REFINITIV STREETEVENTS

EDITED TRANSCRIPT

REGN.OQ - Q4 2022 Regeneron Pharmaceuticals Inc Earnings Call

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OVERVIEW:

Co. reported 4Q22 total revenues of $3b, non-GAAP net income of $1.4b and non-GAAP diluted EPS of $12.56.

REFINITIV

CORPORATE PARTICIPANTS

George D. Yancopoulos Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Leonard S. Schleifer Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Marion E. McCourt Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Robert E. Landry Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Ryan Crowe Regeneron Pharmaceuticals, Inc. - VP of IR

CONFERENCE CALL PARTICIPANTS

Brian Corey Abrahams RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Carter Lewis Gould Barclays Bank PLC, Research Division - Senior Analyst

Christopher Joseph Raymond Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Christopher Thomas Schott JPMorgan Chase & Co, Research Division - Senior Analyst

Colin Nigel Bristow UBS Investment Bank, Research Division - Analyst

Evan David Seigerman BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst

Matthew Kelsey Harrison Morgan Stanley, Research Division - Executive Director

Mohit Bansal Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Robyn Kay Shelton Karnauskas Truist Securities, Inc., Research Division - Research Analyst

Salveen Jaswal Richter Goldman Sachs Group, Inc., Research Division - VP

Tyler Martin Van Buren Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst

PRESENTATION

Operator

Welcome to the Regeneron Pharmaceuticals Fourth Quarter 2022 Earnings Conference Call. My name is Shannon, and I will be your operator for today's call. (Operator Instructions) Please note that this conference is being recorded.

I will now turn the call over to Ryan Crowe, Vice President, Investor Relations. You may begin.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you, Shannon. Good morning, good afternoon and good evening to everyone listening around the globe. Thank you for your interest in Regeneron and welcome to our fourth quarter 2022 earnings conference call. An archive of this webcast will be available on our Investor Relations website shortly after the call ends.

Joining me today are Dr. Leonard Schleifer, Co-Founder, President and Chief Executive Officer; Dr. George Yancopoulos, Co-Founder, President and Chief Scientific Officer; Marion McCourt, Executive Vice President and Head of Commercial; and Bob Landry, Executive Vice President and Chief Financial Officer. After our prepared remarks, we will then open the call up for Q&A.

I would like to remind you that remarks made on today's call may include forward-looking statements about Regeneron. Such statements may include, but are not limited to, those related to Regeneron and its products and businesses, financial forecast and guidance, development programs

and related anticipated milestones, collaborations, finances, regulatory matters, payer coverage and reimbursement issues, intellectual property, pending litigation and other proceedings and competition.

Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those projected in that statement. A more complete description for these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission including its Form 10-K for the year ended December 31, 2022, which we expect to file with the SEC on Monday, February 6. Regeneron does not undertake any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise.

In addition, please note that GAAP and non-GAAP measures will be discussed in today's call. Information regarding our use of non-GAAP financial measures and a reconciliation of those measures to GAAP is available in our financial results press release and our corporate presentation, which can be accessed on our website.

Once our call concludes, Bob Landry and the IR team will be available to answer any further questions you may have.

With that, let me turn the call over to our President and Chief Financial Officer, Len Schleifer. Len?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

I'm the Chief Executive.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Chief Executive Officer.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

But it's okay. Good morning to everybody. And for those of you experiencing the arctic freeze, I hope you're staying warm.

Our strong fourth quarter performance capped a remarkable year at Regeneron, highlighted by significant achievements that better position the company to deliver sustainable growth and shareholder value. Fourth quarter 2022 revenue increased 14% compared to the prior year when excluding the impact of contributions from REGEN-COV and Ronapreve, underscoring the commercial strength and increasing diversity of our business.

We also made several important advances across our pipeline during the quarter, notably the submission of a biologic license application for aflibercept 8 milligrams in neovascular age-related macular degeneration, or wet AMD as well as diabetic macular edema, or DME, positioning us for a potential U.S. launch in late August of this year.

Additionally, we received FDA approval for Libtayo in combination with chemotherapy as a first-line treatment for advanced non-small cell lung cancer, making Libtayo only the second PD-1 or PD-L1 antibody approved in this setting, regardless of a patient's histology or PD-L1 expression level.

We also presented data from our rapidly advancing oncology pipeline, including for fianlimab, our LAG-3 antibody in combination with Libtayo in advanced non-small cell lung cancer; odronextamab, our CD20xCD3 bispecific in B-cell lymphomas; and linvoseltamab, our BCMAxCD3 bispecific in multiple myeloma; finally, Dupixent was approved for prurigo nodularis in Europe.

Briefly reflecting on 2022, we ended the year with 3 strategic imperatives that we felt we had to accomplish in order to position the company for long-term growth. First, we had to fortify the medium and long-term outlook for our retinal franchise. Based on the positive results that we reported

in September 2022, we believe aflibercept 8 milligrams has the potential to change the treatment paradigm for patients with wet AMD and DME by becoming the new standard of care for these patients, positioning Regeneron for prolonged leadership in this category.

Second, we needed to maintain and grow Dupixent leadership across a variety of type 2 allergic diseases. 2022 turned out to be a phenomenal year with Dupixent global net product sales approaching $8.7 billion and growing 44% at constant currency. Despite new competition, Dupixent maintained a leading market position in atopic dermatitis, asthma and nasal polyps and was also approved in new indications, geographies and younger populations, which George will detail shortly. Collectively, these 2022 approvals meaningfully expanded the Dupixent commercial opportunity, allowing the addressable population to increase by approximately 225,000 patients, bringing the total addressable population to over 7 million patients globally.

