BEHIND THE NUMBERS
Quality of Earnings Analysis

August 30, 2021

Jeff Middleswart
jmiddleswart@btnresearch.com

Bill Whiteside, CFA
bwhiteside@btnresearch.com

www.btnresearch.com

Regeneron Pharmaceuticals, Inc. (REGN)
Earnings Quality Review

6- Exceptionally Strong
5- Strong
4- Acceptable
3- Minor Concern
2- Weak
1- Strong Concern
+ quality improving
- quality deteriorating

We are initiating our earnings quality coverage of REGN at 5+ (Strong).

For an explanation of the EQ Review Rating scale, please refer to the end of this report.

Summary

Regeneron is a development biotech firm that is turning the corner from being paid to do R&D into more production and actual sales of drugs. The stock is widely held and is frequently in the news with its treatment for Covid. We are going to emphasize that we are not doctors and we are not going to review REGN based on its products, its pipeline, or the size of the markets it is pursuing. This is a review of its Earnings Quality and potential risks and positives that exist or may develop for financial results. We are writing from that angle because we see a company with a $70 billion market cap that has had a single finance-related question on its last two earnings calls. [It concerned if incremental SG&A expense would be needed to support a product launch.]

The company was soundly beating forecasts by essentially $1.25 per quarter until 2Q21 when it beat by $8.09. There are recent accounting rule changes to be aware of as well as some minor earnings events with allowances. REGN's largest adjustment for non-GAAP EPS is adding back stock compensation. More importantly, the cash flow is positive, solid, and the company is self-funding. For all these reasons we give high marks to the quality of the earnings and the beats. However, the size of the beats is also an indication that people are having a difficult time modeling forward results.

What is strong?

- REGN is self-funding. Cash flow is consistently positive, and the company is not spending cash on acquisitions. Liquidity is also strong with net cash at $5.8 billion.

- The largest adjustment to Non-GAAP earnings is adding back stock compensation. Many would regard that as tame. We do not like to see recurring costs added back but we do give REGN high marks as it is free cash flow positive even if the stock compensation is viewed as a cash expense and it is only about 10% of earnings.

- The company's accounting changes at the start of 2020 had no impact on earnings. They also made the results more conservative in our view as it decreased revenues. For a company that is rolling out new products, many investors would focus on revenue growth so an accounting change that reduces that is a positive for earnings quality to us.

- Pending stock dilution from stock options does not appear material and the company is already buying back stock to offset dilution.

What is weak?

- Working capital growth has been the largest consumer of cash at REGN. As the company sells more product vs. doing collaborative research, we would expect working capital to continue to rise.

- There are no allowances for bad debt or expiring inventory. As the company's sales are more product-related, it could be more exposed to pricing regulations, discounts, rebates, inventory that expires. Even its deferred tax assets have zero valuation allowances. It would seem more likely that these will become larger expenses going forward.

- Patent infringement lawsuits exist for REGN's most important drugs. The company adds back litigation costs to adjusted earnings. It looks to us that this will be an ongoing cost and an expense that increases going forward.

What to Watch?

- So much is new at REGN that there simply are not many numbers to review. The antibody drug was 63% of product sales in 2Q21. Much of the 2Q sales were to the US government placing a large initial order and this drug had zero sales in 2020 and a very small amount in 1Q21. We are not talking about the market size or effectiveness of the REGEN-COV drug, but we know that almost all products report huge sales when the first channel inventories are built. After stocking the channel, sales are dependent on end-users buying. That may make 2Q sales of the Covid antibody drug difficult to maintain or cause more volatility.

- The biggest risks appear to be the company transitioning to more drug sales rather than being largely an off-balance sheet R&D facility for other drug companies. In many cases, the drug sales are split with other companies and some drugs REGN only has a share of the US market.

Supporting Details

The Primary Difference between GAAP and non-GAAP EPS is Stock Comp.

