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Teva Pharmaceutical Industries Ltd.

(TEVA)

Q2 2020 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by, and welcome to Teva's Second Quarter Financial Results Conference Call. [Operator Instructions] I must advise you this call is being recorded today on Wednesday, August 5, 2020.

I would now like to hand over to your first speaker today, Mr. Kevin Mannix, Senior Vice President, Investor Relations. Please go ahead, sir.

Kevin C. Mannix

Senior Vice President & Head of Global Investors Relations, Teva Pharmaceutical Industries Ltd.

Thank you, Tracy, and thank you everyone for joining us today to discuss Teva's second quarter 2020 financial results. On the call with me are Kåre Schultz, Teva's Chief Executive Officer; Eli Kalif, Chief Financial Officer; and Brendan O'Grady, Teva's Head of North America Commercial.

We hope you've had an opportunity to review our earnings press release which was issued earlier this morning. A copy of the release as well as a copy of the slides being presented on this call can be found on our website at www.tevapharm.com as well as through our Teva Investor Relations app.

Please note that the discussion on today's call includes certain non-GAAP measures as defined by the SEC. Management uses both GAAP financial measures and the disclosed non-GAAP financial measures internally to evaluate and manage the company's operations to better understand its business. Further, management believes the inclusion of non-GAAP financial measures provides meaningful supplementary information and facilitates

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analysis by investors in evaluating the company's financial performance, results of operations and trends. A reconciliation of GAAP to non-GAAP measures is available in our earnings release and in today's presentation.

To begin today's call, Kåre and Eli will provide an overview of the second quarter performance, recent events and priorities going forward. This will be followed by a question-and-answer session. Today's call, which will run approximately one hour, is being webcast live and recorded. You'll be able to replay the call and view the transcript on the Teva Investor Relations website.

And with that, I will now turn the call over to Kåre Schultz. Kåre, if you would, please.

Kåre Schultz

President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

Thank you, Kevin. Welcome everybody. I hope you're all safe and healthy. And I'd like to start by commenting a bit on the COVID-19 situation. So if I could have the next slide, please.

As you know, Teva is the world's largest manufacturer of pharmaceuticals in volume. And I would like to share with you that our manufacturing organization, our QC, our logistics organization has shown great resilience all over the world in this situation. And despite the challenges of COVID-19, we have been able to stay operational, been able to supply customers, and we're very proud about it.

The way we've been thinking about it is illustrated on the next slide. We've really been focused on three key stakeholders: our patients, our employees and our communities. And I won't give you all the details, that would take too long, but just reiterate that we've been committed to our patients we serve, around 200 million patients every day. We've been able to do so on uninterrupted supplies.

Our employees is of course our key concern when it comes to safety and protection, and I'm happy to say that due to a lot of measures worldwide, we have been able to avoid any outbreaks of COVID-19 related to our facilities, and we've had no facilities that had to be shut down for longer periods of time because of any kind of the COVID-19 problems. So it has taken a lot of work. It has taken a lot of new precautions, a lot of new procedures, but we're happy to say that we've able to handle this in a good way.

We've also tried to support communities and patients the best we could. We've donated products in more than 25 countries. We've donated all kind of different products and we've made sure to support also locally near our factories, to people less fortunate than us. And this has been done with great passion and great effectiveness, and I'm very proud about what all our employees have done. So, I would like to share with you my big thanks to all our employees for keeping the business going in a very nice way.

I won't tell you all the details about how much we support the health care systems around the world, but I'll just share here a few hard facts. One in every 10 scripts in the US are filled with a Teva generic product. We actually manufacture by far the most of all medicines listed on the WHO Essential Medicines List. We also provide huge savings around the world, and just in the US alone, more than $41 billion in savings in 2018 and probably even more so this year. But of course, the most important is to supply high-quality medication for patients who need it every day, and we've continued to do so.

But now let's move to the financials. Our revenues came in at $3.9 billion. And I'll, as I show you in a moment, that's slightly below what we would normally expect. There's a phenomenon here where we saw higher demand in the first quarter of certain generics and OTCs products, especially in Europe, and we've seen lower demand in the second quarter, and I'll show you that in a minute.

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Our non-GAAP EBITDA came in at $1.1 billion, the GAAP EPS at $0.13 and the non-GAAP EPS at $0.55. The free cash flow came in just around $0.6 billion, and all in all, for the first half, $1.1 billion has been accumulated in free cash flow. Net debt continues to decline. We're now at $23.9 billion. And as a side issue, I can tell you that in July, we repaid $1.1 billion.

I'm very happy to reaffirm our outlook. There will be a slide at the end of the presentation where you'll see all the different details. We are basically reaffirming all the details of our outlook, including the strong growth of our new products, which I'll be commenting on in a little bit when I comment on our business update.

On the business side, we have a lot of news for you today. Some of them we have reported in the last couple of days. I won't comment on this slide, but there will be a separate slide of each of them in the coming presentation, and I'll comment on them when we get to that.

So if we move to the next slide, then I can show you this phenomenon we've had on the revenues. Really, what you should look at is the Q1 2020 and Q2 2020 column and look at the dark green colored part of the bar, which is Europe. We basically had a $200 million swing factor in Europe. So what it means is that in the first quarter, we probably sold $200 million more. We can see now when we analyze Q2 patient level hoarding and stockpiling of products, and that means in the second quarter, we sold $200 million less.

So, if you move that $200 million, you get to $1.2 billion in each of the two quarters for Europe. That's why we did the half-year comparison to the right, where you can see first half 2019 compared to first half 2020. And what you can see there is we did $2.4 billion in 2019 in the first half in Europe, and we did $2.4 billion in 2020 in the first half. So basically, a very steady market situation.

