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Gilead Sciences, Inc. (GILD) CEO Daniel O'Day on Q3 2019 Results - Earnings Call Transcript

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Q3: 10-24-19 Earnings Summary

Press Release SEC *10-Q* *Slides*

EPS of $1.75 beats by $0.02 | Revenue of $5.6B (0.14% Y/Y) misses by $-9.35M

Earning Call Audio

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Gilead Sciences, Inc. (NASDAQ:GILD) Q3 2019 Earnings Conference Call October 24, 2019 4:30 PM ET

Company Participants

Sung Lee - Senior Vice President of Investor Relations

Daniel O'Day - Chairman & Chief Executive Officer

Robin Washington - Executive Vice President & Chief Financial Officer

Johanna Mercier - Chief Commercial Officer

Diana Brainard - Senior Vice President, HIV & Emerging Viral Infections

John Sundy - Senior Vice President & Head of our Inflammation Therapeutic

Conference Call Participants

Michael Yee - Jefferies

Brian Abrahams - RBC Capital Markets

Geoff Meacham - Bank of America Merrill Lynch

Geoff Porges - SVB Leerink

Matthew Harrison - Morgan Stanley

Alethia Young - Cantor Fitzgerald

Umer Raffat - Evercore ISI

Mohit Bansal - Citigroup

Cory Kasimov - JPMorgan

Salim Syed - Mizuho

Phil Nadeau - Cowen & Company

Evan Seigerman - Credit Suisse

Tyler Van Buren - Piper Jaffray

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Gilead Sciences' Third Quarter 2019 Earnings Conference Call. My name is Liz and I will be your conference operator today. At this time, all participants are in a listen-only mode. And as a reminder, this conference call is being recorded.

I would now like to turn the call over to Sung Lee, Senior Vice President of Investor Relations. Please go ahead.

Sung Lee

Thank you, Liz, and good afternoon, everyone. Just after market close today, we issued a press release with earnings results for the third quarter 2019. The press release and detailed slides are available on the Investor Relations section of the Gilead website. The

speakers on today's call will be Daniel O'Day, Chairman and Chief Executive Officer; Robin Washington, Executive Vice President and Chief Financial Officer; and Johanna Mercier, Chief Commercial Officer. Also in the room are Diana Brainard, Senior Vice President and Head of our HIV and Emerging Viruses Therapeutic area; and John Sundy, Senior Vice President and Head of our Inflammation Therapeutic area.

Before we begin with our prepared comments, let me remind you that we will be making forward-looking statements including plans and expectations with respect to products, product candidates, financial projections and the use of capital, all of which involve certain assumptions, risks and uncertainties that are beyond our control and could cause actual results to differ materially from these statements. A description of these risks can be found in our latest SEC disclosure documents and recent press releases.

In addition, Gilead does not undertake any obligation to update any forward-looking statements made during this call. Non-GAAP financial measures will be used to help you understand the company's underlying business performance. The GAAP to non-GAAP reconciliations are provided in the earnings press release as well as on the Gilead website.

I'll now turn the call over to Dan.

Daniel O'Day

Thank you, Sung, and good afternoon, everyone. Thank you for joining today. I'll share a few opening comments and then turn the call over to Robin. And after that Johanna will take you through the commercial highlights of the quarter as well.

So let me start by saying, I'm very pleased with the progress that we're making on all fronts here at Gilead and a strong third quarter results. Once again, we saw a significant growth in our HIV business, reaching an all-time high in quarterly HIV revenue. As you know in my time at Gilead, I focused on three key areas since coming in the pipeline, commercial delivery and people. And today in my brief remarks, I'll focus on the significant progress we've made in two of those areas: The pipeline and the people, and then Johanna will take you and talk to you about the excellent commercial performance later in the call.

So let me begin by saying a few words about our pipeline, starting with HIV. As you're aware, we received FDA approval for DESCOVY for PrEP earlier this month. This is a really important indication for us as it allows us to extend the benefits of DESCOVY to people who are at risk of HIV. To remind you, the approval was based on the DISCOVER trial, which demonstrates that DESCOVY is just as effective as Truvada and offers advantages in bone and renal safety parameters.

We are excited to build on DESCOVY status as the most-prescribed dual NRTI backbone in the world by advancing its use in PrEP. Happy to say, we've also received endorsement to begin the study of DESCOVY for PrEP in cisgender women, which will allow us to eventually bring the medicine to a broader group of people.

Rest assured, we continue to remain focused on our HIV pipeline beyond our DESCOVY-based regimens as well on our long-acting antivirals programs compounds that will treat -- highly treatment-experienced patients and, of course, on our CARE research as well.

So turning to filgotinib, we've now filed for approval of filgotinib in rheumatoid arthritis in the EU and Japan and are on track to complete our filing in the United States by the end of the year. Our teams around the world are preparing for launch and I'm encouraged about the potential of filgotinib to be best-in-class among the JAK inhibitors. In addition to rheumatoid arthritis, we're continuing to advance filgotinib together with our partner Galapagos. We have a comprehensive program across a number of other inflammatory diseases, including ulcerative colitis, which we expect to have data on next year.

And in addition, we were successful in closing our partnership with Galapagos this past quarter. I'm looking forward to the American College of Rheumatology coming up in Atlanta, so that we can share further updates on filgotinib. Researchers there will present further analysis in the FINCH two study, which evaluated filgotinib in patients with RA who previously -- who were previously treated with a biologic and then results of the pooled safety analysis of filgotinib across the FINCH program will also be presented and updated there.