And third, we wanted to make significant progress towards becoming a leader in immuno-oncology, and 2022 turned out to be a crucial year. Key to this long-term goal was acquiring Sanofi's share of global rights to Libtayo, an antibody discovered by Regeneron, which was a necessary step towards realizing the full clinical and commercial potential of this foundational therapy. It also enables us to unlock combination opportunities from promising candidates in our oncology pipeline, including with our LAG-3 antibody, our costimulatory bispecifics and our 3 -- our CD3 bispecifics. Looking ahead, we expect 2023 to be another notable year with significant incremental progress across these imperatives as well as in other areas of our business.

We are preparing for a potential U.S. launch for aflibercept 8 milligrams in late August. Given prescribers decade-plus experience with EYLEA and now with the 48-week data for aflibercept 8 milligrams, which demonstrated comparable efficacy and safety to EYLEA but with longer treatment intervals, we believe that over time, there is an opportunity for aflibercept 8 milligram to become the new standard of care for wet AMD and DME.

We expect Dupixent to continue to strengthen its leadership position across approved type 2 allergic diseases based on its differentiated mechanism of blocking both interleukin-4 and interleukin-13. In 2023, we have an opportunity to reach even more patients with potential regulatory approvals in new diseases, geographies and younger populations that could add another approximately 500,000 patients globally to the biologic-eligible population. Additionally, we look forward to the upcoming readout of our first Phase III study of Dupixent in COPD in the first half of this year.

In oncology, we expect to continue rapidly advancing our pipeline. For our LAG-3 combination with Libtayo, we are moving forward with expansion beyond melanoma to include lung cancer and potentially other solid tumors.

For our costimulatory bispecifics, in combination with Libtayo, we are continuing dose expansion in our Phase I/II PSMAxCD28 program in advanced prostate cancer. We also expect to report additional Phase I data from our EGFRxCD28 program in solid tumors and to present initial clinical data for our MUC16xCD28 program in recurrent ovarian cancer.

And within hem-onc, we anticipate second half regulatory submissions for odronextamab in follicular lymphoma and diffuse large B-cell lymphoma as well as linvoseltamab in refractory multiple myeloma.

In 2023, we also plan to rapidly move forward with clinical development of our next-generation COVID-19 antibody, which we believe could help protect the millions of vulnerable patients who were unable to mount a sufficient immune response from vaccination and treat those who require other alternatives. Activities enabling clinical manufacturing have commenced, and we expect to enter clinical development later this year.

In closing, 2022 was a pivotal year at Regeneron, and we expect to continue making significant progress in 2023. Our strategy remains focused on investing in our internal R&D capabilities which has historically generated a high rate of return.

We remain confident in our near and long-term growth prospects with approximately 35 pipeline candidates currently progressing through clinical trials. We will also continue looking for opportunities to complement these internal efforts by exploring potential collaborations. With our commercial capabilities continue to drive revenue growth and our strong financial position, Regeneron is extremely well positioned to continue delivering breakthroughs for patients and value to shareholders.

Now I will turn the call over to George.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Thanks, Len.

I would like to briefly walk you through our pipeline's progress in 2022 and touch upon what lies ahead in 2023.

In ophthalmology, we presented pivotal -- positive pivotal results for aflibercept 8 milligram in wet AMD and DME. These trials showed that aflibercept 8 milligram extended dosing intervals to every 12 or even 16 weeks for the vast majority of patients through 48 weeks without compromising the visual improvement or safety seen with EYLEA. These are truly unprecedented and potentially game-changing results who have not -- which have not been achieved using any other anti-VEGF agent.

Moving to Dupixent. In 2022, Dupixent became the only biologic approved in atopic dermatitis, for infants as young as 6 months of age, the first treatment for prurigo nodularis and the first treatment in the United States for eosinophilic esophagitis. And just this week, we obtained the European Commission approval for eosinophilic esophagitis as well. In addition, we submitted a supplemental BLA for chronic spontaneous urticaria and shared positive Phase III data in children with eosinophilic esophagitis.

Dupixent is now approved in 5 related type 2 allergic conditions, and our data shows that these diseases are mediated by IL-4 and IL-13 driven type 2 inflammation because many patients suffer from systemic type 2 inflammation, they often suffer from several of these diseases concurrently. And thus, Dupixent has the potential to holistically address these patients multiple type 2 conditions for which Dupixent is approved.

While many other immunomodulators are associated with worrisome immunosuppression and carry boxed warnings, Dupixent's safety profile supports its approval in infants. In 2023, we are looking forward to the initial results of BOREAS, the first Dupixent Phase III study in patients with chronic obstructive pulmonary disease, or COPD.

Our Dupixent COPD Phase III studies have enrolled patients with elevated blood eosinophils aiming to select the patients with COPD driven by type 2 inflammation. The BOREAS study passed an interim futility analysis in 2020, an encouraging event, which triggered the start of the replicate Phase III NOTUS study. We are looking forward to the readout of BOREAS with the primary endpoint of annualized rate of acute, moderate and severe COPD exacerbations expected in the first half of '23.

Moving on to oncology. 2022 was an important year for our oncology programs. Libtayo was approved by the FDA in combination with chemotherapy in first-line, non-small cell lung cancer, irrespective of histology or PD-L1 expression levels, an achievement met by only one other PD-1 or PD-L1 targeting agent.

Libtayo is also emerging as an essential backbone of our oncology pipeline as several programs in combination with Libtayo are starting to yield encouraging data. First, I'll discuss our LAG-3 antibody, fianlimab in combination with Libtayo, where we have recently shown positive data from a second confirmatory cohort of PD-1 naive metastatic melanoma patients and reported encouraging results from a smaller dataset in non-small cell lung cancer patients. These initial results suggest that the fianlimab Libtayo combination has a potentially best-in-class profile in melanoma and we are advancing broad pivotal programs in both melanoma and lung cancer. Phase III studies in metastatic melanoma and adjuvant melanoma are already enrolling, we have plans to soon initiate another Phase III study in perioperative melanoma as well as Phase II/III studies in first-line advanced as well as perioperative non-small cell lung cancer.

