



# Drug Pricing Investigation

*Amgen—Enbrel and Sensipar*

*Selected Investigation Documents*

Staff Report

Committee on Oversight and Reform

U.S. House of Representatives

October 2020

[oversight.house.gov](https://oversight.house.gov)

## Amgen Selected Documents

<b>Document #</b>	<b>Citation</b>	<b>Short Description</b>
<b>Amgen 31</b>	AMGN-HCOR-RR-00430788	March 2016 Memo
<b>Amgen 32</b>	AMGN-HCOR-RR-00000010, at Slide 55	December 2016 Presentation Excerpt
<b>Amgen 33</b>	AMGN-HCOR-RR-00000904	May 2017 Emails
<b>Amgen 34</b>	AMGN-HCOR-RR-00039834	2017 Table
<b>Amgen 35</b>	AMGN-HCOR-RR-000434916, at Slides 5 and 6	May 2016 Presentation Excerpt
<b>Amgen 36</b>	AMGN-HCOR-RR-00438104, at Slide 9	December 2016 Presentation Excerpt
<b>Amgen 37</b>	AMGN-HCOR-RR-00029310	December 2017 Emails
<b>Amgen 38</b>	AMGN-HCOR-RR-00003911	January 2017 Emails
<b>Amgen 39</b>	AMGN-HCOR-RR-00041867, at Slide 4	September 2018 Presentation Excerpt
<b>Amgen 40</b>	AMGN-HCOR-RR-00040017	April 2016 Emails
<b>Amgen 41</b>	AMGN-HCOR-RR-00040614	June 2016 Emails
<b>Amgen 42</b>	AMGN-HCOR-RR-00126493, at Slide 10	December 2018 Presentation Excerpt
<b>Amgen 43</b>	AMGN-HCOR-RR-00026372	January 2017 Emails
<b>Amgen 44</b>	AMGN-HCOR-RR-00061731	Company Talking Points

# Amgen Document 31

Memorandum

**AMGEN**

**To:** ▶ Bob Bradway  
**From:** ▶ Tony Hooper  
**Subject:** ▶ GCO March Report  
**Copies To:** ▶ CEO Direct Reports

**Date:** ▶ Mar. 16, 2016

## Q1 and FY Outlook (see attached)

- QTD sales through Mar. 11 are +\$132M ahead of our Plan at constant FX led by the US at (+\$93M) and Europe (+\$24M). Inventory dynamics drive a large portion of over-performance in the US. Expected declines in Sensipar intermediary inventory levels have not occurred (+\$35M), while higher wholesaler inventory levels drive Enbrel favorability (+\$31M). **Redacted - Non-Responsive**

**Redacted - Non-Responsive**

- The March Forecast reflects our latest thinking on Q1. We have increased Q1 product sales by \$50M vs Plan with the other ~\$80M of favorability burning off by quarter end. Product sales in Q1 are now projected to be \$5,212M (+7% YoY, -2% QoQ) at actual FX. This would be over consensus by \$100M for product sales and over \$180M for total revenues.
- Full year product sales in the March Forecast are now projected to be \$21,475M, or 3% YoY growth at actual FX. This represents an increase of \$50M and reflects a number of adjustments – both positive and negative – vs. Plan.
  - Pricing impacts in the US. This includes the benefit of the Dec. '15 Enbrel price increase, moving Sensipar up to Jan./Jun. actions (vs Plan of Apr./Oct.) and **Redacted - Non-Responsive****Redacted - Non-Responsive** It also includes the improvement to the AMP Medicare rate (+\$90M).

**Redacted - Non-Responsive**

# Redacted - Non-Responsive

## Regional Performance Highlights QTD:

- U.S. (Plan: Q1 +9% YoY; FY +5% YoY):
  - QTD Q1 performance is +\$93M above Plan driven primarily by Sensipar (+\$35M), Enbrel (+\$31M) and Redacted - Non-Responsive for the reasons described above. The March Forecast includes an increase of \$30M vs. Plan for the quarter.

**Redacted - Non-Responsive**



# U.S. PRICING COMMITTEE

**DECEMBER 12, 2016**

Redacted - Non-Responsive

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# FINANCIAL ANALYSIS OF ENBREL® PI SCENARIOS

Oct LEDR Date of PI's Jan 6, 2017, Jan 5, 2018	Included in LE/LEDR	Comparison	Overall Est. Change in Net Revenue for 2016	Overall Est. Change in Net Revenue for 2017
Dec 22, 2016 – 6.0%	N	Compared to Oct LEDR	(\$2.1M)	\$5.4M
Dec 22, 2016 – 7.9%	N	Compared to Oct LEDR	(\$2.5M)	\$47.2M
Dec 22, 2016 – 6.0% Jul 14, 2017 PI – 7.9%	N	Compared to Oct LEDR	(\$2.1M)	\$75M
Dec 22, 2016 – 7.9% Jul 14, 2017 PI – 7.9%	N	Compared to Oct LEDR	(\$2.5M)	\$114M