When we look at GAAP and non-GAAP results, Regeneron does add back items such as gains/losses on investments, the occasional litigation item, and upfront/milestone payments received from partners on R&D efforts in the past. The accounting for the upfront/milestone payments was changed 1/1/2020, which we will describe below.

That really leaves only stock compensation, which is an ongoing expense not a one-time item, as the primary driver to inflate non-GAAP earnings.

Adjusted EPS	**2Q21**	**1Q21**	**4Q20**	**3Q20**	**2Q20**	**1Q20**
GAAP Net Income	$3,099	$1,115	$1,149	$842	$897	$625
GAAP EPS	$27.97	$10.09	$10.24	$7.39	$7.61	$5.43
Stock Comp.	$146	$131	$122	$101	$104	$106
Litigation			$121		$9	$20
Upfront R&D					$85	
Gains/Losses on Inv.	-$410	-$144	-$60	$37	-$256	$57
Tax Impact	$60	$5	$15	-$31	$14	-$37
Non-GAAP Income	$2,895	$1,109	$1,080	$961	$854	$771
Non-GAAP EPS	$25.80	$9.89	$9.53	$8.36	$7.16	$6.60

Frequent readers of *Behind the Numbers* know that we frown on using the excuse that stock compensation is a non-cash item and should not penalize earnings. We think that is particularly true for a start-up research company as few people are signing up for 3-weeks of vacation and their own parking space as perks. They want a chance at a sizeable payday if the research works and they view the stock compensation as the most important part of their pay. In many cases, companies spend more than the stock compensation amount in cash to repurchase stock to limit dilution – signaling this is a cash expense.

We will not berate Regeneron as harshly for three reasons:

- The stock compensation is only about 10%-12% of adjusted earnings. We see other companies where stock compensation may be more than 50% of adjusted earnings.

- Adding back stock compensation is not the difference between Regeneron posting income or losses. GAAP EPS with stock compensation still shows profits and the overall accounting is not aggressive as we'll discuss in the next section.

- Regeneron is generating very high cash from operations and free cash flow that exceeds the stock compensation:

	2Q21	1Q21	4Q20	3Q20	2Q20	1Q20
Cash from Ops	$627	$669	$1,231	-$254	$943	$698
Capital Exp.	$149	$115	$162	$153	$130	$170
Free Cash Flow	$479	$553	$1,069	-$408	$814	$528
Stock Comp.	$146	$131	$122	$101	$104	$106

In 3Q20, there was a sizeable increase in accounts receivable of $1.3 billion that swung cash from operations to a -$254 million. We think working capital may be the bigger problem for cash flow going forward than stock compensation. REGN has $5.8 billion in cash and securities net of debt.

We also see that REGN is not making an endless series of acquisitions, so the cash outflow for capital spending is about it. Capital spending is forecast for 2021 to be $590-$640 million, which is in line with where it has been running. In terms of the stock issuance vs. taxes paid and repurchases to offset employees' shares – RGEN has generated $2.9 billion in cash and spent $2.3 billion in the financing section over the last six quarters. (We are excluding the $5.0 billion it spent to repurchase shares from Sanofi in 2020). At this point, RGEN has $0.9 billion left on its authorized share repurchase plan.

As it currently stands, recent stock issuances have been modest, and the share count is down y/y from the peak of 117.9 million shares, which included 7.8 million stock options considered in the money in 2Q20 to 110.8 million shares, with 4.8 million stock options in the money in 2Q21. There are another 5.0 million options considered anti-dilutive and are out of the weighted average share count at this time. Even adding those back in – REGN would be at about 116 million shares with about 4.5% dilution.

Collaboration Revenues - Accounting Changes

Regeneron has two primary sources of revenue: Product Sales and Collaboration. Product Sales occur between REGN and end customers such as distributors and others selling to end-users. Collaboration sales are deals with other pharmaceutical companies where REGN is working on the research and development of new products. REGN is being paid to do contract work. These deals often have scheduled payments from the partner during the process, milestone/upfront payments for reaching targeted events, and a future business plan to divide sales and costs if a product for consumers is developed.

