

Regeneron Pharmaceuticals (REGN) Change in Accounting Presentation FAQ

April 6th, 2020

Contents

Change in Accounting Presentation:	1
Overview:.....	1
Net Product Sales:	3
Collaboration Revenues:	3
Other Revenue:	3
R&D Expenses:.....	4
SG&A Expenses:.....	5
COGS/COCM Expenses:	5
Other Operating (Income) Expense, net:.....	6
Overall Income Statement Impact:.....	6

Change in Accounting Presentation:

Overview:

1. **Regeneron’s financial presentation has changed. What are the major impacts?**
 - a. Effective Jan 1st, 2020 changes in the presentation of Regeneron’s Income Statement include:
 - i. R&D reimbursements from collaborators netted within the P&L
 - ii. SG&A reimbursements from collaborators netted within the P&L
 - iii. New “Other Operating (Income) Expense, Net” line item containing income earned from upfront payments and development milestone payments
 - b. The net impact:
 - i. Total Revenues more representative of net product sales, collaboration profits, and royalties
 - ii. Cost lines more representative of net costs to Regeneron
 - iii. No impact to Income from Operations, Tax Expense or Net Income per Share
 - iv. Enhanced transparency to Regeneron financials and modeling ease for investment community

Revised GAAP financials for 2019 and 2018 (unaudited):

(In millions)

2019

Statement of Operations

Revenues:

	Three Months Ended March 31, 2019		
	As Previously Reported	Adjustments	As Revised
Net product sales	\$ 1,104.4	-	\$ 1,104.4
Sanofi collaboration revenue	246.4	\$(264.4)	(18.0)
Bayer collaboration revenue	276.2	(12.2)	264.0
Other revenue	84.8	(62.6)	22.2
	<u>1,711.8</u>	<u>(339.2)</u>	<u>1,372.6</u>

Expenses:

Research and development	641.8	(155.7)	486.1
Selling, general and administrative	410.8	(119.7)	291.1
Cost of goods sold	70.9	-	70.9
Cost of collaboration and contract manufacturing	108.3	(7.2)	101.1
Other operating (income) expense, net	-	(56.7)	(56.7)
	<u>1,231.8</u>	<u>(339.2)</u>	<u>892.6</u>

Income from operations

	<u>480.0</u>	<u>-</u>	<u>480.0</u>
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Three Months Ended June 30, 2019		
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As Previously
Reported Adjustments As Revised

Net product sales	\$ 1,205.3	-	\$ 1,205.3
Sanofi collaboration revenue	349.1	\$(273.3)	75.8
Bayer collaboration revenue	289.0	(11.8)	277.2
Other revenue	90.3	(70.8)	19.5
	<u>1,933.7</u>	<u>(355.9)</u>	<u>1,577.8</u>

Research and development	1,048.3	(162.8)	885.5
Selling, general and administrative	417.3	(122.7)	294.6
Cost of goods sold	67.0	-	67.0
Cost of collaboration and contract manufacturing	85.5	(6.7)	78.8
Other operating (income) expense, net	-	(63.7)	(63.7)
	<u>1,618.1</u>	<u>(355.9)</u>	<u>1,262.2</u>

	<u>315.6</u>	<u>-</u>	<u>315.6</u>
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Three Months Ended September 30, 2019		
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As Previously
Reported Adjustments As Revised

Net product sales	\$ 1,238.3	-	\$ 1,238.3
Sanofi collaboration revenue	404.2	\$(229.2)	175.0
Bayer collaboration revenue	302.8	(9.2)	293.6
Other revenue	103.1	(66.3)	36.8
	<u>2,048.4</u>	<u>(304.7)</u>	<u>1,743.7</u>

Research and development	663.4	(137.4)	526.0
Selling, general and administrative	419.9	(115.5)	304.4
Cost of goods sold	115.9	-	115.9
Cost of collaboration and contract manufacturing	110.7	(1.1)	109.6
Other operating (income) expense, net	-	(50.7)	(50.7)
	<u>1,309.9</u>	<u>(304.7)</u>	<u>1,005.2</u>

	<u>738.5</u>	<u>-</u>	<u>738.5</u>
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Three Months Ended December 31, 2019		
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As Previously
Reported Adjustments As Revised

Net product sales	\$ 1,286.4	-	\$ 1,286.4
Sanofi collaboration revenue	427.1	\$(256.3)	170.8
Bayer collaboration revenue	320.8	(10.0)	310.8
Other revenue	135.2	(39.7)	95.5
	<u>2,169.5</u>	<u>(306.0)</u>	<u>1,863.5</u>