Turning to cell therapy. I would like to say a few words about Kite and our working cell therapy. The teams down at Kite are busy preparing for the American Society of Hematology meeting, which will happen in early December, where in addition to exciting

data from our ongoing clinical trials, we will share survival data for Yescarta at three years in large B-cell lymphoma as well as results from the registrational study of KTE-X19 in mantle cell lymphoma.

Recently we also completed enrollment in the pivotal ZUMA-7 study of the Yescarta in second line large B-cell lymphoma and we're excited about the potential this medicine could help for this group of patients. As we discussed also last quarter, we continue to see quarterly variations in Yescarta, but we're very confident in its future and the long-term trajectory of our cell therapy platform.

Finally, a few comments about our leadership team, which is now complete with two new appointments. Merdad Parsey will join us on November 1st as our Chief Medical Officer. Merdad who previously led the early clinical development program at Genentech will have responsibility for all of our global developments and medical affairs functions.

Bill Lee will continue to lead our research organization and he will report directly to me working closely with Merdad. Merdad is an outstanding scientist and leader with a remarkable track record of success. And I believe that Merdad will be a tremendous asset to Gilead maintaining a very high bar for innovation, so that we can continue to build on our legacy of transformational medicines.

I'm also very excited about the appointment of Andy Dickinson to the role of CFO. Andy has been at Gilead since 2016 and currently serves as our Executive Vice President of Corporate Development and Strategy. He transformed the way that the company approaches corporate development before I came in, and expanding the kinds of transactions executed and implemented a broader more strategic approach to dealmaking here at Gilead.

As of November 1st, Andy will succeed Robin Washington whose retirement we announced earlier this year. Happy that Robin will remain at Gilead in an advisory capacity through early next year, while we complete the reporting of our 2019 results. I'd also like to take this opportunity to thank Robin for her outstanding contributions, dedication and tremendous commitment to Gilead. We wish her all the best in retirement. And I'm sure she'll continue to stay busy.

I look forward to working with this outstanding group of leaders here at Gilead, who bring a strong blend of skills and diverse perspectives to the path forward for our future. And in closing, I'm increasingly optimistic about the future and believe we are well positioned as we enter the last part of the year and look ahead to 2020 and beyond. We will continue to build on our success, as we replenish the pipeline and bring the next wave of transformational advances to patients.

On behalf of the leadership team, I want to thank all of our employees and partners around the world for the dedication and hard work that led to the successful quarter and the results that you see here today, and whose commitment will continue to make it successful in the future.

With that, I will now turn the call over to Robin.

Robin Washington

Thank you Dan for your kind words. It has been a privilege to serve as Gilead's CFO for the past 11 years and to work alongside such extraordinary colleagues to bring medicines to people around the world. I know the focus on this mission will continue and I look forward to cheering Gilead on in 2020 and beyond.

I'm pleased to report the financial results for the third quarter, which were marked by strong execution across our therapeutic areas led by the continued growth of our HIV franchise and continued predictability of HCV.

Total revenue for the third quarter were $5.6 billion with non-GAAP diluted earnings per share of $1.75. This compares to revenues of $5.6 billion and non-GAAP diluted earnings per share of $1.84 for the same period last year.

As noted in the earnings press release, on a GAAP basis, we recorded a loss of $0.92 per share primarily due to $3.92 billion or $2.40 per diluted share of upfront collaboration and licensing expense associated with our global research and development collaboration agreement with Galapagos.

Turning to product sales. Product sales for the third quarter were $5.5 billion, down 2% sequentially and up 1% year-over-year. In the U.S., product sales for the third quarter were $4.2 billion, up 4% sequentially and up 2% year-over-year. In Europe, product sales for the third quarter were $804 million, down 23% sequentially and down 8% year-over-year.

The sequential performance was primarily impacted by two items. First, recall that the second quarter benefited from a $160 million adjustment for a statutory revenue clawback reserve. And second, the third quarter was negatively impacted by a statutory clawback reserve adjustment. These two factors, which primarily impacted our HCV and HIV revenues, caused an approximately $200 million decline between quarters.

Turning to cell therapy. Worldwide Yescarta sales for the third quarter were $118 million, up 57% year-over-year and down 2% sequentially. U.S. sales were $86 million for the third quarter, up 15% year-over-year and down 13% sequentially. In Europe, Yescarta sales were $32 million, up 52% sequentially, as we continue to ramp in the region.

It is clear that cell therapy is a validated platform; with hundreds of patients being treated on a quarterly basis in the U.S. Yescarta has established itself as a differentiated leader in an increasingly competitive environment. We will continue to focus our efforts on CAR T education in the community oncology setting to stimulate referrals of appropriate patients to cell therapy treatment centers.

We also observed CAR T eligible patients being enrolled in clinical trials at a much higher rate relative to commercial patients. As such and as Dan outlined, we anticipate further quarterly sales variations, but remain very confident in the future trajectory of Yescarta.

Now turning to expenses. Non-GAAP R&D expenses were $954 million for the third quarter, up 13% compared to the same period last year, primarily due to increased investment in our oncology programs, HIV programs and research projects.

Non-GAAP SG&A expenses were $967 million for the third quarter, up 14% compared to the same period last year, primarily due to higher promotional expenses in the U.S. and expenses associated with the expansion of Gilead's business in Japan and China.

Moving to the balance sheet. During the third quarter we generated $2.6 billion in cash from operations and ended the quarter with $25.1 billion in cash and investments. We paid $5.5 billion in connection with our global research collaboration and equity investment in Galapagos, which was classified in our cash flow statement as cash from investing activities and includes a $1.1 billion equity investment. We also paid $1.5 billion of debt used to finance our acquisition of Kite. We paid cash dividends of $804 million and repurchased 3.4 million shares of stock for $223 million.