Now that's basically a reflection that we have some products that are declining, such as Copaxone, and all our products that are growing, such as Austedo and Ajovy, and the two are basically balancing each other out right now. And then we make a little bit more money because we manage to be more efficient and reduce our cost right now.

So, talking about the two drivers of sales growth that's compensating for Copaxone decline, let's move to the next slide and look at Austedo. As you can see here, Austedo continues to grow very steadily. There are some small variations from quarter to quarter, but basically, if you take the graph in the middle, you can sort of make a straight line and then you have the growth track since the launch, and we see that continuing. We see very good prescription numbers. And as you'll see at the end, we are maintaining our guidance for the year of around $650 million in revenues for Austedo.

Nice to note also is that Austedo has been approved in China. That's a unique thing in the sense that it's approved without a Phase 3 trial. The Chinese authorities realized that this was a drug they would like to have, so we got a regulatory approval without doing a Chinese trial. And we're looking forward to launching Austedo in China. Of course, launches in China are always pretty slow because you start in the private market, but nevertheless, it's a good sign that we bring Austedo to all our patient populations also outside of US. So a very strong growth that continues on Austedo.

Now the other growth driver, Ajovy, is described on the next slide. And here, we have I would say a fantastic story which I have not seen that many times in my 30 years plus in pharmaceuticals because we have a situation where we launch a product and you can see here in the middle with a good NBRx share. You have to consider here that we have three players in the market, and there was one company launching significantly before us and

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we get a decent start. We've had an aim all the time to have at the end of the day around 25% of the market which fits with the fact it's a free-player market and we are not the first to launch, and then we have a negative development with declining NBRx share.

And that's mainly a reflection of the fact that we don't have an auto-injector and since this is a very efficacious therapy for chronic migraine and you self-inject once a month at home, and we only had a prefilled syringe, not an auto-injector, because we had a delay on the approval of the auto-injector. Then what happened was we finally got the approval and since the product has an excellent efficacy profile and an unbeaten safety profile, you can see here, since we got the auto-injector, the NBRx share has continued to grow significantly per month and per week, and I can tell you here that the July numbers are even higher than the June numbers.

So we're very optimistic about the fact that we're getting back to that natural capture share, natural NBRx level, which would be somewhere between 25% and 30% and which would lead to us getting a TRx share in the end of around 25% which is really what our ambition is for this product.

So a very positive story here in the US and I should add also that it's doing well in Europe. We now have reimbursement in 16 countries, so slowly, these numbers will start to add up and you will start to see meaningful double-digit numbers in the millions of euros and dollars per quarter of European revenue going forward, so that's very positive. We also have another positive thing which is our partner Otsuka on Ajovy has filed the product in Japan and we look forward to the approval and launch in Japan.

Now, right now, Austedo and Ajovy are the two products that are driving most of the growth, but there are also things to come in the future and I have three stories here I would like to share with you and the first one is fasinumab. And as you know, fasinumab has been in development in a partnership with Regeneron for a long time and Regeneron are conducting the clinical trials, and we just had a readout from Phase 3 and we had a efficacy readout. And we had two Phase 3 trials, and in those trials, the 1 milligram monthly dose demonstrated significant improvements in pain and physical function over placebo both at week 16 and week 24, respectively, so this is very good, clear-cut efficacy on the 1 milligram monthly.

The 1 milligram monthly dose also showed nominal significant benefits in physical function in two trials and pain in one trial when compared to the maximum FDA-approved prescription doses of non-steroid anti-inflammatory drugs for osteoarthritis, so that's what you normally call NSAIDs. So what we're talking about here is that when we compare the 1 milligram monthly against the normal therapy, we also saw improvements. So this is of course very, very positive.

In the trial where we had 1 milligram every two months, there we saw a numerical benefit over placebo, but we did not reach statistical significance. In the initial safety analysis of the Phase 3 trials, there was an increase in arthropathies reported with fasinumab. In a subgroup of patients from one Phase 3 long-term safety trial, there was an increase in joint replacement with fasinumab 1 milligram monthly treatment during the off-drug follow-up period, although this increase was not seen in the other trials to-date.

So additional longer-term safety data from the ongoing trials are being collected and I expected to report it early next year, and then following that, if everything looks good, then you could expect a filing of the product some time the first half of next year. So that's of course something for the future, and we have the partnership with Regeneron which means that we're sharing the product in the US and we are going to do the commercialization outside of the US.

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If we move to the next slide, then another exciting move here is that you know we have a vision to be the leader in generics which we are, but also to be one of the leaders in biopharmaceuticals, including biosimilars, and as you know, we are just getting started there. And we have a pipeline with six biosimilars in development but we would like to have more, you could say, projects in this area.

So we just entered into an exclusive strategic partnership for the commercialization of five biosimilar products with Alvotech and we very much look forward to this. And we think that our commercial expertise in biosimilars in the US will be a key player in this, combined with Alvotech's strong technology and know-how in development of biosimilars. So this is very exciting for us. It means that we now have more than 10 biosimilars in our development pipeline, which we are very optimistic about.

A last move we've done which is more like a, I would say, part of being focused and part of optimizing our business also on profitability and future growth is that in Japan, we have a business venture together with Takeda, which we're very happy about and we've done a small change here. We've basically taken part of the business which are old generic products with low profitability and some contract manufacturing operation. So contract manufacturing products that are all manufactured at a manufacturing plant we have in Takayama and we are planning to sell this to Nichi-Iko, a main player in the generics space in Japan and they'll be taking over these old products.