At the start of 2020, REGN changed its accounting policy for recognizing revenue and costs regarding collaboration deals:

> *"Effective January 1, 2020, we changed the presentation of cost reimbursements from collaborators who are not deemed to be our customers from collaboration revenue to a reduction of the corresponding operating expense (i.e., either Research and development or Selling, general, and administrative) incurred by us."*
>
> *"We also changed the presentation of amounts recognized in connection with up-front and development milestone payments received from collaboration revenue to other operating income. We made these changes in presentation because we believe the new presentation is preferable, as it better reflects the nature of the Company's costs incurred and revenues earned pursuant to arrangements with collaborators and enhances the comparability of our financial statements with industry peers."*

The key point to realize with these changes is they are primarily recognizing payments from collaborator partners as expense reductions, not as revenue. On the income statement, it's a wash with income remaining the same. The balance sheet and cash flow statement also see a change to deferred revenue (a liability account) replaced with changes to accrued/other liabilities (a different titled liability account).

This is about as tame as it gets for an accounting change. Revenues are lower and the expenses are lower after this change, with "other income" seeing an increase at times vs. lower revenue. The biggest difference is it makes revenue and R&D spending look lower, which may trigger a red flag on a computer screen. But, REGN shows the changes for 2019 and 2018. It's been 6 quarters since the change too:

	2019 reported	change	2019 adjusted
Revenue	$7,863	-$1,306	$6,558
R&D	$3,037	-$587	$2,450
SG&A	$1,835	-$493	$1,342
Manufacturing	$420	-$17	$403
Other income	$0	-$209	-$209
Total	$5,291	-$1,306	$3,986
Current Def. Rev	$592	-$210	$382
N/C Def. Rev	$619	-$514	$105
Accr curr Liab.	$1,087	$210	$1,296
N/C Accr Liab.	$286	$514	$800

The change will make the margins look a little different. For example, R&D went from 39% of revenue to 37%. Overall, it will make it look like there is less spending in R&D and SG&A. The biggest issue on monitoring items could be having deferred revenue moved into catch-all items like accrued and other liabilities.

Deferred revenue is also key because the upfront payments and milestone payments are recognized over time. Often, the estimate is tied to the total project and revenue is recognized as R&D is spent. With the R&D figure changing and more of what was deferred revenue going to accrued liabilities – forecasting the recognition of this type of earnings may become more difficult. Offsetting that is this is now booked into "other income" not as revenue. Thus, it may stand out more. Also, REGN has a history of giving good explanations and footnotes.

Our overall conclusion is the accounting changes result in the same net income and cash flow. The accounting changes happened six quarters ago and REGN is showing current and past results with the new policy. Other than having deferred revenue fall and become part of a catch-all account of accrued and other liabilities – we give REGN high-quality marks here.

Becoming More of a Production Company May Require More Working Capital

As we noted above under the adjusted earnings, REGN has been producing solid earnings and cash flows even if stock compensation is not added back. However, we also pointed out that the company is seeing working capital build as it is now selling more products rather than simply joining other partners in developing new drugs.

Here is the trend for sales:

	2Q21	1Q21	4Q20	3Q20	2Q20	1Q20
Product Sales	$4,138	$1,724	$1,622	$1,482	$1,227	$1,237
Collaboration Rev	$955	$754	$678	$653	$513	$528
Other Rev.	$46	$50	$123	$159	$212	$63
Total	$5,139	$2,529	$2,423	$2,294	$1,952	$1,828

And here is the working capital build:

Change in Wrk Cap	**2Q21**	**1Q21**	**4Q20**	**3Q20**	**2Q20**	**1Q20**
Accts Rec	-$2,826	-$58	-$81	-$1,322	$122	-$169
Inventory	$31	-$253	-$127	-$169	-$163	-$71
Prepaid Exp.	-$228	-$50	$99	-$17	-$36	$70
Def. Rev	$79	-$144	$36	$33	$5	$74
A/P and Accurals	$458	-$35	$110	-$12	$106	-$85
Total	-$2,485	-$539	$37	-$1,488	$105	-$181

It is important to note that other than 3Q20, free cash flow has still been positive in every other period despite the surge in working capital. However, a company growing its product sales may need to build even more working capital.