Does not include WDA fee adjustment

# Amgen Document 33

**From:** [REDACTED]/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0C202577A38F4AA8B38FBD98C8CFD0A8-PCOSTELL]  
**Sent:** Monday, May 22, 2017 2:27:30 PM  
**To:** [REDACTED] Jordan, Helen; [REDACTED] Moore, Tom - US V&A  
**CC:** [REDACTED]  
**Subject:** RE: Action items from today's LRP meeting

Enbrel P.I. @7/8/9/9.9 is worth ~\$10M/\$20M/\$28M/\$36M in 2018, or ~\$10M/pt up to the first 2 pts, ~\$8M/pt for the next 2 pts

**From:** [REDACTED]  
**Sent:** Friday, May 12, 2017 9:17 AM  
**To:** Jordan, Helen <[REDACTED]>; [REDACTED]; [REDACTED]; [REDACTED]; Moore, Tom - US V&A  
**Cc:** [REDACTED]  
**Subject:** FW: Action items from today's LRP meeting

Team,

See [REDACTED] note on follow up from the INBU.

Let me add a few notes to add some color to the LRP presentation

- Generally well received .....and we did not present the entire deck....answered more the questions that Tony had on his mind.....so here are the summaries

**Redacted - Non-Responsive**

o Enbrel

- Soft reaction from Tony that he was surprised how strong the erosion was....after walking him through the market, access assumptions and net price implications...he was ok
- Tony understands the judgement we applied to the forecast.....small variances on market growth, combined with a slightly stronger hold with the payers, combined with a slightly better pull through on price .....easily makes a point or two....and a point or two is about \$100M
- As per [REDACTED] notes.....Tony wants to understand what 1% price higher than LRP is worth in 18.....I told him it is most probably not linear.....but we should find the answer.....what is 7%/8%/9%/9.9% worth in 2018
- Bari delayed....will slow the effectiveness of the IBF movement at least in Rheum.....the product monograph that Regeneron's IL6 gets will be another influencer on that effectiveness
- Wiggle room for 2018 ...back of the envelope math.....LO thinking (-\$75M) could be neutralized by Bari delay....price follower strategy ( plus assumption that humira will go at least 8.4% in 18) could yield \$80M....and we will have some visibility on market growth....before we have to commit to 2018.....so maybe \$4.8B for 2018 is still in reach

**Redacted - Non-Responsive**

Redacted - Non-Responsive

o Calcimimetics

- Spend quite some time on the calcimimetics
- Tony's focus is as follows.....

- **Redacted - Non-Responsive**

- Supported a rethink of the pricing strategy....going to a restricted or very restricted second line pricing.....order of price spread was acceptable.....Tony was more concerned about the second Sensipar PI in 2017
- Plan here is .....to have the alternate price strategies worked out a couple of days after we get the word on the Paediatric extension

**Redacted - Non-Responsive**

- So here are my error bars around 2018
  - o Enbrel with price following, bari delay and small market growth recovery.....plus \$100-150M
  - o Paeds on Calci....plus \$650M ( and we will know soon)

**Redacted - Non-Responsive**

[Redacted]

From: [Redacted]  
 Sent: Thursday, May 11, 2017 6:22 PM  
 To: [Redacted]  
 [Redacted]  
 Larkin, Kate <[Redacted]>  
 Cc: Hamill, Laura <[Redacted]> [Redacted]; [Redacted]; [Redacted]  
 [Redacted]  
**Subject:** Action items from today's LRP meeting

Hello all,  
 I wanted to get this list out to everyone while it's still fresh on your mind.  
 Below is a list of action items that I wrote down. If you can review and please let me know if I have missed any helpful.

**Redacted - Non-Responsive**

# Redacted - Non-Responsive

INBU

## Redacted - Non-Responsive

- Provide a pricing sensitivity analysis for Enbrel based on 1% increase in list price