Turning to our guidance. As we move closer to the end of 2019, we are narrowing our guidance ranges as follows. Net product sales are expected to be in the range of $21.8 billion to $22.1 billion. Non-GAAP R&D expenses are expected to be in the range of $3.7 billion to $3.8 billion. We expect non-GAAP SG&A expenses to be in the range of $4 billion to $4.1 billion. All other components of our guidance remain unchanged. Our guidance is subject to a number of uncertainties which are outlined in slides 22 and 23 in our earnings call presentation.

I will now turn the call over to Johanna.

Johanna Mercier

Thanks, Robin, and good afternoon, everyone. So as I've had the chance to settle into my role, I've been really impressed with the talent here at Gilead and the potential we have to reach even more patients with our medicines. I want to talk today about a few areas, the continued strength of our HIV business, including our recent launch of Descovy for PrEP durability of HCV, and finally touch briefly on our cardiopulmonary business and close by discussing our filgotinib launch preparations.

So, let's start with HIV. Global HIV sales for Q3 were $4.2 billion, up 4% sequentially and 13% year-over-year. This marks the sixth consecutive quarter of double-digit year-over-year growth. As Dan noted, this is an all-time high for quarterly HIV product sales. U.S. HIV product sales were $3.4 billion in Q3, up 6% sequentially and 14% year-over-year.

The year-over-year increase was driven by underlying prescription demand growth of 13% mainly Biktarvy. Biktarvy was a number one prescribed regimen in the U.S. in the quarter. In prevention, they're now approximately 224,000 people taking Truvada for PrEP, an

increase of approximately 25% year-over-year of active patients.

Our teams are now in the field with Descovy with its recent approval in PrEP. We initiated efforts to educate health care providers and people at risk for HIV about Descovy immediately following the approval and are really quite pleased with anecdotal feedback from providers.

Turning to Europe, Q3 HIV product sales were $558 million, down 10% sequentially and 4% year-over-year. The year-over-year decline was expected due to the broad availability of generic versions of Truvada. The impact in generics is starting to wane as the launched of our Descovy-based products namely Biktarvy progress.

As Robin just mentioned, the sequential performance was impacted by an adjustment for statutory clawback reserve in Europe, which benefited the second quarter. Biktarvy is now available across the EU5 and continues to grow. It's on track to be the best HIV launch in Europe and is number one in naive and switch across Germany, France and Spain. It recently launched in Italy and the U.K. and is off to a strong start in both those countries.

Moving on to HCV. Global Q3 HCV sales were $674 million, down 20% sequentially and 25% year-over-year. U.S. product sales for Q3 were $380 million, up 7% sequentially and down 22% year-over-year. The sequential performance was driven by the continued uptake of authorized generics which has improved our overall competitive position in the U.S.

In Europe, HCV product sales for the second quarter were $111 million, down 60% sequentially and 45% year-over-year. As anticipated the sequential performance was negatively impacted by the adjustment for statutory clawback reserve in Europe, which benefited Q2. Overall, the HCV market continues to see a more predictable decline in patient starts and perform in line with our expectations.

Before closing, I wanted to just make a few comments on our cardiopulmonary business, where we have seen generic competition enter the market. As anticipated significant volume erosion has occurred and as of September, we have seen an 85% erosion of Ranexa and 60% erosion of Letairis a trend that we expect to continue.

Finally, I spent time recently in both Europe and Japan, where our teams have completed the regulatory filings for filgotinib in rheumatoid arthritis. Launch preparations are well underway in both regions as well as in the United States, which Dan noted we plan to file before the end of the year.

I believe that, we truly have an opportunity to make a difference in the lives of people with RA, and in the future other inflammatory diseases. We're actively preparing for competitive and innovative launch of a differentiated JAK inhibitor across our key markets. I really look forward to working with this great team of people to deliver on the promise of these medicines.

So, thank you very much for joining today's call and now let's turn it over to questions. Operator?

Question-and-Answer Session

Operator

[Operator Instructions] Our first question comes from the line of Michael Yee with Jefferies. Your line is now open.

Michael Yee

Hey guys. Thanks for the questions. I had a question for Dan. Obviously Dan, you've spent a lot of time this year putting in the right people, getting everything all set up. You did Galapagos deal to build up the pipeline a bit. I guess in thinking about the pipeline and building that out where are you focusing your priorities on? How should we think about your next area whether that's in NASH or oncology? How should we think about that? And maybe just give us a little state of the union there?

Daniel O'Day

Yes. Thanks Michael very much for the question and delighted that we now have the team coming together for the future. I think it's really good diverse team with some strong Gilead legacy colleagues, as well as combined with some talent from the outside the organization with different perspectives.

And I think it's going to lead to a really strong good team that will help us drive kind of the future chapters of Gilead moving forward. Also pleased Michael that we had the Galapagos transaction finalized in the quarter, we're obviously getting going now on a deeper collaboration beyond filgotinib.

And as I said to you in the past and I'll say it again, I mean, I think the team here and I have the pipeline as our number one priority of course. And that -- we approach that from a variety of different ways; one is, the strength of our internal pipeline looking for ways to accelerate differentiated medicines that we can internally and with Galapagos now significantly expanding our research base in addition to other collaborations we have externally that allow us to essentially double our research base of medicines coming into the portfolio -- the development portfolio.

In terms of therapeutic area, I would say our approach to external partnerships and M&A will be very much the same of what you saw in the past. So first and foremost, it will be driven by science, driven by where we think the most unique opportunities are.

Secondarily, will be informed by our own expertise, as you know we play across four therapeutic areas today and strong scientific understanding in the base in antivirals and immuno modulation. And there is no one size fits all of course. I mean, at times it make sense to just do a partnership, but other times it makes sense to do a full acquisition and other times it makes sense to do something like a Galapagos arrangement where we have a deep partnership associated with that.