We will keep our newly launched generics. We will keep our complex generic portfolio. We'll keep our long list of products and specialty assets and this transaction we expect will take place at the end of this year and it will secure future growth of our Japanese business and it will also improve the profitability.

The last update I want to give you on the business is on the next slide. It's about biosimilars. It's about Truxima. As you know we launched Truxima at the end of last year and I always said that we felt we could do better than most people have done with biosimilars in the US due to our commercial footprint and the fact that we are the biggest volume supplier of pharmaceuticals in the US, so we have customer relations to basically nearly everybody. And that's important when you launch a product like a biosimilar such as Truxima. I'm just happy to report here that another good thing that has happened is that injection for rheumatoid arthritis has been approved and that means that we can keep on growing our Truxima business in the US nicely going forward.

Then, we also have a very, very exciting thing that's happened in the say digital slash product slash respiratory space which also bodes well for future growth. Now, this is the world's first product where we have a asthma or COPD respiratory inhaler that has integrated electronics that measures the actual inhalation, the velocity and volume of your inhalation and can give you a feedback on your smartphone both with regard to the quality of your inhalation, with when you did the inhalation with the dose and so on.

But not only can it do it on your smartphone, it can also have the smartphone connected to the cloud and you can then control that that data is handed over to a caregiver, a parent, a doctor, and it will be possible then to have a, you could say, electronic consultation with your doctor, sharing the data, discussing the data, and in that way, staying more on top of the therapy. Or for caregivers, parents, they can share with their children, with relatives, you can share with your partner how the disease is evolving, how you're dosing your medication and this is very, very exciting.

We've just launched the first product, ProAir Digihaler in the US. These are the very first weeks. We see very encouraging take-up in the marketplace. We are collaborating with certain healthcare systems on this product as well. So we're very optimistic that this can bring significant clinical benefits and therapeutic benefits to people suffering from asthma and COPD not only in the US but longer term all over the world.

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So these were some future growth drivers and some current growth drivers, but let me just round off by saying where is this all going to lead from a financial point of view before we slide into the financials. And this slide, you all have seen before and expect to see many times again until the end of 2023 and there's no change to the slide which is good. Our target for operating income margin is still 28%. We need cash earnings about 80% to pay down debt, and when we pay down debt and grow EBITDA then the net debt-to-EBITDA ratio declines and we have a target of less than 3 times at the end of 2023.

And as you know, we're committed to spend all our cash flow on debt reduction. We continue to do so, and we do not have any plans to raise equity. But with this long-term financial target, I'd like to hand it over to Eli Kalif, who will go through the financials.

Eli Kalif

Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.

Thank you, Kåre, and good morning and afternoon to everyone. I hope that everywhere you are in the world that you are safe and healthy. So let's us begin with our financial review of the second quarter.

We begin on slide 18 where we highlight Teva GAAP results including GAAP net income of $140 million and earning per share GAAP basis $0.13 for the second quarter of 2020. Our year-over-year improvement in our GAAP result was the result of lower operating expenses including lower impairment items and legal settlement as well as minority and share in profit offset by smaller tax benefit.

Turning to slide 19, we see impairments, restructuring and other charges which totaled $465 million for the quarter. The main charges in the quarter and the largest was tied to our business in Japan. As previously announced, Teva and Takeda have decided to sell the majority of the business ventures generics and operation assets resulting in impairment charge of $261 million. Amortization was $249 million for the second quarter, aligned with the range of $250 million to $260 million per quarter that we guided to at the beginning of the year.

Turning to slide 20, we review our non-GAAP performance. I want first to start with a complete look at the year-over-year financial performance and then I would like to touch on the sequential swing in the first two quarters of 2020 in more detail.

Second quarter 2020 revenue were approximately $3.9 billion, down 7% compared to Q2 2019. This decrease was mainly due to a lower revenue from generic OTC and Copaxone in all region, and the lower revenue from QVAR and Bendeka/Treanda in North America, as well as the impact of COVID-19 had on certain purchasing pattern partially offset by higher revenue from Austedo, Anda and Ajovy in the US. The decline also reflects a negative foreign exchange impact of $79 million net of hedging.

Non-GAAP gross margin came in at 52% for the second quarter versus 52.4% a year ago. The modest decline in the gross margin was due to a lower gross margin in specialty products coupled with the negative impact from hedging activity, partially offset by lower cost of goods sold related to our ongoing network optimization.

Our non-GAAP operating margin was 25.3% versus 24.2% a year ago. The increase was driven by lower operating expenses as our overall spend base including COGS rose approximately $2.9 billion compare to approximately $3.2 billion for Q2 2019. This result led to a non-GAAP EPS of $0.55 which is $0.05 lower than Q2 2019.

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Now, I would like to touch on the first half of 2020, which was comprised of two very different quarters as purchasing patterns, especially in Europe, were impacted both positively and negatively by COVID-19 pandemic. You will recall that in May when we presented a very strong first quarter result, we noted that we were experiencing increasing demand of certain medicines as was expected during a global crisis of this nature. Nor was this more apparent than in our operating operations where we saw a strong demand for our products, especially generic and OTC.

We did, however, expect that this would reverse in the second quarter results after seeing the strong first quarter out-performance. As you can see by the results we are reporting today, our assessment was correct. The impact is mainly affected by strong revenues of the pandemic-related products and customer stocking in the first quarter at the expense of the second quarter. Still, when we compare the first half of the year to the first half of 2019, we see just slight impact of COVID-19 on our top line, which declined just 1%.