Thanks

# Enbrel Therapeutic Class Price Increases 2013 – Current

	2013				2014				2015				2016				2017			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
ENBREL Amgen	6.9 <sup>1/4</sup>	6.9 <sup>6/21</sup>		6.9 <sup>1/2</sup>	6.9 <sup>6/6</sup>		7.9 <sup>11/14</sup>	9.9 <sup>5/1</sup>	7.9 <sup>9/2</sup>	7.9 <sup>12/23</sup>	9.9 <sup>7/1</sup>		8.4 <sup>1/20</sup>							
HUMIRA Abbvie	6.9 <sup>1/3</sup>	6.9 <sup>7/3</sup>		6.9 <sup>11/27</sup>	7.9 <sup>7/1</sup>		7.9 <sup>11/14</sup>	9.9 <sup>4/1</sup>	7.9 <sup>8/28</sup>	9.9 <sup>1/21</sup>	7.9 <sup>6/23</sup>		8.4 <sup>1/18</sup>							
REMICADE Janssen	4.9 <sup>3/5</sup>		3.9 <sup>9/4</sup>	4.9 <sup>3/5</sup>	4.9 <sup>9/4</sup>		4.9 <sup>3/4</sup>	4.9 <sup>9/3</sup>	4.9 <sup>3/3</sup>		4.9 <sup>9/27</sup>		4.9 <sup>2/9</sup>							
SIMPONI Janssen	6.9 <sup>2/5</sup>		6.9 <sup>8/5</sup>	6.9 <sup>2/5</sup>	6.9 <sup>8/6</sup>		9.9 <sup>3/4</sup>	6.9 <sup>9/3</sup>	8.9 <sup>8/3</sup>				8.9 <sup>2/9</sup>							
SIMPONI ARIA Janssen		new <sup>7/5</sup>		4.9 <sup>3/5</sup>	4.9 <sup>9/4</sup>		4.9 <sup>3/4</sup>	4.9 <sup>8/3</sup>	4.9 <sup>3/3</sup>		3.9 <sup>9/27</sup>		4.9 <sup>2/9</sup>						3.8 <sup>9/6</sup>	
STELARA Janssen	6.9 <sup>2/5</sup>		6.9 <sup>8/6</sup>	6.9 <sup>2/5</sup>		3.9 <sup>11/5</sup>	6.9 <sup>5/6</sup>	2.9 <sup>1/4</sup>	4.9 <sup>4/6</sup>				7.9 <sup>2/9</sup>							
CIMZIA UCB		5.5 <sup>4/1</sup>	13.5 <sup>10/1</sup>	9.9 <sup>1/1</sup>		9.9 <sup>11/1</sup>		9.9 <sup>1/1</sup>	5.0 <sup>7/1</sup>				4.8 <sup>1/1</sup>					4.8 <sup>7/1</sup>		
ORENCIA (v) BMS	3.0 <sup>2/15</sup>		4.9 <sup>8/15</sup>	4.9 <sup>2/14</sup>	3.9 <sup>10/1</sup>	3.9 <sup>1/1</sup>	3.9 <sup>4/1</sup>	3.9 <sup>7/1</sup>	3.9 <sup>10/1</sup>	3.9 <sup>1/1</sup>	4.9 <sup>4/1</sup>	4.5 <sup>7/1</sup>								
ORENCIA (s) BMS			new <sup>11/1</sup>	6.9 <sup>1/15</sup>	6.9 <sup>7/1</sup>	7.9 <sup>12/1</sup>		9.9 <sup>6/1</sup>	7.9 <sup>12/1</sup>		4.5 <sup>6/1</sup>									
ACTEMRA (v) Genentech					4.5 <sup>7/1</sup>	4.5 <sup>1/5</sup>		4.9 <sup>7/1</sup>	4.9 <sup>1/1</sup>		4.9 <sup>7/1</sup>	4.8 <sup>1/1</sup>							4.8 <sup>7/1</sup>	
ACTEMRA (s) Genentech			new <sup>11/6</sup>	6.0 <sup>7/1</sup>	3.0 <sup>1/5</sup>		8.0 <sup>7/1</sup>	8.0 <sup>1/1</sup>	8.0 <sup>7/1</sup>		1.5 <sup>7/1</sup>								8.0 <sup>1/1</sup>	1.5 <sup>7/1</sup>
RITUXAN Genentech		2.75 <sup>7/2</sup>		2.75 <sup>1/3</sup>	2.75 <sup>7/1</sup>		2.75 <sup>1/5</sup>	3.25 <sup>7/1</sup>	3.5 <sup>1/1</sup>		3.8 <sup>7/1</sup>								4.0 <sup>1/1</sup>	4.0 <sup>7/1</sup>
XELJANZ Pfizer				6.9 <sup>1/1</sup>	6.9 <sup>8/1</sup>		6.9 <sup>1/1</sup>	6.9 <sup>6/1</sup>	7.9 <sup>10/1</sup>	9.4 <sup>1/1</sup>	9.4 <sup>6/1</sup>								9.4 <sup>1/1</sup>	
OTEZLA Celgene				new <sup>4/3</sup>				7.9 <sup>3/10</sup>	9.9 <sup>6/25</sup>		8.0 <sup>1/4</sup>	7.9 <sup>4/4</sup>							6.9 <sup>1/10</sup>	6.9 <sup>4/4</sup>
COSENTYX Novartis								new <sup>1/30</sup>	6.9 <sup>7/7</sup>		6.9 <sup>2/2</sup>	4.0 <sup>7/12</sup>							6.0 <sup>3/7</sup>	2.7 <sup>7/11</sup>
TALTZ Eli Lilly												new <sup>3/23</sup>							8.9 <sup>10/14</sup>	6.9 <sup>5/2</sup>
INFLECTRA Pfizer																			new <sup>10/7</sup>	

Grey - subQ, dark red - infused, dark blue - oral  
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# U.S. PRICING COMMITTEE

**MAY 12, 2016**

**Redacted - Non-Responsive**

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# EXECUTIVE SUMMARY

## ENBREL<sup>®</sup> PRICE INCREASE

Product: ENBREL<sup>®</sup>

Customer or Segment: Price Increase

### Background

- Enbrel<sup>®</sup> last price Increase was 7.9% on Dec 23<sup>rd</sup> 2015
- Price increase strategy is to follow AbbVie's price increases
- Feb LEDR assumed a 7.9% price increase in June of 2016
- Anticipated net sales of \$6.1B in 2016