So we'll continue on in that area. I think more to come as the team comes together as we continue to evaluate. Certainly the areas that you mentioned are areas that we're looking at carefully to complement our internal expertise, but we're not driven by any one therapeutic area.

We're driven much more by where is the next innovation going to come from in science and how do we complement that portfolio. With an acknowledgment by the way that we understand that we have to accelerate the development of our later-stage pipeline as well. And that can happen by both accelerating our internal pipeline or having partnerships arrangements with the companies outside of the Gilead orbit today.

So Michael more to come and obviously some of the conferences coming up and into next year, I can be even more specific and articulate about how some of our strategies are forming.

Michael Yee

Perfect. Looks forward to that. Thank you.

Daniel O'Day

Thanks Mike.

Operator

Our next question comes from Brian Abrahams with RBC Capital Markets. Your line is now open.

Brian Abrahams

Hi, there. Thanks very much for taking my question. So you narrowed the R&D and SG&A guidance to the upper end of the previous ranges. And so I guess -- I'm wondering maybe bigger picture perhaps longer term especially as we're getting closer now to the filgotinib launch how do you guys balance the importance of margin preservation and earnings growth against the potential to invest as you build out in inflammation? And how might the changes in leadership potentially influence this? Thanks.

Daniel O'Day

Yes. Let's -- let Robin give her commentary Brian and then maybe I'll add as well so please.

Robin Washington

Hi, Brian. Thanks for the questions. I'd say we manage them very carefully. As you know we've always been a very highly efficient organization, really focused on operational excellence and ensuring that even as we've grown, we've grown profitably as we think about margins.

And at the same time, as you've heard me say before we're always balancing the need to invest for the long term, and as you know that can have implications in the short term. You've seen us with previous launches and with acquisitions make the necessary investments upfront that may yield shorter operating margins in a short term, but ultimately get us to higher revenues in overall margins long term. So I think that's how we think about our model. There's -- it's not by quarter or by year, it's really ensuring that when we make investments that we make the necessary actions in the short time to ensure the overall ROI on those investments. And I'll turn it over to Dan to talk about the future but I think we're pretty much aligned going forward.

Daniel O'Day

It's well said Robin. And Brian you may want to hear it from my vantage point as well just particularly with the CFO transition to make sure you understand the stability from my side as well. So I have really admired Gilead's efficiency as Robin mentioned and the careful management of expenses. And I think that's something that we will continue to make sure that we have the size here as well. I've also been a student of the history here at Gilead and I've looked back in the past and seen in times of important launches that investment has increased correspondingly in the interest of patients, in the interest of shareholders. And I think that type of philosophy I think will continue.

And certainly we will also be -- as we have generic erosion, of course, coming now this year and next year, we also have the ability to redeploy those resources as we already have done with cardiopulmonary to other areas of focus and interest including the upcoming -- or the current launch for DESCOVY in PrEP. And then we will also make sure that we have a competitive launch of filgotinib because we know that it will be essential to have the right share of voice to get that off to a good start.

We have one chance to launch a product in this industry and therefore we have to make that accordingly. So as we get into providing you with more guidance in 2020, we can elaborate a little bit further about how we see that expense management for next year. But I hope you get a sense that much of the discipline that Gilead has in the past you can expect to have in the future as well Brian.

Brian Abrahams

Thanks so much.

Operator

Our next question comes from Geoff Meacham with Bank of America Merrill Lynch. Your line is now open.

Geoff Meacham

Hey, guys. Thanks for the question. Congrats, Andy and Robin. It's been great to work together. Wish you the best. Just wanted to ask about HIV market expansion outside of PrEP, and with Biktarvy, the share gains are impressive and with its profile, are you seeing an uptick though in treated patients on ART overall? I just wanted to ask because HIV market expansion used to be a secondary driver of the market but I'm not sure about that today. And how do you think this differs in Europe? Thanks so much.

Johanna Mercier

Maybe I'll take that one. Geoff, it's Johanna. I think as you're mentioning the HIV business overall and treatment is a huge part of that 80% of our total HIV business has never been stronger. And what we're seeing, it's a bit of a mix what you're saying, but in those U.S. and Europe, you have about 80% of the patients that are switch patients and 20% are naïve patients. So the naïve patients is a smaller play and less of a market expansion per se to your earlier point, but much more in the switch. And so where the switch come from are really important to us for Biktarvy. And what we're seeing with Biktarvy and that's been our strategy all along in our expectations is, we are seeing about 20% to 25% are coming from dolutegravir-based regimens and about a 1/3 coming from Truvada-based regimen and then the rest -- another 1/3 probably from Genvoya and so that's the piece where from a switch standpoint that's the biggest most important piece of the business. Both in U.S. and Europe it's quite similar actually.

The challenge in Europe is obviously there is more Truvada pieces of the puzzle just because of the genericization in Europe. But, overall, what we're seeing is very consistent both in naïve and switch and Biktarvy is number one not just in the U.S. but also in

Germany, France and Spain and we only just got reimbursement in the last quarter for U.K. and Italy, but those launches are off to the similar, very consistent way of launching than we've seen in the other markets.

Daniel O'Day

Thank you, Geoff. So we'll go on to the next questioner.

Operator

Our next question comes from the line of Geoff Porges with SVB Leerink. Your line is now open.

Geoff Porges

Thank you very much. I'm just wondering if you could help me understand a little bit on the research side. You've sort of lost over that a bit. Firsthand, could you break out the $4 billion or so in annual spend that you have now between immunology, oncology, hepatology and then research? Just give us a sense of those allocations?