Other notable Libtayo combination used from this year was the early but very encouraging data with our PSMAxCD28 costimulatory bispecific in advanced metastatic castrate-resistant prostate cancer, a tumor type considered immunologically cold with multiple recent Phase III failures demonstrating that prostate cancer is largely unresponsive to anti-PD-1 therapy in other (inaudible) as well as in other types of chemo combination.

Our proof-of-concept study of our PSMAxCD28 costimulatory bispecific, we observed first evidence that combining this new class of bispecifics with anti-PD-1 can confirm profound responsiveness to tumors previously thought to be cold and unresponsive to anti-PD-1 therapy with 3 out of the 4 patients treated at the highest dose levels showing greater than 90% reductions within 6 weeks of initiating combination therapy in the

prostate cancer biomarker, PSA. Following up on these early but exciting results, we're continuing to enroll patients in this study, and we are planning to present additional data at medical meetings in 2023.

We also presented our first clinical data for a CD3 bispecific in a solid tumor. For ubamatamab, our MUC16xCD3 bispecific in development for advanced ovarian cancer. As a single agent in a Phase I dose escalation study in heavily pretreated recurrent ovarian cancer patients, we observed a 4% [14%] overall response rate with a 31% response rate in a small subset of patients with high MUC16 expressing tumors. We expect initial does escalation data later this year for ubamatamab with Libtayo as well as for our MUC16xCD28 costimulatory bispecific with Libtayo in advanced ovarian cancer. We also expect updated clinical data for our EGFRxCD28 costimulatory bispecific in combination with Libtayo in various solid tumors later this year.

Moving on to our hematology oncology pipeline. At the American Society of Hematology, or ASH, Annual Meeting, we presented new data from odronextamab, our CD20xCD3 bispecific as well as linvoseltamab our BCMAxCD3 bispecific. For odronextamab, we presented pivotal Phase II ELM-2 data. Odronextamab in third or later line relapsed or recurring follicular lymphoma has a potential best-in-class efficacy profile with 82% of patients responding and 92% of these responders achieving a complete response with encouraging durability.

Our optimized step-up dosing regimen has improved odronextamab's safety profile while retaining efficacy similar to the prior dosing regimen. In third or later line relapse or recurrent diffuse large B-cell lymphoma, odronextamab demonstrated efficacy regardless of prior CAR T experience and a safety profile generally similar to that seen in follicular lymphoma.

We are planning regulatory submissions in the second half of 2023 for both indications, which we hope will support potential accelerated approvals. In 2023, we anticipate initiating several Phase III studies in follicular lymphoma and diffuse large B-cell lymphoma, including in earlier lines of therapy. These trials will serve as confirmatory studies which could potentially support conversion to full approval. We also expect to initiate a proof-of-concept study of our CD22xCD28 costimulatory bispecific in combination with odronextamab in diffuse large B-cell lymphoma, which we hope could further add to the anticancer benefit for these patients.

For linvoseltamab, our BS -- BCMAxCD3 bispecific antibody, we presented efficacy and safety data from our pivotal Phase II study in third or later line multiple myeloma at ASH. Early, deep and durable responses were observed in patients with high disease burden, and these responses may improve with longer follow-up.

In 2023, we plan to initiate a confirmatory Phase III study of linvoseltamab in second line multiple myeloma and are on track for a BLA submission in the second half of the year. As with odronextamab, we plan to initiate combination studies for linvoseltamab with costimulatory bispecifics in the near future.

I'd also like to update some additional clinical programs. Our antibody blocking Factor XI for anticoagulation in an antibody that activates the NPR1 receptor for heart failure are both completing proof of mechanism trials.

Moving on to Regeneron genetics medicine. Regarding our collaboration with Alnylam in siRNA therapeutics, we are planning a broad and multipronged approach to develop treatments for NASH, nonalcoholic steatohepatitis. We are initiating a Phase II study of ALN-HSD in NASH patients with genetic risk factors. We also dosed first subjects in the first in-human study of another siRNA medicine in development for NASH, ALN-PNP, which targets a different gene and can be potentially combined with ALN-HSD in appropriate patients. We have discovered additional NASH targets, which we have validated using our Regeneron Genetics Center, including CIDEB, which will potentially be the next NASH therapeutic candidate to enter the clinic. With regard to our collaboration with Alnylam for central nervous system targets, our initial dose escalation study is ongoing.

Our collaboration with Intellia in CRISPR-based therapeutics is expected to progress further in 2023, building on continuing data readouts from the Phase I study of NTLA-2001 in transthyretin amyloidosis in both cardiomyopathy and neuropathy patients, which provided the first demonstration in humans that CRISPR-based technologies can deliver up to 90% reduction of the pathological gene product for over a year.

Regarding our gene therapy efforts, our collaborators at Decibel Therapeutics recently announced that a clinical trial has been authorized by both the U.S. FDA and the U.K. MHRA for DB-OTO, a virally delivered gene therapy designed to restore hearing to individuals with otoferlin-related hearing loss. A Phase I/II study in patients 2 years of age and younger is expected to initiate in the first half of 2023 with initial data from the first [cohort] of patients anticipated in the first quarter of 2024.

I'd like to conclude with our next-generation COVID-19 efforts. As we recently announced, we have identified a potent broadly neutralizing COVID-19 antibody, which, unlike other neutralizing antibodies binds outside of the so-called receptor binding domain, or RBD, of the [spike] protein. This antibody retains activity against all the viral variants seen throughout the pandemic because it binds to an epitope that has remained highly conserved, greater than 99.9% across all known variants. The vast majority of antiviral antibodies generated as a result of vaccination or due to natural infection target the RBD domain, which results in overwhelming selective pressure driving the emergence of these resistant variants. We hope that by targeting this unique and conservative epitope outside of the RBD, this antibody will also retain its activity in the face of future variants. We plan to initiate clinical trials to test this antibody this year, and we are looking to develop it in both treatment and prophylactic settings.

