BofA SECURITIES

US Biopharmaceuticals

4Q23 Earnings Quotes – Weeks 1 & 2

Earnings Review

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Equity
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With the first two weeks of 4Q23 earnings season behind us, we have compiled what we'd highlight as the most important thematic quotes from earnings calls across the Biopharma space. Areas that particularly stood out which have industry relevance, include **1)** 2024 outlook, **2)** new launches / pipeline development, and 3) M&A / Business Development.

2024+ outlook

MRK on 2024+ outlook: *"As we go beyond 2024, we still point to an operating margin of greater than 40% in 2025, but our focus as a company and as the team is to really ensure that we are fueling the pipeline supporting the portfolio of products that we're launching to drive growth into the long-term."*

ABBV on 2024+ outlook: *"Today, we are also reaffirming our long-term sales outlook, which includes a return to robust revenue growth in 2025 with a high-single-digit CAGR through the end-of-the decade. Included in this outlook is an updated forecast for Skyrizi and Rinvoq. Based on the impressive growth of both therapies, which we expect will collectively generate approximately $16 billion of revenue in 2024"*

New launches

PFE on new launches: *"We are also looking forward to Phase 3 Data readouts from Vepdegestrant in second line HR+ metastatic breast cancer and Braftovi in first line BRAF colorectal cancer. We also plan to advance our late-stage pipeline with Phase 3 Starts of CDK4 in post-CDK4/6 metastatic breast cancer and B6A in non-small cell lung cancer."*

MRK on new launches: *"In cardiometabolic, we're very excited by the anticipated FDA action on our application for Sotatercept in the United States, which we believe has the potential to transform the treatment journey for many patients suffering from pulmonary arterial hypertension. Our commercial and manufacturing teams are fully prepared with a strong uptake, we expect. Sotatercept is an important component of our growing cardiometabolic pipeline, which we believe has significant long-term potential."*

M&A / Business Development

JNJ on BD: *"We continue to work in identifying deals in our pharmaceutical space that enables us to be able to put all our capabilities to work in the clinical development side, in manufacturing and in commercial, and that's been the source of very significant value creation in products that all of you know, like DARZALEX or CARVYKTI, that come from that type of approach of going earlier on into the development process."*

REGN on BD: *And with regards to business development, I mean, just because we can, it doesn't mean we're going to force something, it has to be right, it has to be a franchise, has to be modality, you've heard George mentioned that it has to be kind of incremental to what we currently have in the clinic here with regards to RGC and the targets we develop and all of that*

See pages 2-7 of this note for additional key thematic quotes from 4Q23 calls

Abbreviations:
IRA: inflation reduction act
BD: business development
M&A: mergers and acquisitions
EGFR: estimated glomerular filtration rate
ESMO: European Society for Medical Oncology
FDA: Food and Drug Administration
CD19: Protein
MS: Multiple Sclerosis
PBM: Pharmacy Benefit Manager
CAR-T: Cell oncology technology
BCMA: B-cell maturation antigen

Key Quotes from 4Q23 Earnings Calls

2024+ Outlook

JNJ on 2024+ Outlook: *"As we look ahead, I have never been more excited about the future of our business. At our enterprise business review, we share that we expect our Innovative Medicine business to grow 5% to 7% from 2025 to 2030, with our industry-leading pipeline and portfolio delivering more than 10 assets that have the potential to generate over $5 billion in peak year sales by 2030. We also expect a further 15 assets to have the potential for $1 billion to $5 billion in peak year sales."*

"Turning to other items on our P&L. We expect our 2024 adjusted pre-tax operating margin to improve by approximately 50 basis points, driven primarily by a continuation of efficiency programs across the organization. We expect this to be partially offset by anticipated STELARA biosimilar entrance in Europe in the second half of this year and some lingering inflation impact in MedTech inventory that will flow through 2024's P&L. This margin improvement encompasses dilution of additional investment associated with our planned acquisition of Ambrx, which will be treated as a business combination. Now we do acknowledge that this 50 basis point improvement simply gets us back to what your models expected given the elevated Q4 2023 R&D investment for new pipeline assets. Regarding other income and expense, we anticipate income to be $1.2 billion to $1.4 billion for 2024. This is less than the 2023 amount driven by the impact of actuarial assumptions on certain employee benefit programs, such as lower discount rates."