Furthermore, we saw 8% increase in EBITDA and 10% increase in both net income and EPS. Free cash flow for the first half actually doubled compared to last year. These strong results are mainly due to the cost reductions and efficiency measures that the company implemented in 2018 and 2019. In addition, we are also benefiting from stricter management of quarterly cash flow fluctuations, resulting in a greater linearity in our cash conversion trends.

Turning to slide 21. I'd like to highlight just a few of the revenue trends where we've been seeing throughout the different segments and regions. We'd remained focus always being on the sequential trends. In the first quarter of 2020 we experienced increasing demand of certain medicines as will expected during the global crisis of this nature. We saw a compensating effect, lower demand for certain medicines, during the second quarter of 2020.

We start with North America where our generic business generated $923 million in sales which was sequential drop of 3% from the first quarter. In the absence of any major launches in the second quarter, sales were supported by the strength of Truxima, our biosimilar for Rituxan, our ProAir HFA authorized generic of our own specialty product and our generic equivalents of EpiPen and EpiPen Jr.

Looking at our specialty product, both Austedo and Copaxone bounced back nicely compared to the first quarter. While we begin to see at the early positive signs of the introduction of the auto-injector device for Ajovy, we expect Ajovy sales to continue to grow as the launch of the auto-injector continues.

Turning to Europe. As I mentioned, this was the region that benefit significantly from COVID-19 effect on the purchasing patterns in the first quarter. The significant purchases were more than reversed in the second quarter as demand for certain products declined. The pandemic effect also led to a decline in doctor visits by patients, resulting in fewer new prescriptions during the second quarter of 2020.

Furthermore, our specialty portfolio saw a price decline for oncologic products as a result of a generic competition as well a decline in Copaxone revenue due to competing [indiscernible] (26:23) products which were partially offset by new launches of generic products.

Our international markets segment was lower by almost 14% compared to the first quarter of 2020 or 2% in local currency terms. The decrease was mainly related to the effect of the COVID-19 pandemic.

Now let's take a look at our spend base on slide 22. As you know, the cost reduction plan that was introduced at the end of 2017 led to an overall reduction in our spend base of more than $3 billion to the 2019 total of $12.7 billion. Since the start of the year, our spend base has continued to decline due to a number of factors which I

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highlight in the Q1 call and that continued to impact our spend base. The most significant decline this quarter versus Q1 is our cost of goods sold, which is certainly attributable to the reduced top line as well as our ongoing efforts to improve our gross margin through the transformation of our network.

Looking at the operating expenses, we are always mindful of our spending and continue to actively control it, especially in the face of COVID-19 pandemic. Selling and marketing and G&A both saw significant decline for the second straight quarter. All of this gave us a total spend base of approximately $6 billion for the first half of 2020, and expected our full year spend base to be lower than our full year 2019 total.

Turning to slide 23. We see our free cash flow for the quarter came in at $582 million compare to $168 million in Q2 2019. The increase resulted mainly from the higher cash flow generated from operating activities. This bring our total free cash flow generation for the first half of 2020 to more than $1.1 billion. This was an unusually strong start of the year, especially given past first half performance which are usually impacted by annual incentive payments to our employees. Based on the first two quarters, and our outlook for the remainder of the year, we are now not changing our free cash flow guidance for 2020 which is in the range of $1.8 billion to 2.2 billion.

Continuing our review of cash, on slide 24, you can see our strong cash conversion for the first half of the year came in at 79% versus 40% for the first half of 2019. Cash conversion is one of our key long-term financial targets and we are targeting at least 80% for Teva cash conversion. As Kåre described, since the long-term financial targets were introduced in 2018, a high level of cash conversion is especially important for Teva as we focus on our main goal of reducing our significant debt load. Teva is focused on ensuring that our cash conversion continues to improve each year.

There are many touchpoints within the organization that we are focusing on, thus will enable us to assure these long-term targets including the active management of our working capital and the improvement of our gross and operating margin. These efforts are especially reflected in the cash conversion for the first half of 2020.

Now turning to our debt development on slide 25. As I just mentioned, our main focus from the start has been to reduce the company's significant debt load including the net reduction of $400 million in the second quarter. The company has reduced its net debt by more than $10 billion in the last three years. There is still a lot of work to do, and I'm pleased to report that this work continue in July with an additional repayment of $1.1 billion that is not affected in the quarter-end totals.

Our net debt-to-EBITDA ratio fell for a fourth straight quarter dropping to 4.9 times. As we noted last November following our successful financing and again on our fourth quarter call in February, we have liquidity and cash flow to cover bond repayments for the years 2021 and 2022 before looking refinancing at 2023 maturities.

Turning to our outlook for 2020 on slide 26. As I mentioned last quarter, we're operating in a unique environment created by the COVID-19 pandemic. As you can see, based on our financial results for the first two quarters of the year, the pandemic had a significant effect on the purchasing patterns of our large global customers and overall utilizations of by patients, which has led to a swing in our results. Still, our team has done a very good job in managing through the pandemic and its effect, staying focused on driving the business forward including the growth of our two key specialty assets, Austedo and Ajovy.

Based on the results of the first half 2020 as well as what we have seen in the first month of the third quarter, we are reaffirming our annual financials outlook that was first presented in February and reaffirmed in May, including total revenue of $16.6 billion to $17 billion, earning per share in the range of $2.30 to $2.55, and free cash flow between $1.8 billion to $2.2 billion.

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We'll continue to monitor and analyze the current and potential impact of COVID-19 on our business. Where we end up in each of the guiding range will depend on the performance of all the three regions, including their normalization of purchasing patterns and patient demand, the timing of generic launches, the continuation of the growth of Austedo and Ajovy, and foreign exchange rates. At the same time, we'll continue to manage our overall spend base.