In conclusion, Regeneron's R&D engine continues its productivity, including the early-stage pipeline. Just in the first weeks of this year, we have initiated clinical studies for 2 new drug candidates and we anticipate clinical trials starting or IND submission for up to 10 new therapeutic candidates this year, as well as for additional indications for candidates that are already in the clinic.

So with that, I will turn it over to Marion.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Thanks, George.

The fourth quarter capped off a strong year of execution and growth, delivering results across our commercial portfolio. We expanded into new indications, which, coupled with our existing business, is expected to drive meaningful growth in 2023 and beyond. We look forward to several important potential approvals and subsequent launches this year, providing additional opportunities for growth.

Starting with EYLEA, where we announced in January, fourth quarter U.S. net sales of $1.5 billion, full year 2022 net sales were $6.3 billion, representing 8% year-over-year growth and outpacing total growth of the anti-VEGF category for the year. At the end of the fourth quarter, EYLEA category share was approaching previous levels of approximately 50% of injections. This followed the short-term shift earlier in the quarter where EYLEA was negatively impacted by a temporary increase in use of off-label compounded Avastin. During this time, there was a short-term closure of a not-for-profit patient co-pay assistance fund, which re-opened later in the quarter.

We believe we have substantially recovered from the issue encountered in the fourth quarter. We continue to expect competitive pressures but remain confident in Regeneron's overall retinal franchise as we look forward to our potential upcoming aflibercept 8 milligram launch.

In summary, our retinal franchise leads the anti-VEGF category with EYLEA as the current standard of care and aflibercept 8 milligram, if approved, offering a differentiated clinical profile that can potentially shift the treatment paradigm.

Turning to Libtayo. Total fourth quarter global net sales were $169 million, growing 44% on a constant currency basis. In the U.S., net sales grew 36% to $110 million with contributions across all indications. In advanced non-melanoma skin cancers, we continue to build our leadership position in the PD-1 class. In lung cancer, Libtayo continues to see steady growth in utilization in prescribers. Customer ordering has accelerated following the chemotherapy combination approval last November. We are working to maximize launch uptake by increasing depth and breadth of prescribers.

Early launch indicators are positive, community and academic centers have welcomed Libtayo's expanded role as an important treatment option in advanced non-small cell lung cancer. There are more than 200,000 new cases of lung cancer per year in the U.S. alone for which Libtayo is an important treatment option.

Outside the U.S., Libtayo net sales grew 60% on a constant currency basis to $59 million driven by steady demand growth and additional launches as we secure access and reimbursement globally. We continue a targeted approach to extend our global commercial footprint in priority international markets designed to maximize opportunities for Libtayo in potential future medicines.

Finally, turning to Dupixent, where in the fourth quarter, global net sales grew 42% on a constant currency basis to $2.45 billion. In the U.S., net sales grew 44% to $1.94 billion, with strong growth continuing across atopic dermatitis, asthma, nasal polyps with additional contributions from recent launches in eosinophilic esophagitis and prurigo nodularis. Dupixent is well positioned to expand market penetration and drive revenue growth across established new and potential future indications in 2023 and beyond.

Atopic dermatitis, Dupixent's largest indication continues to rapidly grow across all age groups, firmly establishing Dupixent as the preferred systemic therapy for patients with moderate to severe disease. There continues to be rapid uptake in younger populations, further confirming Dupixent's differentiated efficacy and safety profile. We've also seen meaningful early adoption in prurigo nodularis where Dupixent is the only FDA-approved medicine for this debilitating disease. We expect ongoing uptake of Dupixent as the launch progresses and physicians identify patients' need.

Dupixent continues to perform well in the highly competitive biologic asthma space with steady market share gains and strong growth in total prescriptions and new patient starts. In nasal polyps, Dupixent's differentiated clinical profile continues to drive uptake as the leading first line treatment option in patients requiring systemic therapy.

In the eosinophilic esophagitis, the launch is going exceptionally well, finally offering physicians and their patients a treatment to effectively manage the underlying mechanism of their disease. Patients treated with Dupixent have experienced dramatic improvements in their symptoms and quality of life. We've seen rapid uptake across both gastroenterologists and allergists. We also continue to advance our clinical efforts in younger patients where there is also substantial unmet need.

Outside the U.S., Dupixent net sales were $513 million, growing 37% on a constant currency basis, driven by rapid uptake across approved indications and launches in new geographies. In Europe, Dupixent was approved for prurigo nodularis in December. And earlier this week, Dupixent was also approved for eosinophilic esophagitis. We expect these new indications to contribute to Dupixent's ongoing international growth.

In summary, during 2022, we executed on our core focus to deliver life-changing medicines to patients. Our commercial initiatives and strategies are driving increases in market penetration for our in-line brands and optimizing the potential of new and upcoming launches. Taken together, we are confident in Regeneron's future and are well positioned to deliver long-term and sustainable growth.

Now I'll turn the call to Bob.

Robert E. Landry - Regeneron Pharmaceuticals, Inc. - Executive VP of Finance & CFO

Thank you, Marion.

My comments today on Regeneron's financial results and outlook will be on a non-GAAP basis, unless otherwise noted.

Regeneron ended 2022 with a strong fourth quarter with continued execution driving positive results across the business. Excluding contributions from REGEN-COV and Ronapreve, fourth quarter total revenues increased 14% year-over-year to $3 billion, driven by growth across our core brands. Fourth quarter diluted net income per share was $12.56 on net income of $1.4 billion.

