded by the recent disappointing FDA draft guidance, which we believe will ultimately be resolved in Revance's favor (as we've described previously here), but nonetheless that initial guidance has caused heightened concerns. We would note that management is planning a comprehensive response to the draft guidance that will likely be filed and publicly disclosed in early November, which should provide more perspective on that issue. But as for yesterday's disclosure of the new study, we note that the transfer and verification of RT001 drug product (described below) – which is causing the delay – appears to be a routine part of the drug product scale-up process, and we are apparently only learning about it because management is being transparent as to what has caused the Phase III initiation delay. Once this new RT001 Phase III-ready drug product is fully verified, the studies will begin.

As noted above, although this delay is frustrating, there is one potential positive takeaway. It appears that on Revance's third quarter earnings call to be held in mid-November, management will be in a position to confirm whether RT001 will be able to proceed forward into the Phase III studies. If it were to move forward (which we clearly believe it will), it would be because management received the proper quantitative confirmation of efficacy as the ongoing open-label study will assess – via both the investigators and the patients – that the RT001 clinical response and safety has been positive. Stated more clearly, if Revance is able to confirm the initiation of the RT001 Phase III program, this would be another confirmation of RT001 efficacy, which could further de-risk the program heading into Phase III.

# **Specifics Of The RT001 Transfer And Clinical Study Verification**

As for the specifics, 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 this study discussed above. It appears that this is fairly normal drug development work, but was disclosed via yesterday's press release due to a delay in completing this validation work in time to initiate the Phase Please see addendum of this report for important disclosures.

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Ill studies to meet their previous target of Phase III data release by year-end. The study will take 4-weeks, is open-label, and will include 60 patients. Once this study is complete, Revance is expected to initiate the first Phase III RT001 study in crow's feet lines with this same drug product, and results are now expected in Q1:2015. 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. The bottom-line is that it does not appear that this brief delay will prove meaningful.

# **Despite Recent Frustrations We Believe This Asset Is Exceedingly Compelling**

Assuming clinical success for RT001 alone, we arrive at a base valuation of \$55 per share. This assumes that Revance embarks upon its own marketing/promotional effort, which we believe this management team is very well equipped to do.

Alternatively, a potential acquirer with its own commercial infrastructure – which would significantly lower our spending assumptions in the DCF – would argue for a valuation of the RT001 opportunity of \$80. Importantly, this valuation excludes RT002, which given the recent initial data, appears too conservative. If we add in successful development of RT002 this results in a valuation in excess of \$100+ per share. Given the very positive initial profile demonstrated by RT002 and its underappreciated – yet very sizable – market opportunity and the pivotal Phase III results expected from RT001 in the first quarter of 2015, we would be adding aggressively at these levels. There is almost no other small cap name that appears to have so grossly disconnected from what is its real, inherent value, especially in-light of the data generated to date.

# 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**

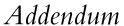
# **Pharmaceuticals/Specialty**

**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.

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# **Stocks Mentioned In Important Disclosures**

Ticker	Company Name
RVNC	Revance

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Cowen and Company, LLC. New York (646) 562-1000 Boston (617) 946-3700 San Francisco (415) 646-7200 Chicago (312) 577-2240 Cleveland (440) 331-3531 Atlanta (866) 544-7009 London (affiliate) 44-207-071-7500

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Cowen and Company Rating System effective May 25, 2013

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

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

**Hold** – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with 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 10/01/2014

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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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# Points Of Contact

# **Reaching Cowen**

### **Main U.S. Locations**

### **New York**

599 Lexington Avenue New York, NY 10022 646.562.1000 800.221.5616

### Atlanta

3399 Peachtree Road NE

Suite 417 Atlanta, GA 30326 866.544.7009

### **Boston**

Two International Place Boston, MA 02110 617.946.3700 800.343.7068

# Chicago

181 West Madison Street **Suite 1925** Chicago, IL 60602 312.577.2240

# Cleveland

20006 Detroit Road Suite 100 Rocky River, OH 44116 440.331.3531

### San Francisco

555 California Street, 5th Floor San Francisco, CA 94104 415.646.7200 800.858.9316

# **International Locations**

# **Cowen International**

# Limited London

1 Snowden Street - 11th Floor London EC2A 2DQ **United Kingdom** 44.20.7071.7500

# Cowen and Company (Asia)

# Limited

# **Hong Kong**

Suite 1401 Henley Building No. 5 Queens Road Central Central, Hong Kong 852 3752 2333