And with this, I want to conclude my review for the second quarter results of 2020 financial guidance. We'll now open up the call for the questions and answers. Operator, will you please open the call for questions?

QUESTION AND ANSWER SECTION

Operator: Thank you, sir. [Operator Instructions] Thank you. Your first question today comes from the line of Gregg Gilbert, SunTrust.

Gregg Gilbert
Analyst, SunTrust Robinson Humphrey, Inc.

Q

Thank you. Kåre, putting aside the strong performance for a moment, I wanted to ask about liability management. Is there any progress you can discuss around your proposed opioid settlement? And on the price-fixing allegations, how do you plan to balance the need to create certainty for long-term investors with the desire to achieve your long-term deleveraging targets, as well as other considerations that we should be aware of? Thank you.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Yeah, thank you for that question. So first, on the opioids, we have continued our positive dialogue with the AGs, and we're continuing to refine you could say the framework with of course the objective to implement it. There has been a significant delay in the process due to COVID-19. It basically is the case for most big settlements like the framework settlement that when you have a lot of parties, you need to bring together with a lot of lawyers involved.

Unless there's a triggering event, it doesn't really happen, and we were expecting that triggering event as some of you probably remember to be the trial in New York in February, but that got delayed, postponed because of COVID. It's still being postponed, so we don't have a clear timing on that. So I would say a very positive dialogue with the AGs but no clarity on when exactly the framework will come to fruition. It is still a very I think desirable thing for the framework to get implemented.

It does include as you know from us, donation at the level of $23 billion, $25 billion of products at the [ph] WAG (35:02) price, probably half of that net price in the category where the states can alleviate some of the problems about substance misuse and help treat patients better. So we think it's a good thing for the American people if this framework does get implemented, and we are still very optimistic and hopeful it will get implemented. But on the timing, I must admit, I don't really have a good clear answer as to when that might be. I think it will sort of be once we have clarity on a sort of legal situation, a major trial in one of the key states and the fact that that is actually progressing and that might result in a clarification on that.

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On the price fixing situation, we remain in dialogue with DOJ. We of course see a situation where we do not see that the company in any way participated in criminal organized price fixing or were a part of creating a cartel or anything like that. So we would like to resolve it together in a positive way with DOJ and we don't know whether this will be possible, but there's of course the option that we resolve it which would be nice and then there's the option that it goes on in the legal system. And we are looking at all options and we think that we can manage the situation no matter what option and that we have good plans for doing so, but right now we're still in a dialogue with DOJ. Thank you.

Gregg Gilbert
Analyst, SunTrust Robinson Humphrey, Inc.

Q

Thank you for that.

Operator: Thank you. Your next question comes from the line of Ronny Gal from Bernstein.

Ronny Gal
Analyst, Sanford C. Bernstein & Co. LLC

Q

Good morning, and congratulations on the nice quarter. Two if I might. Kåre, we're seeing some significant [ph] cash CapEx awards (36:47) in the US government to companies who are not directly involved historically in the generics industry and we've not seen the traditional companies that are in that industry participating. Now you have both formulation capabilities and significant API capabilities and I kind of wonder if you can give us an update about that process, your ability to participate in it, your ability to shift manufacturing of API and dosage forms to the US or Europe as the countries require. Second, do you see this as something you will participate in given that apparently it's going forward?

Second, in the first half of the year, we've seen on the bulk volume oral products which we all track to IQVIA, a significant drop in Teva's volumes. And can you describe to us a little bit the dynamics there and your strategy going forward? Is this a significant segment for you? Is this something that is nice to have? How do we think about the progress of your volumes as a kind of a bulk generic supplier to the US market? Thank you.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

So just to clarify the last question, Ronny, to be absolutely certain what you asked about, you said bulk generics when you thinking about API, or you were thinking, just clarify.

Ronny Gal
Analyst, Sanford C. Bernstein & Co. LLC

Q

Yeah, I meant commodity generics, so finished dosage forms, but you just look at the raw volume numbers that we get from IQVIA [indiscernible] (38:11) you see significant declines there over the last six months.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Yeah, so let me address both questions. So if we take the US first and the discussions about API and so on that has been going on for a while, but really got more you could say at the front page in connection with COVID-19. So first of all, Teva is a company with a very strong manufacturing base, basically in US, Europe, and I would say would recall in NATO-allied countries or US and NATO-allied countries. So we have a disproportionately large

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parts of our entire manufacturing in countries that are politically aligned with US and Europe, which of course is a good thing from a US perspective.

It's also true that there's been discussions about getting API manufacturing, actual API manufacturing back into the US. It's a fact that it has basically all left the US within the last 30 years, so there is nothing left, which means that getting it back for real would take probably 10, 20 years and would have to depend on major structural changes in pricing and all these kind of elements, as you can imagine.

Now we are of course positive towards any collaboration with the US government. We have been in dialogue with the US government all along and sketched out possibilities on specific products where we might help, also specific products that are related to COVID-19 therapies where we might help. So far, it hasn't come to anything specific. I would say with regard to what has happened so far, there's probably, without me getting into any details, a mixture of operational, and in some cases, political agendas that get mixed up here.

Teva is not really interested in the political side of it. We are more an operational company, so if it makes operational sense, we would love to do more manufacturing in the US. But it will take certain structural changes in the marketplace, which we are currently not seeing happening. And therefore, without those changes, you will not see us do a major relocation to the US, but we are open to make any kind of deal on different products. We've offered that as well to the US government.