And then, related to that, Dan, could you talk about, if you were to contemplate significant M&A or for that matter, additional licensing, do you envisage that that $4 billion run rate will have to go up to accommodate those new programs? Or do you have some savings from big trials coming to an end and/or other efficiencies that might take the $4 billion down and accommodate incremental programs from outside the company?

Daniel O'Day

Terrific. Yes. Thanks, Geoff. And actually, I'm glad you asked the question because on the previous question I spoke more about how we look at allocation resources on the commercial side more so than the research side. So, yes, let me first of all state that -- the first part of your question relative to how we allocate that across therapeutic areas, it's not something that we disclose accordingly.

So I can't help you with that but I think I can help you with the forward question, which is, as we think forward to either partnerships or M&A, how is that going to help -- or what impact will that have, if you like, on the overall R&D spend.

Now, I think, there's one aspect of that that's very important which is -- and you mentioned it a bit. But, A, we're constantly prioritizing our portfolio internally. And that is based upon making sure that we have the most-attractive programs that we're funding.

Every organization has to draw a line and I think we also have to do that as well. And of course, things change, because of the nature of data that's read out, competitive environments, variety of things that happen. So the portfolio is constantly kind of evolving and moving internally based on that portfolio.

And therefore, to your point, there are times when we stop studies, studies come to a natural conclusion and they've been successful and we have those to then reinvest again accordingly. Many of the structures that we've looked at in our partnerships have also been designed to be, first of all, innovation forward but also allow for some balanced risk across the portfolio and spend.

For instance, with Galapagos. Our relationship with them is that they are covering trials up until Phase 2 and they take the decisions and they take the risk associated with that and all the diversity and benefit that comes from having another organization look at that differently.

And then, post our opt-in of course then we would start to incur expenses on our R&D line as well. So many of our partnerships and collaborations have been designed with that in mind as well and we'll continue to do it that way to be efficient with risk versus investment. And I think that's the way we'll continue to look at moving forward. So more to come on that.

I would just say -- I mean, the one thing we do disclose Geoff on the R&D line is that around 15% to 20% of the $4 billion goes into research and the remaining is into development human trials accordingly. So that I can give you. But we don't really break it down further by therapeutic area. Does that help?

Geoff Porges

Somewhat. Thanks, Dan.

Daniel O'Day

As much as I can, I think. But thanks, Geoff.

Operator

Our next question comes from Matthew Harrison with Morgan Stanley. Your line is now open.

Matthew Harrison

Great. Good afternoon. Thanks for taking the question. I guess, I was hoping you could just talk briefly, I know it's very early in the switch from Truvada to Descovy. But maybe you could talk about your expectations for some of the markers we should be looking for there and then maybe anecdotal feedback, as you maybe been in the market a couple weeks already with that. Thanks.

Robin Washington

Thanks, Matthew, for the question. So, yes, only a few weeks in, right? We got the approval early October. But even within a few weeks we're off to a strong start. I think, the team is very excited about it, but more importantly the early feedback from physicians is very positive and we're hearing a lot of enthusiasm from our prescribers.

I do want to explain that the PrEP market is a little bit different than the treatment market and that is that it's much larger in the number of prescribers. So there's over 50,000 prescribers that have actually written at least one script of PrEP with Truvada.

So having said that, more than half of the volume that we're seeing in PrEP is actually very concentrated in a couple of thousand specialists who also prescribe in treatment. So that has been our number one focus and target physicians that we have been calling on over the last couple of weeks, because these are folks that obviously largest volume pool, but also folks that have experienced converting from TDF to TAF and also understand the value of DESCOVY and its clinical profile, specifically around the safety with bone and renal.

So we assume a very similar conversion than what we've seen in the past. We have a lot of experience here of TDF to TAF conversions and we assume that same conversion rate will happen with these top prescribers. For the balance of the volume, obviously we are assuming a little bit of a slower uptake with those prescribers just because it's so much more diffuse. But having said that, we've augmented the field team.

I think Dan mentioned this earlier, how we've taken a lot of our field forces from the cardiopulmonary in light of the generics hitting there. We basically train them and move them over there to supplement the team and also augmented our consumer approach to get really rapid awareness of DESCOVY both to physicians as well as targeted consumers. So so far so good, very excited about the launch and probably in the next quarter we'll have more to talk about with data.

Operator

Our next question comes from the line of Alethia Young with Cantor Fitzgerald. Your line is now open.

Alethia Young

Hey, guys. Thanks for taking my question. And I just wanted to talk a little bit about NASH strategy from here. I understand you have the ATLAS study in the fourth quarter, but I also saw you started semaglutide GLP-1 study combination with doubles and triples. So can you maybe frame for us how you think about like what might be your backbone asset in NASH and possibly your plans going forward there?

Daniel O'Day

Yes. Thank you very much, Alethia. So I think you rightly pointed kind of an important data point coming up here that will allow us to think about how we pivot our NASH strategy moving forward and that's the ATLAS study that we will be reading out before the end of the year. So those of you that don't know, I mean that's a combination trial that will allow us to look at the results of a variety of different combinations on the progression of NASH.

But as you also know I mean, we've had a number of other collaborations, we've looked at with Novo Nordisk on GLP-1 and some of the other ones that you've already mentioned there Alethia that are approaching this from different angles as well. So I do think though that most progressed clinical trial is currently the ATLAS trial. And once we can see the results for that and dig into that then I think it will help us really understand how to progress ahead with NASH in what format and what way.