Research and development	683.1	(130.7)	552.4
Selling, general and administrative	586.8	(135.0)	451.8
Cost of goods sold	108.5	-	108.5
Cost of collaboration and contract manufacturing	115.4	(2.2)	113.2
Other operating (income) expense, net	-	(38.1)	(38.1)
	<u>1,493.8</u>	<u>(306.0)</u>	<u>1,187.8</u>

	<u>675.7</u>	<u>-</u>	<u>675.7</u>
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(In millions)

2018

Statement of Operations

Revenues:

	Three Months Ended March 31, 2018		
	As Previously Reported	Adjustments	As Revised
Net product sales	\$ 987.9	-	\$ 987.9
Sanofi collaboration revenue	189.5	\$(246.0)	(56.5)
Bayer collaboration revenue	247.9	(5.8)	242.1
Other revenue	86.2	(66.2)	20.0
	<u>1,511.5</u>	<u>(318.0)</u>	<u>1,193.5</u>

Expenses:

Research and development	498.6	(177.3)	321.3
Selling, general and administrative	330.8	(87.5)	243.3
Cost of goods sold	69.2	-	69.2
Cost of collaboration and contract manufacturing	45.7	2.2	47.9
Other operating (income) expense, net	-	(55.4)	(55.4)
	<u>944.3</u>	<u>(318.0)</u>	<u>626.3</u>

Income from operations

	<u>567.2</u>	<u>-</u>	<u>567.2</u>
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Three Months Ended June 30, 2018		
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As Previously
Reported Adjustments As Revised

Net product sales	\$ 996.4	-	\$ 996.4
Sanofi collaboration revenue	237.8	\$(273.3)	(35.5)
Bayer collaboration revenue	262.9	(5.7)	257.2
Other revenue	110.9	(82.6)	28.3
	<u>1,608.0</u>	<u>(361.6)</u>	<u>1,246.4</u>

Research and development	529.3	(179.7)	349.6
Selling, general and administrative	364.8	(106.5)	258.3
Cost of goods sold	36.0	-	36.0
Cost of collaboration and contract manufacturing	55.7	1.7	57.4
Other operating (income) expense, net	-	(77.1)	(77.1)
	<u>985.8</u>	<u>(361.6)</u>	<u>624.2</u>

	<u>622.2</u>	<u>-</u>	<u>622.2</u>
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Three Months Ended September 30, 2018		
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As Previously
Reported Adjustments As Revised

Net product sales	\$ 1,025.5	-	\$ 1,025.5
Sanofi collaboration revenue	256.3	\$(264.3)	(8.0)
Bayer collaboration revenue	264.4	(9.7)	254.7
Other revenue	117.3	(83.5)	33.8
	<u>1,663.5</u>	<u>(357.5)</u>	<u>1,306.0</u>

Research and development	557.0	(179.1)	377.9
Selling, general and administrative	369.2	(107.6)	261.6
Cost of goods sold	30.8	-	30.8
Cost of collaboration and contract manufacturing	79.6	(6.9)	72.7
Other operating (income) expense, net	-	(63.9)	(63.9)
	<u>1,036.6</u>	<u>(357.5)</u>	<u>679.1</u>

	<u>626.9</u>	<u>-</u>	<u>626.9</u>
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Three Months Ended December 31, 2018		
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As Previously
Reported Adjustments As Revised

Net product sales	\$ 1,096.4	-	\$ 1,096.4
Sanofi collaboration revenue	427.6	\$(453.2)	(25.6)
Bayer collaboration revenue	301.5	(19.4)	282.1
Other revenue	102.3	(55.5)	46.8
	<u>1,927.8</u>	<u>(528.1)</u>	<u>1,399.7</u>

Research and development	601.2	(181.2)	420.0
Selling, general and administrative	491.3	(127.4)	363.9
Cost of goods sold	44.0	-	44.0
Cost of collaboration and contract manufacturing	73.2	(13.6)	59.6
Other operating (income) expense, net	-	(205.9)	(205.9)
	<u>1,209.7</u>	<u>(528.1)</u>	<u>681.6</u>

	<u>718.1</u>	<u>-</u>	<u>718.1</u>
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Net Product Sales:

- 2. Is there any impact to Net Product Sales as a result of the change in accounting presentation?**
 - a. No, there is no impact to the sales of U.S. EYLEA, U.S. Libtayo, and Arcalyst as a result of the change in accounting presentation.
 - b. Effective April 1st, 2020, Regeneron will begin to record U.S. Praluent net sales in Net Product Sales along with U.S. EYLEA, U.S. Libtayo and Arcalyst.