"We are comfortable with you modeling net interest income between $450 million and $550 million, consistent with 2023 levels. Finally, we are projecting an effective tax rate for 2024 in the range of 16% to 17%, based on current tax laws and anticipated geographic income mix across our businesses. This tax rate takes into account an increase of approximately 1.5% or 150 basis points relative to the recently enacted Pillar 2 legislation."

"Given all these factors, we expect adjusted operational earnings per share to grow 7.4% at the midpoint for a range of $10.55 to $10.75. Based on the euro spot rate of 1.09 from last week, we do not estimate any currency impact on earnings per share. I'll now provide some qualitative considerations on quarterly phasing for your models. We expect Innovative Medicine sales growth to be slightly stronger in the first half of the year compared to the second half given the anticipated entry of STELARA biosimilars in Europe towards the middle of the year. This headwind will be partially offset by continued uptake from our recently launched products. We project MedTech operational sales growth to be relatively consistent throughout the year, expecting procedures in 2024 to remain above pre-COVID levels. The first half of the year will continue to have modest impact from Russia sanctions as our licenses are approved. We anticipate China VBP pricing for surgical IOLs and orthopedic sports to begin in 2024, with impacts from 2023 VBP in electrophysiology, endocutters, energy, spine and trauma to begin to anniversary throughout 2024."

PFE on 2024+ Outlook: *"Upon achieving our de-levering goals, we anticipate returning to a more balanced capital allocation strategy, inclusive of share repurchases. Now given that we issued our full year 2024 revenue and adjusted diluted earnings per share guidance on December 13th, let me just hit a few of the highlights. We expect total Company full year 2024 revenues to be in the range of $58.5 billion to $61.5 billion, which reflects our expectation of strong contributions across our product portfolio. Importantly, excluding Comirnaty and Paxlovid, we anticipate operational revenue growth of 8% to 10%. We remain confident on delivering at least $4 billion of net savings from our cost-realignment program by the end of this year. We believe right-sizing the cost base will put us on a strong footing towards margin expansion and increased operational efficiency moving forward. With it, we expect adjusted diluted earnings per share to be in the range of $2.05 to $2.25 a share for the full year of 2024. And as a reminder, this range is inclusive of an anticipated $0.40 of earnings dilution from the Seagen acquisition, and again, with the vast majority of this dilution resulting from the financing costs associated with the deal."*

"Our guidance for gross margin, although we don't provide it specifically, we give you some color around the fact that it's approximately 70%. Obviously, our focus going forward is to improve our margin rate and more importantly, improve our operating margin rate to the bottom-line. As we look here at 2024, there is a few things that have compressed our margin rate versus -- as COVID has declined year-over-year, that has served to, I'll say de-lever if you will, the P&L as COVID takes up and covers some fixed overhead. But importantly, what's happening is we are in-sourcing products that we've recently acquired. Those -- that in-sourcing requires time before we get up to peak yield and performance. So, that in the short-term dampens gross margin rate, but has a trajectory to improve gross margin rate over time. And then secondly, we have new launches that are coming online late in Q3 -- or late in the second half of 2023 and moving into '24, again those are not at peak performance yet, that will ultimately improve gross gross margin rate as we cycle into later years. And then finally, I will say that, over the last several years, we have absorbed some amount of inflation within our cost of goods sold. That is an area of opportunity for us as we think about improving performance longer-term. So, I hope that gives you some color."

"R&D came in a little favorable than our expectations previously. A part of this is the fact that we are very focused on realigning our cost base, so consistent with the program. And then secondly, there probably is some timing that's dampening R&D in the fourth quarter that will slide into 2024 and into 2025. So, there is some timing implications to that performance level. But I think importantly, back to my prepared remarks, is, our focus is on delivering net savings of $4 billion and if you look through the end of 2023, about half of that, we have achieved already. We're now focused on achieving the additional $2 billion or so as we cycle into 2024, and all eyes are on that objective."