For earnings, REGN also has some issues with reserves. It currently has a zero balance for allowances on receivables. That may likely change going forward as product sales include rebates, discounts, distribution fees, and co-pay assistance that could all change and reduce net sales.

Inventory can also expire or be subject to discounts when sold. REGN has had inventory write-downs of $39.2 and $73.8 million in 2020 and 2019. It wrote off $140 million in 2Q21. We would expect more of that going forward and every $13 million in charges is 10-cents of EPS. The company also capitalizes inventory costs before products are approved. With $1.9 billion of inventory, this could be a sizeable issue if the net selling price differs from expectations or there are delays in approval.

At this point, REGN has several lawsuits over patent rights that it is fighting with its collaboration partners. The patent lawsuits are often shared costs with the collaboration partners or fully paid by the partners. The various deals with the collaborators give REGN geographic regions to sell products. As it transitions to more direct product sales, we would expect to see more litigation over product side effects that are common in the pharmaceutical industry.

It is difficult to project and quantify things like inventory write-downs, litigation costs, and receivable reserves. However, these reserves are at zero and appear more likely to become larger costs as inventory did in 2Q21. There will be higher revenues with these rising costs, but it does not take much in the way of costs exceeding expectations to be a material size hit to EPS. As 2Q21 showed, REGN modeling is difficult as the company's $25.80 in EPS beat forecasts by $8.09, despite having a $140 million inventory charge vs. $39 million for all of 2020.

REGN Is Dependent on Two Drugs

EYLEA is a drug for macular degeneration. It was 34% of product sales in 2Q21. REGN shares this drug with Bayer and has full rights to US sales, gets 33.5%-40.0% of profits/losses in Japan, and shares equally with Bayer on other non-US sales. It is required to reimburse Bayer for its 50% of the development costs Bayer incurred. They are effectively paying 5% of the development costs back from profits at this point, so REGN could see the net profits of this drug increase in the future when this payment stream is complete. The contingent reimbursement remaining after 4Q20 was $276 million and the payment in 2020 was $47 million.

There are patent infringement lawsuits for EYLEA and the injection syringe outstanding. There have been some proceedings withdrawn already. The risk here would seem to be having to pay a royalty to Novartis. At this point, the litigation does not appear to be a near-term risk.

The REGEN-COV drug is 63% of product sales for 2Q21 and the reason many are interested in REGN stock as it deals with Covid antibodies. This product is shared with Roche with REGN handling distribution in the US and Roche distributing in the rest of the world. There is a patent infringement lawsuit here too. There is very little discussion on this lawsuit in the 10-Q. This appears likely to be something that may not be an issue in the near term either.

We do believe that litigation will become a larger cost item for REGN going forward.

The other issue to be aware of with REGEN-COV is the US Government ordered 1.25 million doses and the company filled that request in the 2Q. That sounds like initial stocking of the channel to us, and it may be difficult to repeat that type of sales.

Explanation of EQ Rating Scale

6- (Exceptionally Strong)- Indicates uncommonly conservative accounting policies to the point that revenue and earnings are essentially understated relative to the company's peers. Higher possibility of reporting positive earnings surprises

5 (Strong)- Indicates the company has no areas of concern with its reported results and we see very little risk of the company disappointing due to recent results being overstated from aggressive reporting in recent periods.