Beginning with collaboration revenue and starting with Bayer. Fourth quarter 2022 ex U.S. EYLEA net product sales were $839 million, up 7% on a constant currency basis versus fourth quarter 2021. Total Bayer collaboration revenue was $355 million, of which $324 million related to our share of EYLEA net profits outside the U.S.

Total Sanofi collaboration revenue was $836 million in the fourth quarter and grew 61%, driven by Dupixent. Our share of profits from the commercialization of Dupixent and Kevzara was $619 million, an increase of 60% versus the prior year. We also recognized a $50 million sales-based milestone in the fourth quarter of 2022 due to achievement of $2.5 billion of ex U.S. sales of antibody collaboration products on a rolling 12-month basis.

Finally, we recorded Roche collaboration revenue of $396 million in the fourth quarter for our share of gross profits from ex U.S. sales of Ronapreve related to a previously signed contract.

Moving now to our operating expenses. Fourth quarter 2022 R&D expense increased 43% year-over-year to $911 million, driven by the impact of the Libtayo transaction with Regeneron now recording all R&D expense for Libtayo and our full 50% share of antibody collaboration R&D spend for Dupixent and itepekimab as well as additional costs incurred in connection with the company's late-stage pipeline and increasing clinical manufacturing activities and higher headcount-related costs.

SG&A expense increased 17% year-over-year to $579 million due to higher headcount and related costs, incremental costs to fully support the global commercialization of Libtayo and higher contributions to an independent not-for-profit patient assistance organization. Product gross margin in the quarter increased to 93% as compared to 86% in the prior year. The improved gross margin was driven by a favorable change in product mix and no longer having to pay Sanofi for their share of U.S. Libtayo gross profits. Finally, fourth quarter 2022 effective tax rate was 11.3% compared to 12.6% in the prior year.

Shifting now to cash flow and the balance sheet. For full year 2022, Regeneron generated $4.4 billion in free cash flow, favorably impacted by our first quarter 2022 payment from the U.S. government for sales of REGEN-COV that were recorded in the fourth quarter of 2021. We ended 2022 with cash and marketable securities less debt of $11.6 billion.

We continue to deliver on our capital allocation priorities in 2022 by deploying approximately $3.4 billion towards business development and share repurchases while continuing to fund our internal R&D efforts. In 2022, we executed approximately $1.3 billion in business development initiatives, including the acquisitions of Checkmate Pharmaceuticals in the exclusive worldwide rights to Libtayo.

We also purchased approximately $2.1 billion of our shares in 2022, including $431 million in the fourth quarter. This morning, we announced a new $3 billion share repurchase authorization reflecting our continued confidence in our business and our pipeline. We remain buyers of our shares at current levels, and this new authorization enables us to continue returning capital directly to shareholders.

I'd like to conclude with our initial financial guidance and outlook for 2023. We expect 2023 SG&A spend to be in the range of $2.13 to $2.28 billion. This primarily reflects the full year impact of global Libtayo commercialization expenses, the build-out of our international commercial infrastructure in select markets, and higher headcount to support our growing organization.

We expect our 2023 R&D expense to be in the range of $3.725 to $3.925 billion. As George mentioned, we have numerous strategically important development programs advancing in 2023, including late-stage studies for our fianlimab-Libtayo combination in melanoma and lung cancer in confirmatory Phase III studies for odronextamab, both in FL and DLBCL and linvoseltamab in myeloma.

In addition, we continue to advance programs in our early pipeline across multiple therapeutic areas including with collaborators such as Alnylam and Intellia positioning us for long-term growth. This range also includes the full year impact of the Libtayo transaction, we are now recording all development expenses for Libtayo and recognizing our full 50% share of development expenses for Dupixent and itepekimab.

COCM is expected to be in the range of $720 to $800 million, similar to 2022 reflecting the gradual phase-in of a new Regeneron developed manufacturing process for Dupixent that is designed to improve drug substance yields. We expect our capital expenditures in 2023 to be in the range of $825 to $950 million. These expenditures will support the continued expansion of our manufacturing facilities, including ongoing construction of a fill/finish facility as well as the previously announced expansion of R&D facilities at our Tarrytown, New York headquarters.

Finally, we anticipate 2023 gross margin to be between 90% to 92% and our effective tax rate to be in the range of 11% to 13%. In addition to our full year financial guidance, we expect higher interest income in 2023, given our greater cash balance plus higher interest rates as compared to last year, which will favorably impact other income and expense. We also expect 2023 other revenue to be slightly lower than 2022. Finally, as I said in November, we no longer expect to record any material other operating income or expense in 2023 or beyond, absent a new transaction.

In conclusion, Regeneron continued to deliver robust financial results in 2022, and we are well positioned to drive continued growth in 2023 and beyond.

With that, I will now pass the call back to Ryan.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you, Bob.

Shannon, that concludes our prepared remarks. We'd now like to open the call for Q&A. To ensure we are able to address as many questions as possible, we will answer one question from each caller before moving on to the next. Shannon, please go ahead and poll for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Tyler Van Buren with Cowen.

Tyler Martin Van Buren - Cowen and Company, LLC, Research Division - MD & Senior Equity Research Analyst

Congratulations on the results. Regarding EYLEA, it'd be great to hear the latest on what you're seeing in the marketplace with respect to Vabysmo. Apparently, Roche is not seeing switches from Vabysmo back to EYLEA, despite what we are hearing from the KOLs. So any additional color there would be helpful.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

Hi Tyler, yes, and let me comment that certainly, EYLEA performance in the market, as I reported, continues to be very strong. A quick reminder on the year, growing at 8% to $6.3 billion, and certainly, a very strong competitive performance.