I would just mentioned that as we've always mentioned, we think that NASH is a very high unmet medical need, but also a challenging disease to develop in given the nature of the disease, given the heterogeneity of the disease, given the end points. And yet, we think a company like Gilead with expertise in this area need to be informed by the science and solve the science to see what our path forward will be. So more on the NASH strategy after the ATLAS trial at the end of this year.

Operator

Our next question comes from the line of Umer Raffat with Evercore ISI. Your line is now open.

Umer Raffat

Hi. Thanks so much for taking my question. I wanted to focus on a couple of R&D topics if I may. One on filgotinib. I noticed FDA called entospletinib review documents. FDA effectively implied class labeling on thrombosis risk for the class. And my question is what's your expectation? Do you think you'll get a black box for thrombosis? And do you think that impacts commercial uptake?

And then secondly, there was a program in your pipeline which I was starting to get really excited about perhaps mostly because it was sort of in the exactly type of thing Gilead has been very good at novel nukes GS-9131 and it could have formed a base of life cycle management. I noticed it's not in the slide deck this time around and I was wondering if you could catch us up on any learnings from that program. Thank you.

Daniel O'Day

Terrific, Umer. So we're going to start with John and - then we'll go to Diana for HIV question.

John Sundy

Sure. Umer, I mean as you know and we've spoken of before, we know that patients with inflammatory diseases are at risk for thrombosis. And so it's always a comparison against expected background rates of this event in patients. And we think it's possible that selected JAK1 inhibition as we have with filgotinib may have some advantages. But certainly at this point it would be premature to speculate on what the label outcomes maybe. We're going to go through the process. We believe we have a strong story with regard to thrombosis risk and at the same time reassured by the overall efficacy and safety profile. So we've seen this across all of our programs and we are looking forward to having that discussion with the regulators.

Diana Brainard

This is Diana Brainard. I'll speak to your question around GS-9131, which is a nucleotide reverse transcriptase inhibitor with an improved resistance profile over the currently improved drugs in that class. And this is a compound that we've been excited about and moving through the clinic in early phase studies because we do have a commitment to highly treatment-experienced patients who have failed higher regimens and have multidrug resistance.

In parallel with the GS-9131 program, as you know, our capsid inhibitor program with GS-6207 has also progressed very rapidly. And GS-6207 is the first-in-class compound. It's got a novel mechanism of action. It's got an orthogonal resistance profile. We haven't seen any pre-existing resistance among all of the samples we've tested from treatment-naïve patients and heavily treatment-experienced patients.

These data have been published at recent conferences. And so because of this novel mechanism of action, because of the potency, because of the lack of pre-existing resistance, we really feel that the capsid inhibitor is the really best and lead compound to bring forward in highly treatment-experienced patients.

And in fact its promised was recognized by FDA when they granted us breakthrough designation for this population. And so we're moving ahead with capsid in this population into a registrational trial. And therefore won't be bringing GS-9131 forward for this population because we prioritize our capsid inhibitor.

Q – Umer Raffat

Thank you very much.

Operator

Our next question comes from the line of Mohit Bansal with Citigroup. Your line is now open.

Mohit Bansal

Great. Thanks for taking my question. So looking at your slides, you have some plans to develop capsid inhibitor in the Phase 2 -- started trial in Phase 2 trial with capsid inhibitor. Have you discussed internally about what kind of combination agent you will be using for this long-acting treatment at this point? And when can we learn more about your PrEP strategy for capsid inhibitor? Thank you.

Johanna Mercier

Sure. So we're really envisioning the capsid inhibitor to have multiple different applications for people living with HIV. I just mentioned, its use for heavily treatment-experienced patients where it could be added on to optimize background therapy as is commonly done for this population.

But it also has a huge potential for people living with HIV who might want to switch to a long-acting regimen because of its ability to be given at least every three months, every six months and potentially in the future longer. And there we are still actively looking for what's the right partner for our capsid inhibitor will be and we have multiple internal programs which are preclinical or in the very earliest stage of assessments in the clinic.

And we're looking forward to sharing more details as we have more certainty about what the right combination will be to partner with capsid. What we're prioritizing is ease of administration. So we're looking at subcutaneously administered drugs. We're looking at drugs that can go the distance in terms of longer, at least monthly, if not longer and match capsid's potential. And so as we prioritize those features and bring forward different compounds we'll -- we're really excited actually to share that data.

Mohit Bansal

Thank you.

Operator

Our next question comes from Cory Kasimov with JPMorgan. Your line is now open.

Cory Kasimov

Hey, good afternoon, guys. Thanks for taking my question. I wanted to see if you could talk a little bit more about the quarter-over-quarter trends for Yescarta? I know you mentioned there are or there were a higher number of potential patients going into clinical trials in 3Q, but how much do you think this sequential drop can also be attributed to the launch of Polivy? Are you seeing center slot that in the head of CAR T products or potentially any other dynamics taking place? Thanks.

Daniel O'Day

Yes. Absolutely, Cory. No, thanks for the question. Happy to talk about it. I mean, I think it is important that I start out with letting you know that the team here is really confident with the longer-term opportunity of the Yescarta and also cell therapy. But as we know, I mean this is a pioneering platform and just to point out some of the dynamics that we're seeing in the market, cell therapy really literally changes everything to the touches, from patient identification to clinical practice to reimbursement to safety management.

So I would say, some of the growing challenges with getting the pioneering technology in or what we would expect. But what's kind of unquestionable is in the patient set, where it has been studied so relapsed/refractory DLBCL so far in the market, I mean the efficacy

and durability are unprecedented.

I mean the majority of extremely six patients who are alive at two years, and as we know and many of my colleagues and the team hematology/oncology is a data-driven space.

So I would say that -- and we also have a very strong and good manufacturing capacity which is critical for this technology. Now you mentioned some of the challenges. Let me talk about some of the drivers and some of the challenges that we're seeing in general in the market.