### Seeking approval on:

- Approve an Enbrel<sup>®</sup> price increase up to 9.9% prior to Aug 1, 2016, as soon as operationally feasible, following AbbVie's anticipated price increase

## SUMMARY – ENBREL® PI

Feb LEDR Date of PI's Jun, 1 2016 , Dec 1 2016 Jun 1 2017, Dec 1, 2017	Included in LE/LEDR	Comparison	Overall Est. Change in Net Revenue for 2016**	Overall Est. Change in Net Revenue for 2017**
Jul 1 2016 – 7.9%	N	Compared to Feb LEDR	Commercially Sensitive Material Redacted at Amgen's Request	
Aug 1 2016 – 7.9%	N	Compared to Feb LEDR		
Aug 1 2016 – 9.9%	N	Compared to Feb LEDR	(\$32M)	\$60M
May LEDR PI's Jul 1 2016 – 7.9% Dec 2016 PI – 0% Jan 1 2017 – 6% Dec 2017 PI – 0%	Y	Compared to Feb LEDR	Commercially Sensitive Material Redacted at Amgen's Request	

\*\*Financial Impact based on June 1, 2016 Price Increase



**U.S. PRICING COMMITTEE**

**DECEMBER 12, 2016**

**Redacted – Not Responsive**

**AMGEN**<sup>®</sup>

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## EXECUTIVE SUMMARY

Product: Enbrel®

Customer or Segment: All

## ENBREL PRICE INCREASE PENDING LEGAL APPROVAL

### Background

- Last price increase for Enbrel® was 9.9% on July 1, 2016
- October LEDR assumed a 6.0% price increase in January 2017
- Anticipated net sales of \$5.8B in 2017

### Seeking approval to:

Execute an Enbrel price increase as follows:

- Scenario 1: Abbvie does not increase before Jan 6 → execute Enbrel price increase of 7.9% on January 6
- Scenario 2: Abbvie increases before Jan 6 by up to 7.9% → execute Enbrel price increase up to 7.9% following Abbvie on or before January 6
- Scenario 3: Abbvie increases before Jan 6 by more than 7.9% → come back to Pricing Committee for approval of higher rate

# Amgen Document 37

**From:** Niksefat, Kave [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=80085F1047D5465AAC8EF82A5E0C30A3-KAVEN]  
**Sent:** Thursday, December 21, 2017 11:50:58 PM  
**To:** [REDACTED]  
**Subject:** Fwd: PI Decision

For your records.

Sent from my iPhone

Begin forwarded message:

**From:** "Niksefat, Kave" <[REDACTED]>  
**Date:** December 21, 2017 at 3:44:00 PM PST  
**To:** [REDACTED]  
**Subject:** Fwd: PI Decision

We're a go with current plan. Kave

Sent from my iPhone

Begin forwarded message:

**From:** "Hooper, Tony" <[REDACTED]>  
**Date:** December 21, 2017 at 3:36:41 PM PST  
**To:** "Niksefat, Kave" <[REDACTED]>  
**Cc:** "[REDACTED]" <[REDACTED]>, "Hamill, Laura" <[REDACTED]>  
**Subject:** PI Decision

Kave,

You have authorization from me - to proceed at 11.01pm on 12/31/17 for 4.9%. In addition, you have authorization to proceed with a competitive price increase for Enbrel - should Humira pull the trigger at any point.

Regards,  
Tony

Anthony C. Hooper  
[REDACTED]

# Amgen Document 38

**From:** [REDACTED]  
**Sent:** Thursday, January 19, 2017 11:18:12 PM  
**To:** Niksefat, Kave  
**Subject:** FW: Question on drug purchase pricing through pharmacy

fyi

**From:** [REDACTED]  
**Sent:** Thursday, January 19, 2017 2:48 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Question on drug purchase pricing through pharmacy

Hi [REDACTED] I'll do my best to help you with this while [REDACTED] is on vacation. I'll reach out to two folks in GSS right now for guidance: one who is responsible for buying non-Amgen drugs for head to head type of trials (what we call non Amgen medicinal product/NAMP) even though I don't think they buy from pharmacies and another who is responsible for dealing with specialty pharmacies on contracting their adherence services, buying data from them, etc. In the interest of time (and since your request is sufficiently clear below), let me connect with these folks and hopefully connect back with you soon (say tomorrow/Friday or Monday) for a live conversation and problem solving session if the solution is not obvious. Does that work?

**From:** [REDACTED]  
**Sent:** Thursday, January 19, 2017 2:39 PM  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Question on drug purchase pricing through pharmacy

[REDACTED]

I hope all is well and you're enjoying the return to GSS. I've got an issue that I hope you can help us with a possible solution.