We're conscious of competition in the marketplace. But to give a bit of an update, we continue to hear that faricimab use has been modest and results, in some cases, have resulted in patients switching back to other agents, including EYLEA, probably most frequently EYLEA. Certainly, we look forward to continued efforts on EYLEA this year as the standard of care. And as you know, from many of us talking to KOLs, they're incredibly enthusiastic about the launch -- potential launch of aflibercept 8 milligram coming later this year.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Next question, please.

Operator

Our next question comes from the line of Matthew Harrison with Morgan Stanley.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Matt, we don't hear you.

Matthew Kelsey Harrison - Morgan Stanley, Research Division - Executive Director

Sorry, could you not hear me, Len?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

We hear you now.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Yes, we can.

Matthew Kelsey Harrison - Morgan Stanley, Research Division - Executive Director

Okay. All right. Sorry. So I was just wondering if you could comment on COPD and what you view as clinically meaningful in terms of result there. Other companies have reported sort of 15%. But I think in the past, you've talked about that as not being a particularly high bar. So maybe you could just talk about how you view clinical meaning from this.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Well, we powered our futility analysis as well as our clinical trial to deliver what we believe would be clinically meaningful benefit if the study proves positive, which we hope it will. And remember, we're going to be looking at both exacerbations, but also improvement in lung function. So it will be a sort of integration of the benefit that patients can receive from both those measures. I remind you that in other settings in asthma, in particular, Dupixent has distinguished itself from other immunomodulators in delivering pretty substantial improvements in pulmonary lung function.

So it's not only all about exacerbations, but we hope to have significant improvements in exacerbations as well as in lung functions which will hopefully provide important benefits to patients.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you. Next question, please.

Operator

Our next question comes from the line of Carter Gould with Barclays.

Carter Lewis Gould - Barclays Bank PLC, Research Division - Senior Analyst

You do have some APP data on the horizon here with Alnylam. I would love to kind of hear your thoughts on how you're thinking about that. And if we should be thinking about that as more just a proof of concept or as a potential product opportunity even with intrathecal delivery? And if, I

guess, more of the former, how much of this is sort of a gating factor to really kind of expanding the effort here potentially dramatically across a number of CNS diseases.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Well, as you say, the important thing about that aspect of the Alnylam collaboration is together, we were hoping for the first time to see if we could develop technology that would actually allow us to do what's been done now by Alnylam and others in the liver to bring it to other tissues, particularly to the central nervous system in this case. So this -- the first study, which is focused on APP, is really a proof of concept that can we get this technology to work.

We view it as a potential sort of platform enabler, meaning that if we see anything here, and obviously, these are challenging things to be first and to do something that nobody has ever done before. And it's obviously very early in the program. But the goal is to establish proof of principle that this type of technology, which looks like it can be pretty effective in the liver, can it work outside of the liver, particularly in the CNS. So this would be a platform enabler.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, George. Next question, please.

Operator

Our next question comes from the line of Brian Abrahams with RBC Capital Markets.

Brian Corey Abrahams - RBC Capital Markets, Research Division - Senior Biotechnology Analyst

Congrats on all the progress. So with the potential approval coming this summer, I'm curious how we should be thinking about the launch cadence for high-dose aflibercept just considering some elements like the introduction of prefilled syringe, the J-code and maybe your overall strategy and how you're thinking about converting market segments and where you're initially focused.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Give us a second, we'll disconnect all the Roche people on the call, so we can get you our strategy. In all seriousness, obviously, there's a lot of thought that's going to go in between now and what we hope will be our late August approval on pricing, on rollout, on targeting, on strategy, et cetera, et cetera, but we're working on that. We have to get our label. We have to get it approved, and we'll have everything else ready to go. The initial launch will be with a vial, and then we hope down the road, not too far with the prefilled syringe.

Marion, I don't know if you want to give away any of your secrets at this point.

Marion E. McCourt - Regeneron Pharmaceuticals, Inc. - EVP of Commercial

I would just say that we have a highly experienced team in commercialization, and we certainly will be ready for the launch. And in the meantime, we're very focused on our participation in the market today with EYLEA but certainly more to come, and we absolutely look forward to the potential launch of 8 milligrams.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Obviously, the Vabysmo launch has not turned the market sideways on us. It's real competition. But that, I think, there's a window that's sort of closing for them to compete against 2 milligrams, we hope and then 8 milligrams, we hope could become the standard of care. So lots to look forward to later in the year.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Certainly. Thank you. Next question, please.

Operator

Our next question comes from the line of Evan Seigerman with BMO Capital Markets.

Evan David Seigerman - BMO Capital Markets Equity Research - MD & Senior BioPharma Research Analyst

Maybe a follow-up to Matt's question. Can you just speak to what you saw in the (inaudible) interim efficacy analysis of the BOREAS trial? And just any additional color on the level of benefit versus placebo that triggered the initiation of the NOTUS trial?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

All I can say is that we powered it to deliver what we thought would be a clinically significant improvement. There was a combination of measures of exacerbations and lung function improvement, and we haven't disclosed what those numbers were.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

And we remain blinded to that interim analysis, Evan, so. Next question, please.

Operator

Our next question comes from the line of Salveen Richter with Goldman Sachs.

Salveen Jaswal Richter - Goldman Sachs Group, Inc., Research Division - VP

With regard to the oncology portfolio, what do you consider the most meaningful milestones for the next 12 months and particularly here the PSMAxCD28 asset?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Well, we obviously have some important submissions we need to get in later in the year, as we mentioned, for our CD3 bispecifics. And we need to continue to get data later in the year with more patients with PSMAxCD28 bispecifics as well as from some of the other costim bispecifics. And we have to move aggressively enrolling the additional studies we plan for LAG-3. So -- and we have to make Libtayo even more successful, we hope, in the marketplace around the world. So lots to do.