ABBV on 2024+ Outlook: *"We anticipate updates this year from several important R&D programs including. Approvals for Skyrizi in UC, 951 in the US and potentially accelerated approval for DLBCL in third-line plus follicular lymphoma. We also anticipate regulatory submissions for, our novel short-acting toxin and potentially Teliso-V in advanced non-squamous, non-small cell lung cancer. And third, we are focused on closing and integrating ImmunoGen answerable, these two exciting opportunities represent substantial sources of revenue growth well into the next decade. We remain on-track with the anticipated closing of both deals in the middle of the year. Today, we are also reaffirming our long-term sales outlook, which includes a return to robust revenue growth in 2025 with a high-single-digit CAGR through the end-of-the decade. Included in this outlook is an updated forecast for Skyrizi and Rinvoq. Based on the impressive growth of both therapies, which we expect will collectively generate approximately $16 billion of revenue in 2024, we now anticipate Skyrizi and Rinvoq will collectively exceed more than $27 billion in sales by 2027, with robust growth continuing into the next decade. This updated forecast reflects an increase of more than $6 billion in revenue, compared to our prior 2027 guidance. We expect global sales for Skyrizi, to reach more than $17 billion in 2027, reflecting continued share capture in psoriasis, where we are the clear market-leader, as well as strong uptake in IBD. And we expect Rinvoq to achieve more than $10 billion of global sales in 2027, reflecting continued market growth and share momentum across each of Rinvoq approved indications including four in rheumatology, two in IBD and eight atopic dermatitis. This forecast comprehends modest contributions from several new disease areas for Rinvoq, which we anticipate will be launching in the second-half of the decade."*

BMY on 2024+ Outlook: *"We expect 2024 revenues to increase in a low single-digit range, reflecting our confidence in the growing momentum of our growth portfolio. Excluding Foreign Exchange, we expect revenues to increase in the low single-digit as well. Driving our momentum this year will be increasing the sales in our growth portfolio from products like Opdivo and our recently launched products. As we said previously, we expect a more modest pace of growth than last year for Opdivo, with the potential for acceleration in the back half of the year from new indications. And while our legacy portfolio includes assets that are maturing, we expect strong growth from Eliquis in the US this year."*

MRK on 2024+ Outlook: *"So, as you all know, our company has made great progress in expanding operating margin over a number of years. As we look to 2024, we expect operating margin to improve. And that's really driven by the strength of the topline and mix of revenue by the roll-off of royalties that we've noted in KEYTRUDA and GARDASIL being disciplined in our expenses, while we do invest fully behind our expansive pipeline. As we go beyond 2024, we still point to an operating margin of greater than 40% in 2025, but our focus as a company and as the team is to really ensure that we are fueling the pipeline supporting the portfolio of products that we're launching to drive growth into the long-term."*

"We expect another year of strong growth, driven by key marketed products and we'll begin to benefit from the anticipated launches of impactful new products [ph], such as Sotatercept and V116, we project revenue to be between $62.7 billion and $64.2 billion, representing growth of 4% to 7%. This growth includes a negative impact from foreign-exchange of approximately 2% using mid January rates. The headwind is primarily due to the devaluation of the Argentine peso, which we expect will largely be offset by inflation related price increases consistent with market practice. Our gross margin assumption is approximately 80.5%, which includes the benefit from reduced royalties paid on KEYTRUDA and GARDASIL. Operating expenses are assumed to be between $25.1 billion and $26.1 billion, which includes an approximate $650 million one time charge related to the announced acquisition of Harpoon Therapeutics. As a reminder, our guidance does not assume additional significant potential business development transactions. Other expense is expected to be approximately $200 million. We assume a full-year tax-rate between 14.5% and 15.5%. We assume approximately 2.54 billion shares outstanding. Taken together, we expect EPS of $8.44 to $8.59. This range includes an approximate $0.26 per share charge related to the planned acquisition of Harpoon Therapeutics, which is not tax-deductible and the negative impact from foreign-exchange of approximately $0.25 using mid-January rates, including the impact from Argentina."

New launches / pipeline development

JNJ on new launches: *"In 2024, we expect data readouts for many of these assets, including Phase III trials for TREMFYA in IBD, ERLEADA in early stage prostate cancer, our targeted oral peptide JNJ-2113 in psoriasis, nipocalimab in myasthenia gravis, as well as aticaprant and seltorexant in major depressive disorder. We also expect Phase II readouts for our combination therapy guselkumab and golimumab, JNJ-4804, in psoriatic arthritis, nipocalimab in Sjogren's Disease, and TAR-200 in non-muscle invasive bladder cancer. In MedTech, we share that we expect to grow at the upper range of our markets, which are anticipated to grow by 5% to 7% between 2022 and 2027, and that by 2027, we expect one-third of our revenue to be generated by new products. In 2024, we'll see strong progress towards these goals."*