4 (Acceptable)- Indicates the company may have exhibited a minor “red flag”, but the severity of the issue is not yet a concern. Minimal risk of an earnings disappointment resulting from previous earnings or cash flow overstatement

3 (Minor Concern)- Indicates the company has exhibited either a larger number of or more serious warning signs than companies receiving a 4. The likelihood of an immediate earnings or cash flow disappointment is not considered to be high, but the signs mentioned deserve a higher degree of attention in the future.

2 (Weak) Indicates the company’s recently reported results have benefitted materially from aggressive accounting. Follow up work should be performed to determine the nature and extent of the problem. There is a possibility that upcoming results could disappoint as the impact of unsustainable benefits disappears.

1 (Strong Concern)- Indicates that the company’s recent results are significantly overstated and that we view a disappointment in upcoming quarters is highly likely

In addition to the numerical rating, the EQ Review Rating also include either a minus or plus sign. A minus sign indicates that our analysis shows the overall earnings quality of the company has worsened since the last review and there is a possibility the numerical rating will fall should the problem continue into upcoming quarters. Likewise, a positive sign indicates that the overall earnings quality is improving, and the company may see an upgrade in its numerical rating should the trend continue.

Key Points to Understand About the EQ Score

The EQ Review Rating is much more than a blind, quantitative scoring method. While we utilize proprietary adjustments, ratios, and methods developed over decades of earnings quality analysis, the foundation of all of our analysis is reading recent SEC filings, press releases, conference call transcripts and in some cases, conversations with managements.

The EQ Review Rating is not comparable to a traditional buy/sell rating. The Rating is intended to specifically convey the extent to which reported earnings may be over/understated. Fundamental factors such as forecasts for future growth, increasing competition, and valuation are not reflected in the rating. Therefore, a high score does not in itself indicate a company is a buy but rather indicates that recent results are a good indication of the underlying earnings and cash generation capacity of the company. A low score (1-2) will likely result in us performing a more thorough review of fundamental factors to determine if the company warrants a full-blown sell recommendation.

Disclosure

Behind the Numbers, LLC is an independent research firm structured to provide analytical research to the financial community. Behind the Numbers, LLC is not rendering investment advice based on investment portfolios and is not registered as an investment adviser in any jurisdiction. All research is based on fundamental analysis using publicly available information including SEC filed documents, company presentations, annual reports, earnings call transcripts, as well as those of competitors, customers, and suppliers. Other information sources include mass market and industry news resources. These sources are believed to be reliable, but no representation is made that they are accurate or complete, or that errors, if discovered, will be corrected. Behind the Numbers, LLC does not use company sources beyond what they have publicly written or discussed in presentations or media interviews. Behind the Numbers does not use or subscribe to expert networks. All employees are aware of this policy and adhere to it.

The authors of this report have not audited the financial statements of the companies discussed and do not represent that they are serving as independent public accountants with respect to them. They have not audited the statements and therefore do not express an opinion on them. Other CPAs, unaffiliated with Mr. Middleswart, may or may not have audited the financial statements. The authors also have not conducted a thorough "review" of the financial statements as defined by standards established by the AICPA.

This report is not intended, and shall not constitute, and nothing contained herein shall be construed as, an offer to sell or a solicitation of an offer to buy any securities referred to in this report, or a "BUY" or "SELL" recommendation. Rather, this research is intended to identify issues that investors should be aware of for them to assess their own opinion of positive or negative potential.

Behind the Numbers, LLC, its employees, its affiliated entities, and the accounts managed by them may have a position in, and from time-to-time purchase or sell any of the securities mentioned in this report. Initial positions will not be taken by any of the aforementioned parties until after the report is distributed to clients, unless otherwise disclosed. It is possible that a position could be held by Behind the Numbers, LLC, its employees, its affiliated entities, and the accounts managed by them for stocks that are mentioned in an update, or a BTN Thursday Thoughts.