To refresh...I am in the US Commercial contracts & pricing area. We monitor competitor price increases which often impact our pricing strategy. For example, the Enbrel team wants to know immediately when a competitor, e.g. Humira, takes a price increase. Currently, we cannot confirm a competitor price increase until a day after the price increase because compendia price lists are typically updated at midnight at the end of the day in which the price increase became effective. We believe that a pharmacy submitting an order to a wholesaler would see the price increase on the effective day since the pharmacy must be invoiced appropriately. Wholesalers do not provide that ordering price list to Amgen. We are wondering if Amgen orders non-Amgen drugs from pharmacies and has a relationship with a pharmacy whereby we could request the pharmacy to confirm via an order form that a competitor price increase occurred.

I imagine you may want to discuss. Hopefully, you can help us with this. Each day for which a price increase becomes effective is significant revenue for products like Enbrel.

Thank you,  
[REDACTED]



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# ENBREL LIST PRICE AND INVENTORY CONSIDERATIONS

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**September 11, 2018**

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DRAFT

## WHEN ASSESSING POTENTIAL LIST PRICE CHANGES FOR ENBREL IN 2019, NEED TO CONSIDER MAGNITUDE, AND POTENTIAL COMPETITOR AND PAYOR ACTIONS

1. What we've seen, done and planned for to date	2. What some of the options are	3. Recommendation
<p><b>Most recent List Price Increases</b> Humira: 9.7% on 12/31/17, 8.4% on 1/18/17 Enbrel: 9.7% on 12/31/17, 8.4% on 1/20/17</p> <p><b>LRS List Price Assumption</b> Enbrel +3% on 1/1/19, competitively reactive to Humira</p>		<p>React competitively to AbbVie's list price actions on Humira;</p> <p>Impact <b>-\$120M to +\$175M</b>, depending upon Humira change</p>

Any list price increase for Enbrel in 2019 assumes the 60-day notification to the state of CA, potentially impacting Intermediary Inventory levels at YE 2018 if notification occurs prior to YE

\* Excludes potential impact of Inventory changes

DRAFT

# Amgen Document 40

**From:** [REDACTED]  
**Sent:** Monday, April 25, 2016 8:26:47 PM  
**To:** Bradway, Bob  
**CC:** Hooper, Tony  
**Subject:** Sensipar & Pediatric Exclusivity

Bob,

Following the Quarterly Business Review, Tony asked that I clarify for you the current status of the Pediatric Exclusivity extension for Sensipar in the US, and the Product Team's expectations of securing. The current base case LRP assumes patent expiry in March of 2018 without extension, as it is not anticipated that the formal FDA requirements will be met. However the team is proceeding with filing efforts (File: November 2016), with notification of grant of exclusivity in May 2017.

I have briefly summarized the situation below:

- Patent expiry for Sensipar in the US is March of 2018 –with opportunity for 6 month Pediatric exclusivity extension to November 2018
- A Written Request (WR) - formal requirements for pediatric exclusivity from FDA - has been in place prior to initiation of pediatric studies in 2011.
- Unique challenges in meeting the terms of the request have existed from time of request, with some additional hurdles added over time:
  - o Low prevalence in children <6 years
  - o High rate of kidney transplantation
  - o Country selection challenges
  - o Delays & challenges related to partial clinical hold & revised eligibility criteria –further limiting potential eligible subjects
- In addition, regulatory efforts to renegotiate the terms of the WR have been exhausted with the recent request for Type C meeting denied by the FDA in December 2015.
- To be eligible for the patent extension, the terms of the WR must be met –and this will not occur, as shortfalls in the clinical data package remain, despite progress in the past few months.
- The probability of regulatory success for pediatric exclusivity is LOW –and the extension is not assumed as base case in the LRP
- However, it is anticipated that the FDA Pediatric Exclusivity Board can apply some judgment with regards to meeting the terms. The consideration of exclusivity is triggered by our regulatory submission, planned for November 2016. The regulatory team believes the subsequent filing and pre-filing meetings provide an opportunity to continue to delineate our arguments related to good faith efforts to complete the pediatric studies and the strength of the data package.
- Despite low probability of regulatory success, the potential upside to the LRP is meaningful and all available options are being leveraged by the team.
- Notification of grant of exclusivity is anticipated 6 months following submission (May 2017).

Please let me know if you require further details.

Best regards,

[REDACTED]  
Global Product General Manager (GPGM)  
Parsabiv™ & Sensipar®/Mimpara®

Amgen  
One Amgen Center Drive  
[REDACTED]

# Amgen Document 41

From:

Sent: Wednesday, June 29, 2016 7:14:20 AM

To:

CC: Hooper, Tony;

Hamill, Laura

Subject: Re: Pediatric LOE extension for Sensipar

Thank you for confirming these details. The team remains committed and engaged with urgency and best efforts in preparing for the filing. Next steps include a request for pre-filing meeting, including a final request to amend the Written Request (WR) requirements for exclusivity.

Let me know if you require further details.

Sent from my iPhone

On Jun 29, 2016, at 5:12 AM, wrote.