I mean on the positive side the NTAP improvement that just went into effect in October 2019 from reimbursement by CMS of 50% to 65% is a step in the right direction. We -- it does take there is a lag time before that gets fully absorbed and introduced into the community.

I would point out the ASH data coming up. We'll have three key events there; the survival data at three years in relapse/refractory DLBCL, early steroid use and also data on the KTE-X19 in MCL. Would just also point out the ZUMA-7 is now fully enrolled. So that's the second line DLBCL. I look forward to that trial playing through.

And hopefully as we go into next year we can look towards a DRG for CAR-T as well. So those are some of the real positive things we're seeing in the market. And then to your point, I mean there are still challenges with Medicare reimbursement update. There is a high rate of clinical trial usage in DLBCL which is good news for patients. It's just -- there's quite a few clinical trials there still getting the patient referral flow downs.

We do have some new market entrants early days on those. You mentioned one on the call here today and this whole concept between inpatient and outpatient reimbursement.

So I think the team is kind of systematically working through these and that's why we see some quarter-on-quarter fluctuation in the United States. I would point out that we're now getting going in Europe which is also terrific and very good growth there and different -- some of these dynamics are different in Europe as well.

So I think as we learn quarter-to-quarter on some of the dynamics and as the data matures and develops out there, I think that's going to be a real telltale sign for how we continue to see the uptake here. But taking a big step back, the type of data we're seeing and the duration of response in the patients that we've studied is second to none.

So hopefully, as some of this becomes more the trends become more clear in future quarters we'll be able to be more precise about some of these as well. But thanks for the question Cory.

Cory Kasimov

Thanks Dan. Appreciate the color.

Operator

Our next question comes from Salim Syed with Mizuho. Your line is now open.

Salim Syed

Hi guys. Thanks for taking my question. And congrats to Robin and welcome to Andy. Just one for me on hepatitis B; as in boy, if I can, I mean if you guys can give us an update on the core inhibitor what's the status there? I know there's been some safety issues for the core inhibitor class predominantly coming from HAV and SBA derivatives. So I was wondering if you can just give us a little bit of color, if your core inhibitor whether is in development or not in development and whether it is one of those derivatives? Thanks so much.

Diana Brainard

Salim, this is Diana Brainard. Are you talking about the capsid inhibitor?

Salim Syed

For hepatitis B as in boy?

Diana Brainard

Yes. You're talking about the capsid inhibitor? Yes.

Salim Syed

Yes correct, yes.

Diana Brainard

Yes. So I think that we have seen the competitor data regarding capsid and we're looking very closely at our compounds preclinically as well as clinically. Because obviously with hepatitis B we've got a lot of experience in this space and we know very well the value of suppressive treatment and the safety of those regimens and the benefit that viral suppression brings in terms of reducing cirrhosis, reducing rates of hepatocellular carcinoma.

So, while we're committed to cure and recognize that we're going to need combination therapies, we're also really cognizant of the safety barrier that really has to be exceeded to bring combinations forward. And I think that's really all we can say about that right now.

Salim Syed

Are you still developing? Is it still ongoing -- there's been some speculation that it's been terminated in the marketplace?

Diana Brainard

I think that we're in the process of continually evaluating what our best next steps are. And I think in terms of how we prioritize what we bring forward we've got the TLR8 in Phase 2 and we really want to see the results of those studies before making any final decisions on next steps and future combinations.

Salim Syed

Okay, got it. Thanks so much.

Operator

Our next question comes from the line of Phil Nadeau with Cowen & Company. Your line is now open.

Phil Nadeau

Good afternoon. Thanks for taking my question. Just one question on filgotinib. Maybe to ask Umer's question a different way. You've talked a lot about differentiating filgotinib. How important is the differentiated label to that process commercially? How else -- what other key points will you have in differentiating filgotinib?

And then second filgotinib question. We have been expecting data from filgotinib as well as GS-9876 in Sjogren's and CLE in the second half this year. I noticed in your slides neither of those programs are mentioned. Is there any update on those two Phase 2 programs? Thanks.

Daniel O'Day

Yes. I'll let -- Johanna can start on the commercial side Phil, and then we'll go to John on the development.

Johanna Mercier

Okay. So, Phil more on the competitive concept. So, as you know this environment is super competitive and many of us know it well including myself. And so we've really pulled together a team that has considerable experience in this field.

The piece that you would say that the differentiated label, I think it's twofold. I think from a label standpoint what we've seen thus far from the FDA is a little bit of a more of a class labeling. And so our expectations and we'll go through the process, but we're also being conservative in our expectations.

One of the things that I would say is the importance of our data. And I think that if you look at the results of the three FINCH 3 studies in three different patient groups those are really exciting for us, both from an efficacy standpoint as well as safety standpoint.

So, a lot of the work that's being done right now is sub-analysis to ensure that we can better educate physicians about our data. So, that's kind of the plan there. And I do think that the opportunity here is to potentially have a best-in-class drug inhibitor and that could be also related to the sale activity of the JAK1.

So, having said that, that's what we're doing. All hands are on JAK to prepare for a competitive launch, but a differentiated one and an innovative one at the same time. So, we're excited about that and obviously we'll know more about the label in the coming months through 2020.

So, John maybe on the other.

John Sundy

Sure. Let me update you on the status of cutaneous lupus and Sjogren's studies that we conducted. So, these are proof-of-concept studies as you probably know we looked at a couple or even three different drugs in the same trials for these. These studies were exploratory in nature. We set a high bar for ourselves to proceed.