I don't know if George or Marion have anything else to add there.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Yes. I think it's -- it was really critically important for us to validate individual agents in each class. That was our strategy. We wanted to develop the best-in-class checkpoint inhibitors, such as our PD-1 antibody, Libtayo; such as our LAG-3 antibody, fianlimab. We wanted to establish CD3 bispecifics that were best-in-class and that were working in hem-onc settings, but also in solid tumor settings. And then, of course, we want to validate that this incredible principle of costimulatory bispecifics that we introduced into the world, which were truly magical in animal studies with essentially working like turnkey agents to synergize with the other 2 classes in animal studies that we could reproduce that sort of activity in humans.

And so us obviously, it takes years to get to that point, but we feel we're in a very exciting position right now because, as I said, the individual classes are validated. We're starting to see impressive combination opportunities. We talked about combining 2 checkpoints, combining our LAG-3 with PD-1, where it looks like we have maybe taken first line melanoma to a different point where patients can get a lot more benefit from this combination. And now having validated those, we're expanding much more broadly.

Same thing with the CD3 bispecifics. We're growing that franchise now that we've shown that our platform works, and we're working both in hem-onc and outside in solid tumor settings. And the fact that our first costim bispecific delivered the sort of exciting early data that it delivered really gets us, very excited about the possibility now that we have this whole rollout.

We have several of these costim bispecifics in the clinic, clearing their dose escalation safety settings, and we're now going to be rolling out data from these combinations, more data from the PSMA costim bispecific in prostate cancer in more patients, but we're also going to be reporting on a series of other costims, including not only in combinations that we've already talked about in solid tumors, but in the hem-onc space where we're very excited, obviously, about our CD20xCD3 bispecific by itself and our BCMAxCD3 bispecific by themselves, as Len said, we're both filing for those, hopefully, by the end of the year.

But also initiating earlier line studies. But just as importantly, we're going to be initiating combination with these costim bispecifics, which we think yet again, if these continue to work like they work not only in the animal models, but now how they're looking in the early human study, these could really leapfrog the individual agents to a whole place where they're really changing the practice of medicine and delivering much more benefit to patients, which is what we're all about.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Yes. I don't think George's point, can be overstated. Cancer cures in serious advanced tumors are still far and few between. And there's still tremendous need which makes this a very dynamic treatment marketplace because people want that extra benefit because it's not like they're getting cures -- we haven't cured lung cancer or we haven't cured most serious cancers.

So the ability to have foundational individual treatments and then get more by combining them really does position us to leapfrog, to use George's word, in the treatment paradigm out in the world because patients and their doctors are very sensitive to improve outcomes because there's still tremendous, tremendous need.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thank you. Next question, Shannon.

Operator

Our next question comes from the line of Mohit Bansal with Wells Fargo.

Mohit Bansal - Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

Maybe staying with COPD. So talking to some KOLs and reading some papers, it seems like IL-13 has some implication into fibrosis as well. Now so the question is, could -- do you think there could be a beneficial effect of IL-13 blockade and its impact on fibrosis on COPD over and above blocking inflammation? And if yes, do you think a 1-year trial would be enough to see that?

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

I think you bring up really interesting points. We were actually involved in some of the experiments years ago that showed that IL-13 could actually cause fibrosis in animal models. And certainly, we do believe that long term, like in many of the diseases that we studied so far, that the benefit of Dupixent in blocking both IL-4 and IL-13 can continue to accrue for the patient in terms of preventing the chronic inflammation that results in so much of this remodeling that you talked about, we believe this may be true in asthma.

And we're actually involved in programs and studies to show that some of the same things that you're talking about will also benefit in that you will prevent long-term remodeling that decreases lung function over time as structural changes in the asthmatic patients and we believe that, that may also be true, of course, in COPD.

But first, we need, as you say, the shorter-term studies to be positive, but we do believe that if they produce the type of data that we're hoping, Dupixent produces the type of data we're hoping it could in COPD, that longer-term studies, like you say, could end up showing even longer-term benefits in terms of exactly the type of remodeling and fibrotic changes that result in permanent loss of function, lung function in these patients. So we think that you're totally right, but it will probably, as you say, take longer-term studies to actually pick that up.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, George. Next question, Shannon.

Operator

Our next question comes from the line of Colin Bristow with UBS.

Colin Nigel Bristow - UBS Investment Bank, Research Division - Analyst

I wanted to sort of push a little more on the Dupi COPD readout. And just trying to understand what's underpinning your confidence here. It certainly feels like you're more enthusiastic than what we're hearing out of Europe. Is this primarily based on the threshold set for BOREAS interim and these were sufficiently robust that you just -- you feel good about the ultimate result? Or is there something else you can point us to?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Yes. I wouldn't over or under-read our situation right here. And it almost doesn't matter because Regeneron is a data-driven enterprise, and we're all going to see the data coming up, we hope, later this quarter. We are totally blinded to the evaluation that was done on the interim analysis. We have said we set it at a reasonable bar, but it was only a fraction of the patients. So you never know how this is going to turn out. We would not be as confident about something like this compared to another classic type 2 inflammatory disease. So you have that on the negative side. But on the positive side, you do have the fact that we've selected patients who have high eosinophils and we had this interim analysis. Bottom line is we look forward to the data as well as you do.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, Len. Next question, Shannon.

Operator

Our next question comes from the line of Chris Raymond with Piper Sandler.

Christopher Joseph Raymond - Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Maybe a broader question on the VEGF retinal market. Last year, at AAO, there was a lot of discussion and debate around the potential impact on retinal specialist practices if intravitreal therapies for geographic atrophy are approved. And some folks were talking about, just back of the envelope, this could drive a pretty sizable like 30-some percent increase in injection volume, the practices just from treating geographic atrophy patients.

As you guys think about this dynamic, we've heard some KOLs sort of offer up potential fix to that, that they would move in a more accelerated fashion to longer duration, longer-acting therapies for wet AMD. Are you guys seeing that? Is that something that we should be thinking about in terms of a driver from short-acting to longer acting?