PFE on new launches: *"Completing the acquisition of Seagen doubled our oncology research and resources overnight, and meaningfully extended the reach and medical impact of our US commercial and medical footprint, with a range of portfolio expansion opportunities boosted by Seagen's broad and deep pipeline. Seagen's in-line medicines are expected to immediately enhance Pfizer's top-line growth, and our combined portfolio provides the opportunity to lead genitourinary cancers, and be a leader in breast cancer, and deliver at least eight potential blockbuster products by 2030.. On the commercial side, the PADCEV launch in locally advanced metastatic bladder cancer in combination with pembrolizumab and XTANDI launch in nonmetastic castration-sensitive prostate cancer. We are excited by the strength of the PADCEV EV-302 data and recent FDA approval, as it represents an opportunity to broaden the reach of this potentially practice-changing, platinum-free regimen to even more patients in the frontline metastatic urothelial cancer setting.. We are also looking forward to Phase 3 Data readouts from Vepdegestrant in second line HR+ metastatic breast cancer and Braftovi in first line BRAF colorectal cancer. We also plan to advance our late-stage pipeline with Phase 3 Starts of CDK4 in post-CDK4/6 metastatic breast cancer and B6A in non-small cell lung cancer."*

ABBV on new launches: "*These are very impressive results considering all patients who were inadequate responders to anti-TNF therapy. And 70% of the patients were Hurley Stage III, which is the most advanced-stage of the disease. Based on these results, we plan to begin a Phase three program in HF later this year. We also plan to evaluate Lutikizumab in ulcerative colitis and Crohn's given the role that IL-1 likely plays in these diseases. Patients with UC who have an IL one beta signature have shown resistance to anti-TNF and other biologics providing strong rationale for a potential biomarker approach. Additionally, we believe Lutikizumab has the potential to be used in combination to provide transformational levels of efficacy in IBD. We plan to evaluate combo approaches with Lutikizumab and Skyrizi as well as with other pipeline assets in Crohn's. Our Phase-II studies in IBD are expected to begin later this year. Our regulatory applications are under review for Skyrizi in ulcerative colitis. With approval decisions expected in the US and Europe later this year. One Skyrizi is approved in UC, along with Rinvoq we will have two assets with different mechanisms of action in IBD both offering very-high levels of efficacy. AbbVie will be very well-positioned with an industry-leading suite of treatment options for patients suffering from moderate-to-severe ulcerative colitis and Crohn's disease.***"***

"We remain on-track to begin a Phase-III monotherapy study in third-line multiple myeloma. This year, and we plan to begin combination trials in earlier lines of therapy. In 2025. In the area of solid tumors, we recently-announced positive topline results from the Teliso-V Phase-II Luminosity study in previously treated non-small cell lung cancer Teliso-V demonstrated strong clinical benefits across key endpoints including overall response rate, duration of response and overall survival with a tolerable safety profile. We believe these results have the potential to support accelerated approval. And we plan to discuss the data with regulators in the coming months. Pending alignment with the FDA our submission is planned for the second-half of this year. We're also making good progress with our next-generation c-Met ADC ABBV-400 which utilizes the same c-Met blocking antibody has Teliso-V but has a proprietary Topo one warhead to afford, deeper and more durable responses with an improved therapeutic index."

REGN on new launches: "*In mid-2024, we plan to start our first clinical trial to evaluate the combination of our muscle preservation antibodies in combination with semaglutide. Also in 2024, we are anticipating proof-of-concept data for Factor XI antibodies in the setting of prevention of venous thromboembolism after knee replacement surgery. Based on preclinical and healthy volunteer data, our anybody approach demonstrated more complete Factor XI blockade compared to competing approaches and development for coagulation disorders and the program is on a rapid path to a registrational trial starting late this year or early next year."*

MRK on new launches: *"In cardiometabolic, we're very excited by the anticipated FDA action on our application for Sotatercept in the United States, which we believe has the potential to transform the treatment journey for many patients suffering from pulmonary arterial hypertension. Our commercial and manufacturing teams are fully prepared with a strong uptake, we expect. Sotatercept is an important component of our growing cardiometabolic pipeline, which we believe has significant long-term potential. In vaccines, the FDA accepted for priority review our filing for V116. If approved, V116 would be the first vaccine specifically designed to address the majority of invasive pneumococcal disease and adults, ages 65 and older. Based on its compelling profile, V116 has the potential to become an important new preventive option for adults, and we believe it can achieve majority market-share in this setting. We look forward to a potential approval in June. And in oncology, we continue to expand into additional tumor types and earlier stages of certain cancers, as well as progress our increasingly broad pipeline of novel candidates."*