On the second question, I think the reduction you see in volumes here in the first half in the US, that's mainly related to COVID-19. We can see in our market data that we sort of have the same market share. There's no major change in our market share. So the major change we've seen is a reduced volume being bought by patients in pharmacies, both of generics and OTC products in the second quarter of this year. And that's basically related to the lockdown or semi-lockdown or fear of going out or whatever you want to call it, which has reduced the volumes that patients have been buying.

There's an indication related to the macro data from the companies that supplies us data that this is normalizing. It hasn't completely normalized, but if we look at Europe and the US, there's a tendency that it's getting back closer to normal volume levels. It's anybody's guess how the pandemic will evolve the rest of the year. If it gets a lot worse, then probably we'll see a modification of volumes being lower than they were last year. If the situation continues to improve slowly area by area as it has been doing in Europe, then we'll probably get back to a more normal volume level. So, thanks for that question, or those two questions, actually.

Ronny Gal
Analyst, Sanford C. Bernstein & Co. LLC

Q

Thank you.

Operator: Thank you. Your next question comes from the line of Nathan Rich with Goldman Sachs.

Nathan Rich
Analyst, Goldman Sachs & Co. LLC

Q

Hello. Thanks for the question. Just two on the margin's performance and outlook. You've had a nice margin performance so far in the year. I think looking at the midpoint of guidance for the back half certainly implies a 26% EBITDA margin or so, kind of down from the 30% level you saw in the first half of the year. So, can you maybe just talk more about kind of your expectations for margin cadence and kind of any factors that we should keep in mind as we think about modeling the back half of the year?

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And then tied to that, I just wanted to ask one clarification question. Kind of putting together your comments on what you've seen in the first half of the year related to COVID, did you guys kind of have a sense of what the net impact to either revenue or EBITDA was from some of the COVID-related kind of purchasing dynamics that you've seen so far?

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
A

Yeah, so thanks for those two questions. I'll give it a quick answer and then I'll turn it over to Eli to hear if he wants to say more about the margins. But you're absolutely right that for a number of specific reasons, we saw very high margin in the first quarter, which we also indicated that's not really what's part of our – well, it is part of our full-year guidance of course, but we won't maintain that level. And you could say every quarter, you have a couple swing factors which might be to the tune of $50 million, $100 million. Could be exchange rate. Could be launches of products. Could be people either destocking or stocking up and so on. So have some swings there.

If I give you the big picture, then I would say the big picture is that we're going to hit 28% operating margin at the end of 2023. That's a firm target and we are firmly dedicated to that. Now, you're probably also right that this year could be around 26% as there's some swing factors up and down that can affect that, and Eli can comment on that. But I think the most important for you to know is that we'll hit the 28% in 2023.

We'll do that by improving at around 100 basis points per year, and we'll do it in a combination of active portfolio management of our in-line portfolio, active management of our cost in our manufacturing network, and active management of our sales, marketing and G&A cost. So we'll be optimizing the whole thing. And I think it's fair to say that this is something I've done many times before, so this is something I know can be done. So on the margin I'm pretty firm on that.

On the COVID, that's a little bit of a more tricky question actually because there definitely was a positive effect in the first quarter. There definitely was a negative effect in the second quarter. There definitely was probably a wash more or less on the revenue, probably a slight improvement on the cost, but then we also had associated costs that went up. So if you go to the micro level for instance, distribution costs had gone up, it's because transportation costs went up. Travel costs have gone down because travel went down.

So you have all these swing factors up and down, so I would hesitate to give you a firm number other than saying that in my big picture analysis, just like the half year/half year analysis you saw from Eli, I think it's a wash. I don't think there's a significant effect, positive or negative. There's a lot of small effects in both directions, but I think overall it's a wash.

So with that, I'll just let Eli comment a little bit more on the margins for the second half and how we sees the final year operating margin. And then say thank you for your questions, and then after Eli's comments we'll move on to the next.

Eli Kalif
Chief Financial Officer & Executive Vice President, Teva Pharmaceutical Industries Ltd.
A

Okay. Okay. Thanks, Nathan, for the question. So there are kind of a combination of I would say main three elements. First of all, we need to actually understand the OpEx. The OpEx for the first half is trending combined R&D, sales, marketing and G&A at the level of around 25% to 25.5%, and a year ago it's like 27.7%, so here you have like at least a 2%. And we end up 2019 with 51.5% on gross margin and 24.5% on OP. Our planning is to at least top a 100 basis point, additional 1 point for both gross margin and OP by end of the year, by end of 2020.

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What you can see for the first half that we are already on trend on the gross margin. We're actually yielding 250, 2.5%, which in that area we see it's coming. We got kind of an upside in Q1 due to economic hedge revaluation mark-to-market that get a kind of an upside. So we currently, the first half is accumulated 27% but we see it's actually yielding to the level of 25.5% to 26%.

And as you can actually recall from my prepared remarks, mainly you can see that the first half is with the $6 billion spend base, and you can actually recall that we're going to do less than last year which was $12.7 billion. So the numbers for the next half most likely are going to trend on the OpEx at the range of around 26%. So with that one, I think that you can understand how we look on the dynamics.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
A

Thank you, Eli. Let's move to the next question.

Nathan Rich
Analyst, Goldman Sachs & Co. LLC
Q

Great, thank you.

Operator: Thank you. Your next question comes from the line of Elliott Wilbur from Raymond James.