And while we did not see or meet the primary endpoint in these studies, I think I would like to point out is that we did see evidence of activity with filgotinib, particularly in patients who had markers or evidence of more active disease.

So, we just got the first look at these data, we're looking at the full set of data from all of these studies and we'll determine the next steps that we take an Lupus and Sjogren's disease and we'll share those results at an upcoming meeting soon.

Phil Nadeau

That's very helpful. Thank you.

Operator

Our next question comes from Evan Seigerman with Credit Suisse. Your line is now open.

Evan Seigerman

Hi there and thank you for taking my questions and I also want to extend my best wishes to Robin on her retirement. Just one on the Kite franchise. So, I'm just wondering if you can help me better understand the rationale for the increased investment, namely with the manufacturing facility. But more broadly how is expansion into cell therapy beyond Yescarta fit within your kind of new strategy for Gilead then?

And aside from Yescarta, are there any programs that you should think we should focusing on that drive near-term value for the franchise?

Daniel O'Day

Thanks very much for the question. And – yeah, again I would probably start with the investments that you mentioned. I mean I think, it's really important that we acknowledge the fact that the ability to manufacture and the turnaround time associated with cell therapy is absolutely fundamental to patient benefits and also to the efficacy results that we see. And I think it's a real competitive advantage to be able to have a network of manufacturing facilities that are state-of-the-art and are able to reduce that turnaround time including as you mentioned we have made a decision to establish a viral vector facility in one of our current manufacturing sites in Oceanside California that will allow us to not only supports the current products but also future products in the pipeline.

So look I mentioned some of the near-term things on CAR T in addition to what we currently have out there with the Yescarta profile today. The state on the Yescarta at ASH I think will be important looking at the three-year data and the early steroid use. The Kite X19 is now a second product for MCL and we look forward to presenting that data as well.

ZUMA-7 goes back to a Yescarta in an earlier line sitting. So when you think about the long duration of effect, the efficacy and durability that we've seen in the relapse/refractory third line setting, I mean the real question is and more natural obviously oncology developments avenue is to say, can you bring that affect up into earlier lines of therapy and potentially have this effect with more patients and potentially for longer duration, because you're treating them earlier.

So the strategy is very much to continue to expand out the hematology indications first and foremost. I think that's where the greatest product exists or CAR T is right now, but we do also have mid to longer term programs on solid tumors on allergenic and those although risker and earlier are also programs we’re fully committed to as we looked around out our leadership in cell therapy accordingly.

So more to come on this. I personally to the broader oncology strategy, I mean as I said before and I'll say it again, I think the concept of Gilead getting deeper into oncology by starting with a pioneering technology, I think is a smart thing to do in oncology. I mean really to think about where you can get long durations of responses with a new technology.

Having said that, we also have a great deal of expertise in our home-based technologies such as small molecules and an evolving biologic modality expertise at Gilead. And although I'm not prepared to talk more about that today and look forward to Merdad and others coming into the organization, so that we can continue to evolve our oncology strategy.

I think there are opportunities certainly that we can look at outside of cell therapy and complementary to cell therapy, so more on that. We're literally in the process of really doing deep dives on this. As you know we also have some partnerships with other companies where we are fully committed to different aspects of oncology.

And it's been a common question and I totally accept it and it's one that as we go into next year will be laying out deeper and deeper our holistic strategy around oncology that will include cell therapy but not the only cell therapy as we move ahead. So more to come on that.

Evan Seigerman

Great. Thanks for the question. Appreciate it.

Daniel O'Day

Thank you.

Operator

Next question comes from the line of Tyler Van Buren with Piper Jaffray. Your line is now open.

Tyler Van Buren

Thanks guys. Good afternoon. Earlier in the session you guys spoke towards your strategic areas of focus for business development and the Galapagos deal makes a lot of sense from a long-term, broadening out the pipeline perspective and acquiring additional scientific talent in Europe. But could you guys speak a little bit further to your urgency to acquire late-stage or on-market assets particularly maybe within the next year to add to the top-line, which as it stands is relatively flat?

Daniel O'Day

No. Thanks Tyler. I mean, obviously, we're a company that's firmly focused on differentiated medicines and will be driven again by the science both internally and externally. And, obviously, it won't be too long before we start to talk about the guidance for 2020 and beyond and I'm not going to talk about that today.

But the bottom-line is we're -- if I take a big step back and think about my confidence in the long-term growth potential of Gilead, it is captured within the strength of the HIV business. I mean that same business that you see offsetting some of the patent expiry this year continues to be we think a very durable business for the foreseeable future. You have a more predictable HIV-HCV business at this time. And then we have upside potential in filgotinib launching next year and I won't repeat, but the Yescarta programs and success accordingly.

Having said that, we understand that we want to find ways to continue to look to increase and accelerate our growth in the coming years. And that will happen both through internal strategies associated with the launch products and programs I mentioned and then also outside partnerships and M&A. So rest assured, that we are looking at everything that could help complement our later-stage portfolio out there.

And yes, and as you've seen, I think, our behaviors we will be disciplined about that. We will make sure that it's something that we feel scientifically is very strong something that we can add something to and provide strength to. And when and if those opportunities come up we certainly have the financial capacity and ability to act. So that's paramount on our mind. We are in it for short, medium, long-term and we're looking to improve all three of those time periods. But clearly the portfolio is absolutely key for me and a key for the leadership team. So thank you Tyler for your question.

Tyler Van Buren

Yes, thanks very much.

Operator

That will conclude today's question-and-answer session. I'd like to turn the call back to Sung Lee for closing remarks.

Sung Lee

Thank you, Liz and thank you all for joining us today. We appreciate your continued interest in Gilead and the team here looks forward to providing you with updates on our future progress.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.