"So when we think about the tissue targeting, we think of ADCs. And the answer is I think the ADC field will continue to develop and I think there'll be other payload other linkers, but also the specificity by which you do the tissue targeting in relationship to the antibody may change. There is also clearly evidence of potential movements into peptide drug conjugates that we're interested in, as well as the possibility that the payload is no longer

chemotherapy based, but other sort of compound based. So we're interested in that. In tissue targeting, more broadly, we are interested in -- so we view that as -- okay, that's how we're going to move sort of toxic cell chemotherapy agents into tissue targeting sort of scheme, making chemotherapy precision medicine. But we also are very interested in the IO space in relationship to tissue targeting and that is our foray and that has really helped our proposed acquisition with Harpoon that has a very interesting asset in relationship to tissue targeting and engagers."

M&A / Capital Allocation/ Strategy

JNJ on BD: *"M&A and external innovation has been the core of our pharma portfolio growth and transformation. As I said initially, we are agnostic to sector. In the case of pharma, our preferred mode has been trying to go to assets that were around proof-of-concept. So generally speaking, from a size perspective, it's been about deals that have been either of a smaller size or have been different modalities like licenses or partnerships. Just last year, we completed overall at Johnson & Johnson more than 50 deals. The thing is that the headlines are only made by the ones that are M&A. So we've done multiple deals in our pharmaceutical side in order to be able to enhance our existing portfolio, and our bias is to go for transactions that are going to enable us to create more value by leveraging our clinical development strength, our manufacturing capabilities and our commercial reach. So hence, why the majority of the deals that you see in our pharmaceutical side are at an earlier stage."*

"Are we looking broader than that? Yes, we do, but mainly, we find more opportunities to create value at an earlier stage. For example, this year we did a number of deals that went less publicized. We did, as I commented before, a deal with CBMG, now called AbelZeta, in CAR-T with CD19 and CD20, which we believe could be best-in-class CAR-Ts in this area that could launch in this decade. Or at the end of the year, we also did another deal in antibody drug conjugates with a Korean company called LegoChem, which was underreported. We continue to work in identifying deals in our pharmaceutical space that enables us to be able to put all our capabilities to work in the clinical development side, in manufacturing and in commercial, and that's been the source of very significant value creation in products that all of you know, like DARZALEX or CARVYKTI, that come from that type of approach of going earlier on into the development process."

PFE on BD: *"And then, once we bring our de-levers to the levels that we are aspiring, we will start also moving into share buybacks, and of course, M&A, which means that for '24, we will see everything in existence, because we never say never to business development opportunities could come. But our strategy, it is that you will not see anything major in business development in terms of dollars."*

MRK on BD: *Now turning to capital allocation, where our strategy remains unchanged. We will prioritize investments in our business to drive near and long-term growth. We are excited by the significant progress our team has made to advance and augment our innovative pipeline in 2023. In 2024, we will increase this investment, including the initiation of more late-stage clinical trials across multiple novel candidates, each of which has significant potential to address important unmet medical needs. We remain committed to our dividend and plan to increase it over-time. Business development remains a high-priority. We maintain ample capacity, given our strong investment-grade credit rating and cash-flow, to pursue additional, science-driven, value enhancing transactions going-forward. We will continue to execute a modest level of share repurchases.*

BMY on BD: *"As we've discussed previously, as we think about capital allocation, business development continues to be a top priority for us. Obviously, we've just executed a number of deals towards the end of last year, and we've got to stay focused on executing those deals. Having said that, we certainly are going to continue to be interested in bringing innovation into the company that makes strategic and financial sense to do. So I would characterize those a bit more as bolt-on opportunities at this point. We're also, of course,*

continuing to look at partnerships and licensing deals as well. But that's how I would characterize it."

REGN on BD: *"And with regards to business development, I mean, just because we can, it doesn't mean we're going to force something, it has to be right, it has to be a franchise, has to be modality, you've heard George mentioned that it has to be kind of incremental to what we currently have in the clinic here with regards to RGC and the targets we develop and all of that."*

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