Collaboration Revenues:

- 3. With SG&A and R&D being netted in expenses, what are the remaining items that will need to be forecasted for both the Sanofi and Bayer collaborations?**
 - a. The change in financial presentation is a big step in assisting investors model our collaborations.
 - b. As for the collaborations with Sanofi (both the IO and Antibody agreements) and Bayer, there will be primarily two items to model:
 - i. the profit splits (Sanofi Antibody – Dupixent, Sanofi IO – ex U.S. Libtayo, Bayer – ex U.S. EYLEA)
 - ii. reimbursements for manufacturing of commercial supplies
 - c. Cost of Collaboration and Contract Manufacturing primarily relates to costs incurred by Regeneron for the manufacturing of commercial product on behalf of our collaborators. The line items within revenue called “reimbursements for manufacturing of commercial supplies” in our financial statement disclosures are the reimbursements for those manufacturing costs that hit COCM subject to timing and other certain considerations. A majority of the manufacturing reimbursements are from Sanofi as it primarily relates to the manufacturing of Dupixent, followed by Bayer for the manufacturing of ex-US EYLEA.
- 4. What impact does the accounting presentation change have on Sanofi IO collaboration revenues?**
 - a. Regeneron will continue to record Libtayo US product sales and Sanofi will recognize ex-US product sales with Regeneron recording collaboration profits from ex-US sales via the profit split revenue line.
 - b. As for the accounting presentation, included in revenues from Sanofi IO collaboration Regeneron had previously recognized reimbursement revenues for R&D and SG&A. Under the new accounting presentation, Regeneron is no longer recognizing reimbursement revenue for R&D and SG&A from Sanofi, as such amounts will be presented net with the corresponding expense line item.
 - c. Additionally, previously recorded upfront payment revenues are no longer located in Sanofi IO revenues. That item is now presented in Other Operating (Income) Expense, net.

Other Revenue:

- 5. How does the change in accounting presentation impact Other Revenues?**
 - a. Other Revenues are impacted in two ways:
 - i. First, reimbursements of R&D and SG&A expenses previously recognized as Revenues from Teva and Mitsubishi Tanabe are now netted within the R&D expense and SG&A expense lines, respectively.

- ii. Upfront Development and Milestone payments from Teva and Mitsubishi Tanabe that were previously a component of Other Revenues are now presented in Other Operating (Income) Expense, net.
- b. Using 2019 as an example, under the new accounting presentation, Regeneron's Other Revenues were \$239.4MM lower than previously reported (\$174.0MM vs. \$413.4MM).

6. What are the remaining components of Other Revenues?

- a. Other Revenue include reimbursements related to customer-based agreements such as BARDA and RGC consortium where REGN provides R&D-related services to these customers.
- b. Additionally, we will record royalties related to ex-US Praluent.
- c. We continue to recognize revenue from royalties related to sales of Ilaris (canakinumab) and revenues related to the Zaltrap manufacturing and royalty arrangement with Sanofi as a component of this line item.

7. The historic accounting presentation of Other Revenues included "Reimbursement of research and development expenses – other" in which Regeneron recognized \$94.3MM in 2019. What were those R&D reimbursements related to and how will those items be presented under the new accounting presentation?

- a. Our new accounting presentation treats differently certain arrangements in which Regeneron is deemed to be providing a customer (and not a collaborator) with R&D-related services. Regeneron will recognize reimbursements for those R&D-related services in Other Revenues. An example of these type of arrangement includes revenues associated with the BARDA agreement (i.e. Ebola and COVID-19).

R&D Expenses:

8. What adjustments have been made to R&D expenses as a result of the change in accounting presentation?

- a. Using 2019 as an example, under the new accounting presentation, Regeneron's R&D expense is \$586.6MM lower than previously reported (\$2,450.0MM vs. \$3,036.6MM).
- b. Under the historic accounting presentation, Regeneron recognized \$586.6MM in reimbursement R&D revenue from our collaborators of Sanofi, Bayer, and Teva.
- c. Under the new accounting presentation, Regeneron is longer recognizing those R&D reimbursements from our collaborators as revenues and those reimbursements are now netted in the R&D expense line.

9. Regeneron previously disclosed unreimbursed R&D expenses. Will that be disclosed under the new accounting presentation? What is the difference between unreimbursed R&D under the historic accounting presentation and R&D expenses under the new accounting presentation?