During one of our Parsabiv readiness meetings, the question was asked what is a potential 6 month extension on the LOE for Sensipar worth.

The team ran the numbers .....and a six month extension of LOE for Sensipar is worth \$0.25B for the 18-19 period in the US

Both and I wanted to share this number with you.....we realize you know how important maximizing our shot of obtaining this objective is.....now it also has a dollar sign attached to it.



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# USBO 2018 JUNE FORECAST SALES REVIEW

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December 14, 2018

Amgen Proprietary - Confidential

# FULL YEAR JUNE FORECAST VS. PLAN +\$200M DRIVEN BY SENSIPAR DEMAND AND ENBREL PERFORMANCE

Changes from March Forecast driven by:

**• Demand +\$344M**

- Sensipar +\$202M; delay of generic entry from 3/31 to 6/15

**Redacted - Non-Responsive**

- Enbrel +\$122M; demand driven by rheum market +4.9% and derm market +8.8% as compared to March Forecast

**Redacted - Non-Responsive**

**• NSP -\$128M**

**Redacted - Non-Responsive**

- Enbrel +\$32M; favorable sales mix (lower sales through Gov-Fed)

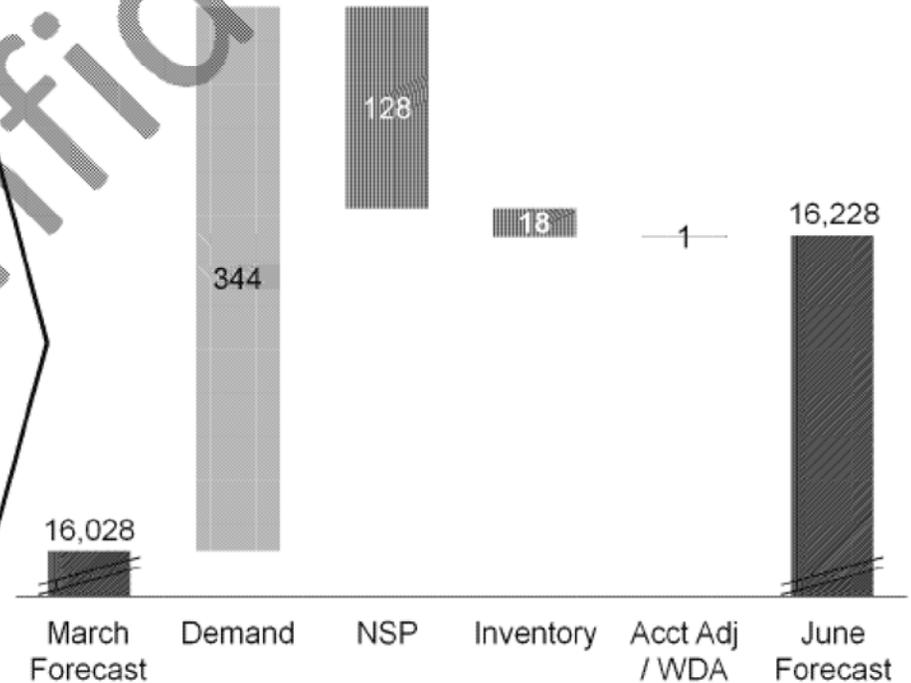
**• Inventory -\$18M**

- Enbrel -\$12M; Primarily 1.7 DoH wholesaler inventory depletion at end-user
- Sensipar -\$12M; wholesaler inventory depletion in Q3

**• Accounting Adjustments / WDA +\$1M**

- Enbrel +\$11M; Favorable Q1 true-up vs. Mar Fcst due to AMP unit reimbursement rate

FY Sales at \$16.2B; results in -5% YoY  
(U: -4%, NSP\* -1%, O: -1%)





# Amgen Document 43

[REDACTED] [REDACTED] [REDACTED], [REDACTED]  
Subject: Re: PI for Sensipar and Enbrel

[REDACTED]  
Go ahead with the 8% for Sensipar - Thursday the 12th Jan. would be even better.

Let's talk in the desert about Enbrel.

Regards,  
Tony

Anthony C. Hooper  
Amgen Inc.  
[REDACTED]

On Jan 10, 2017, at 8:10 AM, [REDACTED] wrote:

Tony and Laura,

The numbers mentioned below have been confirmed by Kate's group.

As such the recommendation of the INBU team would be to move forward with the 8% price increase for Sensipar this Friday Jan 13th.

I understand that the sensitivity around Enbrel is higher.....as such here are the increases we have seen in 2017

- so far no increase from Humira
- Orenzia took 6% on Jan 1
- Cimzia took 4.8% on Jan 1
- Actemra took 4.8% on the IV and 8% on the sq on Jan 1
- Xeljanz took 9.4% on Jan 1

Once more the recommendation of the INBU team would be to implement our suggested PI for Enbrel on Friday Jan 13th at 6%

I have the teams work up with me here at the ED&O....so hopefully we can find some time to get your guidance.

[REDACTED]  
Sent from my iPad

On Jan 8, 2017, at 8:13 PM, [REDACTED] wrote:

enbrel's PI was always scheduled for 6% in 2017.  
We will present the detailed work up....but I think the %numbers are correct.