Elliot Wilbur
Analyst, Raymond James & Associates, Inc.
Q

Thanks. Good morning. Kåre, specifically just wanted to ask you a couple of follow-up questions around the fasinumab program in light of the new data. Obviously, replacement cycle may be new with respect to fasinumab, but not something that's new to the class. Just wondering how you're thinking about the benefit/risk profile now of the product and approvability in light of the new data and whether or not there's any insight that you could share with us with respect to that particular subgroup where the signal was seen on lines such as patient demographics or concomitant medication use. Or anything there that may help us to sort of put that into a little bit better perspective. Thanks.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.
A

Yeah, thank you for that question, Elliott. I'm afraid I can't give you that detail yet because the detail analysis of all those very relevant factors have not been completed yet and we haven't also got the full sort of long-term safety database that we're collection. We haven't got that yet which we will get at the end of this year, so the beginning of next year, we'll have that ready for you.

So the way I look at it is basically, you could say in a way unchanged to what I've said the last two years, which is that I believe that this is a very efficacious product. I think that's confirmed now, the 1 milligram monthly dosing is definitely very efficacious. I think there is a very low level of safety risk here, but of course it remains to be assessed completely once we have the full long-term safety and it remains to be discussed with FDA.

But the way I look at it, unless something new pops up in the final analysis is that it's a, from my overall point of view, and I have to say I'm not a clinical expert, right, but I've seen a lot of clinical trials. I think this makes sense and it also makes sense because the alternative pain medication that people often use does have a risk of misuse, does have a risk of addiction, and this product does not have any risk of addiction.

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So you could say you need to take the risk/benefit in a way if you look at it holistically and look at the product itself, the strong improvement it has on pain and physical function, which is proven beyond doubt in the clinical trial, and then the associated improvement which is that you will be avoiding alternative therapies that have a risk of abuse. And in that sense from a commercial point of view, if it does end up getting approved FDA, then I think it has a strong commercial opportunity here to the benefit of many patients suffering from severe pain. So thank you for that question, Elliot.

Operator: Thank you. Your next question comes from the line of Gary Nachman, BMO Capital Markets.

Q

Hey. This is [ph] Eli (51:16) on for Gary. Thanks for taking the question. I was wondering if you could provide some info on what portion of the new Ajovy prescriptions are coming from the auto-injector and if you're seeing any migration of existing patients from the syringe to the auto-injector?

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Yeah. Thank you for that question, Gary (sic) [Eli]. I think I remember the number, but I think maybe I even had it on the slide. So I'm just going to look back to see what we have on the slide. I've got it here. So yeah, it's right here. I think the auto-injector is launched, of course, now accounts for 40% of total NBRx and 50% of TRx.

So out of the NBRx you're seeing, it's 40%, which roughly if I do just rough math on the curve here without having done it in detail, indicates that the growth we're seeing is basically identical to the auto-injector scripts but we still have a lot of scripts on the prefilled syringe. So it indicates that we're not seeing a switching but that we're seeing generation of new scripts which is very, very positive.

Q

Okay. Great. And then just a follow-up. You recently announced data from a Phase 3b open-label focus study. Can you just comment on how you see that contributing to the value of Ajovy versus competitor?

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

I would say if I look at it in general with the focus studies and the long-term Phase 3 programs we have, Ajovy has shown a fantastic – maintains its efficacy in a really, really strong way. It's well known in many CNS drugs that efficacy wears down over time. That's quite a normal phenomenon. This is not the case with Ajovy. So the long-term data, the long-term focus data we have indicates that Ajovy keeps on working, sometimes even better which is maybe just random, right, that you get some results that are slightly better that you had in the previous period.

But it's quite remarkable that the efficacy of Ajovy keeps on working, even in long, long-term use and that's of course extremely positive because this is a chronic disease, and what you really want is a drug that works well from the beginning, but keeps working. So I think it's very, very positive. I don't have any direct comparison to our competitors because they're not in that trial, but I can just say that for Ajovy, the results are really, really strong. Thank you for that question.

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Q

Thanks.

Operator: Thank you. Your next question comes from the line of Umer Raffat, Evercore.

Umer Raffat
Analyst, Evercore ISI

Q

Hi. Thanks so much for taking my question. I have two if I may. First, we saw the US government cash outlays to Kodak recently on securing drug supply. I'm curious if Teva could possibly be in a position around something similar, especially if it guarantees some sort of supply chain on critical ingredients.

And also, Kåre, I saw in the press release there were arthropathies in the osteoarthritis trial. Can you speak to what percentage of that was Type 2 RPOA? Thank you very much.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Yeah. So the first one on US government and Kodak, I don't really have a comment on that specific deal. I only know what you also know what we read in the press that they got a loan of some $750 million and that they will use that to establish API manufacturing in the US. Structurally right now, it's not profitable to do API in the US. That's why nobody does it, so unless there's some structural changes, then it's probably going to be a very, very tough challenge even if you get a very cheap loan to make that a positive business venture, but that remains to be seen.

We're very open to doing API manufacturing in the US and we also are open and are in discussions with the US government about it. But it has to be sustainable and has to be long term and hopefully, we can end up working something out like that, but I think a lot of what's happening right now is political and it's not really sustainable and operational but that remains to be seen.

Then, I can't comment on the details on the different types of RPOA simply because we haven't had the time. This is hot off the press you could say, the Phase 3 readout here and I haven't had the time to look at all the details, so that will have to wait until we sort of have more time to analyze. That's also why I couldn't ask about the details about do we see any differences in soft groups and so on. That analysis has to follow and we'll share it with you once we have it. Thanks for the questions.

Operator: Thank you. Your next question comes from the line of Akash Tewari from Wolfe Research.