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Yes. I mean I think despite all of these practice aspects, the primary driver will be that patients would prefer to get a needle in the eye less frequently. With every time you put a needle in the eye, there is a risk of inflammation or more serious complications, hemorrhages, detachments, things like that. So the less you have to do that and get the same benefit is better for the patients from the needle-in-the-eye perspective. And it's better for the patient from the number of times they have to come to the doctor's office. These are elderly patients frequently; they have to have a caregiver.

From a practice perspective, certainly, as many doctors' offices are overwhelmed by -- in the number of injections that they're giving and that they could free up time with -- if you could get the same result. From a practice point of view with less frequent injections. Certainly, that would free up more time and would drive them. But I believe at the end of the day, docs do make the decision with their patient on this primarily because less injections in the eye are just safer and more convenient for the patient.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Well, we also shouldn't lose sight of the fact that if treatments for geographic atrophy become much more -- take off and become much more prevalent that they do have a side effect. They're actually increasing levels of macular edema in these patients, which will, of course, necessitate a treatment there as well.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks. We have time for 2 more questions, Shannon.

Operator

Our next question comes from the line of Chris Schott with JPMorgan.

Christopher Thomas Schott - JPMorgan Chase & Co, Research Division - Senior Analyst

Just on the costim platform, I guess once you land on the right dose for these products, do you expect that there could be accelerating filing pathways given the few options available for most of these patients? Or do we still need to think about needing to go slowly even with the registrational studies as you're kind of balancing, I guess, safety versus efficacy.

Leonard S. Schleifer - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, CEO & Director

Well, we certainly believe that when you're in something where there's tremendous medical need and no alternative, that there will be opportunities to move for accelerated approval. We're all aware of the new FDA guidelines that they want you to be underway with your pivotal studies are well underway, I think, is a phrase they use. So we're taking that into account. But there's no question that if we can reproduce the efficacy that we saw in these late-stage prostate cancer patients. There's not only the need, but there will be a mechanism to get that to patients as quickly as possible.

Remember, the main issue, as you referred to, is keep being mindful of the safety. And of course, we're doing everything we can to mitigate that. But remember, thus far, for the most part, there's been an extremely tight linkage of safety and efficacy. That is the adverse events occurred in those patients who were having the substantial benefit. So that makes the risk/reward even more attractive from a regulator's and a doctor's and frankly, a patient's perspective.

So the short answer is we think we're not going to go too fast where one would be reckless. We have to be careful. But we do think there is an opportunity for an accelerated approval if we follow the new approach the FDA has laid out.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, Len. Last question, please, Shannon.

Operator

Our last question comes from the line of Robyn Karnauskas with Truist.

Robyn Kay Shelton Karnauskas - Truist Securities, Inc., Research Division - Research Analyst

Great. So just a follow-up on the prior question. So for your MUC16xCD28 and MUC16xCD3 combination, what are you expecting regarding the safety profile? And how do you think about that type of combination efficacy and safety wise versus a CD28-CPI combo? And just a follow-up to that. I know the FDA was concerned back in the day about dosing up with CD28 superagonist, like do you think that your initial data might alleviate some of the needs of (inaudible) doses for CD28 bispecifics.

George D. Yancopoulos - Regeneron Pharmaceuticals, Inc. - Co-Founder, President, Chief Scientific Officer & Director

Well, a lot of good questions in there. I'll start from the end first. For sure, when we started the program, there was very serious concerns about previous experience with general CD28 activators that activated all over the body that resulted in really horrific situations for patients, which almost killed the field. We invented this new approach to tightly limit where we were limiting CD28 activation right at the tumor surface and so forth.

And of course, there was a concern from the FDA, which is why, as you said, they made us employ a very, very conservative dose escalation program. We had to go through 5 or 6 dose levels just to get to where we thought were the active dose levels where we then start to see the rather dramatic antitumor activity that we began to report. We are hoping that as we get more experience and show that what we had demonstrated preclinically is really holding true in humans.

In fact, the side effects that Len was talking about immune-related adverse events are totally unrelated to the sort of toxicities that were seen with nonspecific CD28 superagonists in the past, they were really much more on target and on mechanism that is we were generating a presumably a polyclonal T cell response against the tumor and some of that cross-reacted to tissues in the patients, and that's what we were seeing.

So we're hoping that increasingly, we might be able to move a little bit more quickly through some of these dose escalation stages to get to the active doses with these other agents. What we're seeing so far, as we've presented in our posters on MUC16xCD3 that right now, it's having an acceptable safety margin.

And we also hope to see that when combined, either the CD3 combined with the MUC16xCD28 or when the MUC16xCD28 is combined with Libtayo that we will see the same sort of things that we saw with the PSMAxCD28 that will be getting, hopefully, marked synergy and increase in the antitumor activity with hopefully a satisfactory safety window. And -- but that remains to be seen, and that's why we're carefully going through the combination studies and the dose escalation studies.

But once again, I mean, just to say how, I mean, exciting it is for those of us who've been working on these programs for over 10 years to be at this point where the individual agents and the individual classes are now validated and we now get to mix and match these things. And as Len said, the history of the field is when you have active agents and you start combining this, you can then leapfrog and get to the next level that would change the practice of medicine for these cancers. That's what we're aiming to do to try to save more lives, extend more lives, and it's an exciting place to be in.

Ryan Crowe - Regeneron Pharmaceuticals, Inc. - VP of IR

Thanks, George.

That's all the time we have for today. Thanks to everybody who dialed in and for your interest in Regeneron. We apologize to those remaining in the queue that we did not have a chance to get to. As always, the IR team is available to answer any questions you may have. Thank you once again, and have a great day and a nice weekend.

Operator

This concludes today's conference call. Thank you for participating. You may now disconnect.