# Amgen Document 43

# Amgen Document 43

Sent from my iPhone

On Jan 8, 2017, at 8:09 PM, Hooper, Tony [REDACTED]  
wrote:

**Commercially Sensitive Material Redacted at Amgen's Request**

Anthony C. Hooper  
Amgen Inc.  
[REDACTED]

On Jan 8, 2017, at 6:57 PM, [REDACTED]  
[REDACTED] wrote:

Laura and Tony,

In our 2017 forecast we had two price increases scheduled for Jan 6.....6% for Enbrel and 8% for Sensipar. Both were not executed.

As discussed at the MM.....we should find some time at the ED&O to talk strategy on how to proceed. The team has done the impact analysis and we are ready to suggest a plan forward.

Here are some of the numbers

<!--[if !supportLists]-->• <!--  
[endif]-->A one month delay of the Enbrel PI of 6% will impact the 2017 number by (\$12M)

<!--[if !supportLists]-->• <!--  
[endif]-->A one month delay of the Sensipar PI of 8% will impact the 2017 number by (\$3M)

<!--[if !supportLists]-->• <!--  
[endif]-->No PI for Enbrel in 2017 has a negative impact on 2017 net sales of \$164M

<!--[if !supportLists]-->• <!--  
[endif]-->No PI for Sensipar in 2017 has a negative impact on

# Amgen Document 43

# Amgen Document 43

2017 net sales of \$ 58M



# Amgen Document 44

Reuters Enbrel Redacted - Non-Responsive Price Inquiry

## On-Record Response

In 2015, the Amgen R&D engine was developing 45 molecules in inflammation, hematology/oncology, cardiovascular disease, neuroscience, nephrology and dermatology, and over the past decade Amgen has spent over \$33B in drug discovery and development. In addition to the R&D costs necessary for breakthrough discoveries, products on the market require significant investment for new indications, new delivery systems for better patient care and required safety and adverse event monitoring.

## Redacted - Non-Responsive

It is important to consider net vs. list price – since PBMs, health insurers and other purchasers of drugs (e.g., hospitals, physicians, etc.) negotiate with manufacturers for considerable discounts and rebates for the products they purchase. These discounts drive down drug prices and are not reflected in the list prices (known as “wholesaler acquisition cost” or “WAC”).

The decision to adjust price over time is based on many factors, and can be the result of competitive dynamics, and/or related to the extent of formulary restriction, utilization controls and cost-sharing (e.g. tier placement) that impact the market potential of the product.

Enbrel is in an extremely competitive marketplace where several large players are fighting for formulary placement. The health plans and PBMs extract price concessions and large rebates in exchange for preferred formulary status. Because of the magnitude of the rebates, price increases have become part of the competitive dynamic in these negotiations. Thus, when any one player takes a price increase or changes the rebate amount, others may alter their pricing strategy to remain competitive. (delete)

Ensuring that patients have access to our medicines is critical to Amgen. We offer many types of support programs for commercially insured patients (ENBREL Support copay card Redacted - Non-Responsive Redacted - Non-Responsive We make donations to various independent co-pay foundations to further help provide access to our products for patients with Medicare Part D coverage, and are The Safety Net Foundation offers therapy for free to qualifying underinsured or uninsured patients, including Medicare when other foundations are not available. In addition with the complexity of obtaining access to specialty products for very sick patients, Amgen like many other companies, has had to build robust reimbursement support programs to help the physician and patients navigate the complexities of prior authorization, escalating co-pay and coinsurance costs to the patients that in many cases impede their ability to afford and access vital drugs.

## Background Response

At Amgen, we price our products to reflect the economic value that is delivered to patients, providers and payers, the unmet medical need, the size of the patient population, the investment and risk undertaken, and the need to fund continued scientific innovation.

Over the last 10 years, Amgen has studied more than several dozen potential drug targets, investing \$33 billion in Research and Development, resulting in xx molecules in development and nine new innovative medicines available to patients [Redacted - Non-Responsive]

## Redacted - Non-Responsive

Patient access is critical to Amgen. We offer co-pay programs for commercially insured patients (ENBREL Support copay card [Redacted - Non-Responsive]).

- For Enbrel, patients pay nothing for the first 6 months of therapy and then only \$10 a month out of pocket. Overall the program helps ensure more patients can access therapy. Over 316,000 patients have used the ENBREL Support copay card to help pay for Enbrel.

## Redacted - Non-Responsive

- The Safety Net Foundation offers therapy for free to qualifying underinsured or uninsured patients, including Medicare when other foundations are not available.
- Amgen also makes donations to various independent co-pay foundations to further help provide access to our products.

### On-Background Responses to Questions

It is important to consider net vs. list price – since Health insurers and other purchasers of drugs (e.g., hospitals, physicians, etc.) negotiate with manufacturers for considerable discounts and rebates for the products they purchase. These discounts drive down drug prices and are not reflected in the list prices (known as “wholesaler acquisition cost” or “WAC”).