- a. Under the new accounting presentation, total R&D expense is now more representative of the net R&D expenses to Regeneron.
- b. It's conceptually similar to our previous disclosure of "unreimbursed R&D" which was defined as "total R&D less R&D reimbursements from collaborators". Under the new accounting presentation, we are no longer recognizing reimbursements related to R&D from our collaborators as revenues; those reimbursements of R&D are now netted in the R&D expense line.
- c. Our new accounting presentation treats differently certain arrangements in which Regeneron is deemed to be providing a customer (and not a collaborator) with R&D-related services. As we did previously, Regeneron will continue to recognize reimbursements for those R&D-related services in Other Revenues. An example of these type of arrangement includes revenues associated with the BARDA agreement.

- d. Under the new accounting presentation, 2019 non-GAAP R&D expenses were \$1,769.6MM (\$2,450.0MM - \$250.4MM non-cash share-based compensation expense - \$430.0MM in upfront payments related to license and collaboration agreements). Previously, we disclosed 2019 non-GAAP unreimbursed R&D as \$1,675.3MM.

SG&A Expenses:

10. What adjustments have been made to SG&A expense as a result of the change in accounting presentation?

- a. Using 2019 as an example, under the new accounting presentation, Regeneron's SG&A expense is \$492.9MM lower than previously reported (\$1,341.9 vs. 1,834.8MM)
- b. Under the historic accounting presentation, Regeneron recognized \$492.9MM in reimbursement SG&A revenue primarily from Sanofi.
- c. Under the new accounting presentation, Regeneron is no longer recognizing those SG&A reimbursements from our collaborators as revenues; those reimbursements are now netted in the SG&A expense line.

COGS/COCM Expenses:

11. What adjustments have been made to COGS and COCM expenses as a result of the change in accounting presentation?

- a. For COGS, there is no change.
- b. For COCM, using 2019 as an example, under the new accounting presentation, Regeneron's COCM expenses are \$17.2MM lower than previously reported (\$402.7MM vs. \$419.9MM). This is a result of certain payments between collaborators now being netted within COCM.

12. Why can't you collapse COGS and COCM?

- a. The team thoroughly explored different accounting presentations.
- b. We did not combine these two expense items as it would be inconsistent with our accounting presentation of revenues whereby we separately disclose product sales from reimbursements for commercial supplies.

13. Regeneron is still recording reimbursement for manufacturing of commercial supplies. Why can't these costs be netted in COCM?

- a. Regeneron thoroughly explored different accounting presentations.
- b. Consistent with our peers and industry practice, revenues recorded for manufacturing reimbursements will remain as revenues. As it relates to our collaboration agreements, such amounts will be disclosed as "reimbursements for manufacturing of commercial supplies" within the applicable collaboration revenue line item.
- c. Cost of Collaboration and Contract Manufacturing primarily relates to costs incurred by Regeneron for the manufacturing of commercial product on behalf of our collaborators. The line items within our revenue disclosures called "reimbursements for manufacturing of commercial supplies" are the reimbursements for those manufacturing costs that hit COCM subject to timing and other certain considerations. A majority of the manufacturing reimbursements are from Sanofi as it primarily relates to the manufacturing of Dupixent, followed by Bayer for the manufacturing of ex-US EYLEA.

Other Operating (Income) Expense, net:

- 14. Other Operating (Income) Expense is a new line item. What is contained in this new line item?**
- a. Upfront payments and development milestones from our current collaborators (Sanofi, Teva, and Mitsubishi Tanabe) previously recognized as a component of Total Revenue are now presented within a new line item called Other Operating (Income) Expense, net.
 - b. For Other Operating (Income) Expense, net, using 2019 as an example, under the new accounting presentation, Regeneron's expenses are \$209.2MM lower than previously reported (\$(209.2)MM vs. \$0.0MM).

Overall Income Statement Impact:

- 15. What happens to Revenues and Expenses as a result of the change in accounting presentation?**
- a. Total Revenues should be adjusted downward with the removal of R&D and SG&A reimbursement components and the relocation of upfront and development milestone payments that historically been recognized in Total Revenues. Under the new presentation, total revenues are now more representative of net product sales, collaboration profits, and royalties.
 - b. Total Expenses should be also be adjusted downward to account for those R&D and SG&A reimbursements now being netted in the appropriate expense line items.
- 16. Will Earnings Per Share increase or decrease as a result of the change in accounting presentation?**
- a. As it pertains to the change in accounting presentation only, there is no impact to Income from Operations or any line-item below that including Earnings Per Share.