Akash Tewari
Analyst, Wolfe Research LLC

Q

Hey, guys. Thanks so much for taking my questions. So there seems to be a big delta between the drugs that are named in the criminal complaints for generic price fixing versus civil complaints. As we size up kind of the potential liability impact, what's more appropriate I think just for building up a framework? And there's also admittedly a minority perception that there could be minimal to no DOJ liability for Teva. Is that a reasonable base case assumption for investors?

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And then just one question on the rest of the world business. It's been underperforming for a few years but consensus keeps modeling this line to kind of stabilize. Over what timeframe could rest of world kind of return to growth for Teva and how long would kind of the growing pains with the new Japan strategy last? Thanks a lot.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Yeah. So thanks for those two questions. So if we look at the price fixing first, then there's a criminal side to it which is something we discussed with the DOJ. There's also a civil side with the DOJ and then there's a sort of a AG NDL side to it which is also civil. And I think you're referring to the fact that with DOJ on the criminal side, their allegations I think around 10 products and on the civil side the allegations around 110 products.

Now, first of all, it's important to repeat that in our internal investigation, where we've been through more than 1 million documents, we don't see any evidence of organized price fixing, organized cut sale or anything involving a structured approach to this by Teva. Now we do have continued discussions with the DOJ and I think it's not really possible right now to give you a sort of firm basis for how you should model this.

It's an unclarified legal situation and as you know with legal situations, they can develop in all kind of ways in the US and we will do our best of course based on the fact that we believe we did nothing wrong to not have a sort of unsurmountable financial damage coming out of this and there's a lot of tactical elements to that which I can't really comment on. So I can't really give you a firm answer on that one. I'm sorry.

When it comes to the rest of the world then you're absolutely right that we've had a number of events that have been dragging down the total revenue development of the rest of the world or international markets. Actually, underlying most of the markets are growing nicely. And the last sort of problem child left, you could say, in terms of growth has very much been Japan. And with the new restructuring of the business in Japan, we hope to put that behind us, which basically means that I'm optimistic that we will see modest growth in the rest of the world in the years to come.

We don't have anything left that we feel we have to sort of reorganize or clean up or whatever you want to call it. So that part of the restructuring should be done by the deal we're doing in Japan at the end of this year. So thank you for the questions.

Akash Tewari
Analyst, Wolfe Research LLC

Q

Thanks a lot.

Kåre Schultz
President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

I think now we're hitting close to the hour, so I guess we have time for one more question?

Operator: Thank you. Your final question comes from the line of Jason Gerberry, Bank of America.

Q

Hi. This is [ph] Ashramal (60:03) on for Jason. Just wanted to get a little bit more details on the Alvotech biosimilar partnership. How do you think this positions you to compete in this evolving market? And can you also elaborate

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on the profile of the programs you will advance? Are these early or near to market assets? Or do you have any therapeutic focus? Thanks.

Kåre Schultz

President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

A

Thanks for that question. So our collaboration, our strategic collaboration with Alvotech involves five biosimilar products that are, you could say, at different stages of development. But they are compared to our own portfolio, slightly earlier than our own portfolio, so they hopefully will secure, assuming that they all are successful, they will secure that we have a sort of long string of launches over the coming 10 years in the US in the biosimilar space.

We do feel that with our commercial presence in the US where we are the biggest volume supplier of pharmaceuticals that we can handle products in basically all therapeutic categories. And we are very happy about the development we've seen on Truxima, so we very much look forward to this. I can't comment on which specific products we're talking about, but that will evolve as time goes by. We'll of course make you aware of that.

But I can just say that now we have a portfolio of more than 10 biosimilars in the US marketplace. And I think that Brendan and his organization has shown a very good performance on Truxima. And maybe we will end the session with giving the word to Brendan so you can round it off by just commenting on how you see our performance on Truxima since we launched, and going forward and how you see the Alvotech deal. So over to you, Brendan, for the final comments.

Brendan O'Grady

Executive Vice President, North America Commercial, Teva Pharmaceutical Industries Ltd.

A

Yeah. Thanks, Kåre. I appreciate the question. I think that if you look at our commercial performance on Truxima, it's been one of the most successful biosimilar launches in the industry. We're up to a 17% weekly new-to-brand share and mid-20s when you factor in business that's not captured in IQVIA. So if you look at Teva's commercial footprint, as Kåre said earlier in the call, we have a strong footprint with customers on both the generic and specialty side which I think lends to our capabilities in the biosimilar markets.

As we think about the Alvotech deal, I think that that deal fills a nice gap in our portfolio between the two assets that we currently have and some of our own assets here later on, four, five, six years out. So I think it's a great deal for us, a great deal for Alvotech, and I think it'll be a nice match of our capabilities. So I look forward to commercializing those assets. Thanks, Kåre.

Kåre Schultz

President, Chief Executive Officer & Director, Teva Pharmaceutical Industries Ltd.

Thank you, Brendan. So over to you, operator. And thanks for listening in, to all of you.

Operator: Thank you.

Kevin C. Mannix

Senior Vice President & Head of Global Investors Relations, Teva Pharmaceutical Industries Ltd.

Thank you, everybody, for joining us. Tracy, if you could please provide the replay information. As usual we are available to take your calls, and look forward to speaking to you in the coming days and weeks. Thank you.

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Operator: Thank you. Ladies and gentlemen, this conference will be available for replay after today's call. You may access the remote replay system at any time by dialing 00-44-333-300-9785 and entering the access code 6145548. Those numbers again are 00-44-333-300-9785 and access code 6145548. That does conclude our call for today. Thank you all for participating, and you may now disconnect.

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