It is also important to recognize that our list prices do not reflect the Medicaid rebates and discounts provided to 340b institutions (across the industry, Medicaid Part D rebates generally equate to 15-30%). Are discounts here are huge. I would use a number like great than 50 percent

In addition, for our Medicare Part B drugs, [Redacted - Non-Responsive] most providers and institutions mark-up – some quite substantially – their acquisition price.

- 1) The price increases for Enbrel in wholesale acquisition cost (WAC) have totaled 119 percent since the beginning of 2011, including two increases per year in 2012, 2013 and three increases per year in 2014 and 2015. The price I am using in the story is the 50 mg/ml subcutaneous solution, which rose from \$427.24 to \$932.16, according to Truven. Are these WAC figures and increases accurate?

Need to confirm WAC with Tom Moore. The Average Selling Price (ASP) for 50 mg/ml subcutaneous solution of Enbrel is \$704.23. ( I would stay away from these details)

2)

## Redacted - Non-Responsive

## Redacted - Non-Responsive

- 3) PBM sources say that pharma companies typically negotiate a 6 to 10 percent annual price increase cap in their contracts with drug makers. Is that practice and that size annual increase usual and customary?

The decision to adjust price over time is based on many factors, and can be the result of competitive dynamics, and/or related to the extent of formulary restriction, utilization controls and cost-sharing (e.g. tier placement) that impact the market potential of the product.

- 4) Customers who buy drugs outside of contract say they pay something close to WAC. True? Yes, but this is a very small percentage of customers.

- 5) PBM sources say that that an Enbrel contract typically carries an aftermarket rebate to them of 20 to 30 percent. Is that correct?

Enbrel is in an extremely competitive marketplace where several large players are fighting for formulary placement. The health plans and PBMs extract price concessions and large rebates in exchange for preferred formulary status. Because of the magnitude of the rebates, price increases have become part of the competitive dynamic in these negotiations. Thus, when any one player takes a price increase or changes the rebate amount, others may alter their pricing strategy to remain competitive.

Enbrel is currently a preferred biologic medicine for nearly 90% of commercial and Part D patient lives in the United States.

- 6) Payers say that Enbrel's Redacted - Non-Responsive price increases are reflective of a pharmaceutical pricing system based on regular and standard price increases, and that there is a lack of transparency about why they are being put in place. Do you explain to payers and PBMs negotiating on their behalf why these price increases are needed, and why they are so much higher than the rate of inflation for medical spending or CPI? What do they reflect?

The decision to adjust price over time is based on many factors, and can be the result of competitive dynamics, and/or related to the extent of formulary restriction, utilization controls and cost-sharing (e.g. tier placement) that impact the market potential of the product.

[Per stat from Alex] Despite list price inflation, SSR Healthcare recently published data demonstrating that net price (after all rebates and discounts for U.S. prescription brands grew just 0.7% in Q2 2015. We should keep price increases in perspective. CMS projects pharmaceutical spending to grow 6.3% from now until 2024. IMS also estimates that only 4% growth in spend is attributable to price increases for branded products.

In addition, according to CMS data, drug prices today account for just 10% of all healthcare spending, roughly the same percentage as in 1960. [PhMRA analysis based on CMS data. National health expenditures by type of service and source of funds, CY 1960-2013.]

- 7) Data from IMS Health shows that Enbrel prescriptions rose by 2 percent between 2010 and 2014, while total dollar sales rose 66 percent. Does this accurately reflect the mix of volume and pricing that drive Enbrel's revenue growth?

Amgen data from IMS show prescriptions for Enbrel rose by 10% between 2010 and 2014. [Per Tom Moore]

## Redacted - Non-Responsive

- 9) Dr. Peter Bach used 2014 U.S. sales to calculate that the 2015 pricing increase on Enbrel resulted in more than \$1 billion of increased cost. Do you agree with that math? If not, what was the increase in Enbrel revenue in 2015 attributable to the price increase?

According to Amgen's data, Dr. Peter Bach's assertion that pricing increases on Enbrel resulted in more than \$1 billion of increased cost is incorrect. While Amgen is not familiar with the Dr. Bach's methodology, it's important to remember that other participants in the healthcare system add to the aggregate cost of a product. If his calculations are accurate then a significant percentage of the \$1 billion would be attributed to other participants in the healthcare system such as PBMs, pharmacists and health plans.

Recognizing that many commercially covered patients have significant co-pays required by their insurance, Amgen offers a co-pay card, which limits patient's out of pocket costs to \$10.

- 10) PBMs say that branded drug increases are currently a top issue and subject of intense negotiation. For 2016, do you anticipate a change in your pricing strategy?

To create a sustainable healthcare system, all stakeholders must recognize that the overall economic burden of disease will make health care costs unsustainable, and that innovative medicines are part of the solution and not the problem. At Amgen, we are committed to an ongoing dialogue with patients, providers, payers, policymakers and regulators to find ways to promote innovation, while also alleviating the financial and societal burden of some of the world's most serious diseases.