Guardant Health

Q4 2020 Earnings Call

Operator: Ladies and gentlemen, thank you for standing by, and welcome to the Guardant Health Q4 2020 Earnings Conference Call. At this time, all participant's lines are in a listen-only mode. After the speakers' presentation, there will a question and answer session. To ask a question during the session you will need to press star one on your telephone.

Please be advised that today's conference is being recorded. If you require any further assistance, please press star zero. I would now like to hand the conference over to your speaker today, Ms. Carrie Mendivil. Thank you. Please go ahead, ma'am.

Carrie Mendivil: Thank you. Earlier today, Guardant Health released financial results for the quarter and full year ended December 31st, 2020. If you've not received this news release or if you'd like to be added to the company's distribution list, please send an e-mail to investors at guardant health dot com. Joining me today from Guardant Health is Helmy Eltoukhy, Chief Executive Officer; AmirAli Talasaz, President; and Mike Bell, Chief Financial Officer.

Before we begin, I'd like to remind you that management will make statements during this call that are forward-looking statements within the meaning of federal securities laws. These statements involve material risks and uncertainties that could cause actual results or events to materially differ from those anticipated.

Additional information regarding these risks and uncertainties appears in the section entitled forward-looking statements in the press release Guardant issued today. For a more complete list and description, please see the Risk Factors section on the company's annual report on Form 10-K for the year ended December 31st, 2020, and in its other filings with the Securities and Exchange Commission.

This call will also include a discussion of certain financial measures that are not calculated in accordance within generally accepted accounting principles. Reconciliation to the most directly comparable GAAP financial measure may be found in today's earnings release submitted to the SEC. Except as required by law, Guardant disclaims any intention or obligation to update or revise any financial projections or forward-looking statements, whether because of new information, future events or otherwise. This conference call contains time-sensitive information and is accurate only as of the live broadcast, February 24th, 2021.

With that, I'd like to turn the call over to Helmy.

Helmy Eltoukhy: Thanks, Carrie. Good afternoon and thank you for joining our fourth quarter and full year 2020 earnings call. We founded Guardant with a mission to improve outcomes for patients across the continuum of cancer care. The cornerstone of everything we do at Guardant is motivated by this commitment to serve patients. I am particularly encouraged by the resilience and perseverance of our team to maintaining this commitment despite the strain that the pandemic has presented to the care delivery systems in the U.S. and abroad. And so, consistent with these values, I will start off our call with a patient story.

Shortly after giving birth, a 43 year old woman was diagnosed with metastatic cancer. By the time of her diagnosis, her cancer had progressed so aggressively that she was not a candidate for chemotherapy. She was extremely weak, only able to drink a bit of water throughout the day. The hospital immediately brought in palliative care and began making plans to bring her to a hospice. At the same time, her oncologist ordered a Guardant360 test and receive the results within a matter of days.

Results showed a RET mutation and her oncologist was able to confirm with a PET CT scan that she had non-small cell lung cancer. He immediately made the decision to put her on Gavreto, a targeted therapy for patients with RET positive metastatic

non-small cell lung cancer. It arrived the next morning and the patient was able to begin treatment just 18 hours after getting her Guardant360 test results.

Within four days, she was already showing encouraging progress. She was much more alert and awake, eating throughout the day, and able to hold her newborn daughter. Her story demonstrates how critical time can be when treating patients with aggressive late stage cancers and how our liquid biopsy platform can rapidly produce results to enable oncologists to make quick treatment decisions and match them with cutting edge therapies.

There is no doubt that 2020 was an extraordinarily challenging year. I could not be more proud of the Guardant team for their steadfast commitment to serving cancer patients in our core business as well as our recent efforts to alleviate the testing gap during the pandemic by assisting with COVID testing for underserved communities.

Despite all the macro challenges throughout 2020, we continued to make important progress across both our commercial business and product pipeline. We ended the year with $287 million in revenue, growing 34% over 2019. In therapy selection, clinical volumes for Guardant360 grew 27% to 63,254 tests. Clinical growth was strong despite a virtual selling environment

and widespread office closures which recent data has shown resulted in a 65% decline in new patient diagnosis this year.

We continued to make progress on the reimbursement front and now have more than 200 million covered lives for non-small cell lung cancer and more than 100 million covered lives for multi cancer testing. This progress in reimbursement led to 70% growth in our clinical revenues compared to the prior year.

We received FDA approval for Guardant360 CDx for use in any cell (INAUDIBLE), and added companion diagnostic to identify non-small cell lung cancer patients with EGFR alterations who may benefit from treatment with Tagrisso. Following this approval, we launched two versions of our Guardant360 test: Guardant360 CDx, the FDA-approved version of our assay; and Guardant360 LBT, the next-generation version of the assay that offers additional biomarkers. We also announced three new CDx partnerships with Janssen, Amgen, and Radius Health.

In recurrence monitoring we initiated multiple studies which are aiming to establish clinical utility for the detection of ctDNA in the adjuvant setting in colon cancer. And in early detection, we continued to make progress enrolling patients in our ECLIPSE study, onboarding more than 150 enrollment sites exceeding our target and are on track to complete enrollment in 2021.

Looking at the fourth quarter, we ended with $78.3 million of revenue, growing 25% over the fourth quarter of 2019. Clinical volumes for Guardant360 grew to 17,353 tests, a 14% increase compared to the fourth quarter of 2019. After the successful launch of Guardant360 CDx in September, we were encouraged by the acceleration of volume and addition of new customers that we saw in October. Unfortunately, the COVID resurgence adversely affected access to oncology accounts with office closures approaching early pandemic levels towards the middle of November and for all of December.

Despite these extraordinary challenges, we are encouraged by the growth of not only Guardant360 test orders, but by the continued growth in the total number of oncologists ordering our tests per quarter, another record number in Q4. We are confident that outside of the impacts related to COVID, the fundamental drivers of adoption for liquid biopsy remain intact. This belief is certainly bolstered by the strong recovery we are seeing at the beginning of this quarter from the lows in December.

Outside of the United States, we continue to make progress and are investing in programs to expand global access to our liquid biopsy program. We have partnered with one of the premier cancer centers in Spain, Vall d'Hebron Institute of Oncology, to help build a liquid biopsy lab that will physically bring our technology to Europe. We have also achieved critical regulatory

accreditations, including CE marking for Guardant360 CDx, and important ISO certifications.

In APAC, through our joint venture, we are also making excellent progress in expanding our commercial reach with testing now being provided in over 40 countries. I'm excited to announce that we recently submitted our application for regulatory approval in Japan, and our new lab is expected to be operational in Japan later this year. Looking ahead in 2021, we expect revenues to continue to increase over 2020 with accelerated growth in the second half of the year. I believe this will be a pivotal year for Guardant as we continue to invest across our business to build the foundations for complete cancer testing across the continuum of care.

In our therapy selection business, we expect to continue to expand the utility of Guardant360 with additional approvals, clinical data, as well as broadening use of the test in the molecular response and monitoring settings. These developments will serve to grow the total addressable market from $6 billion today as these new applications of liquid biopsy take hold.

We are also very excited for the upcoming launch of our first tissue product, which we believe will address the unmet need that persists in the therapy selection market due to the challenges with many of the existing tissue offerings. In recurrence monitoring, we are breaking new ground just as we did

with Guardant360 several years ago, ushering in a new era of precision oncology for earlier stage patients through the launch of Guardant Reveal last week. This launch marks our formal commercial entry into the estimated $15 billion opportunity of residual disease detection and recurrence monitoring that we believe will only grow as clinical and as pharma applications of this technology increasingly become a new standard of care.

In screening, we expect to complete enrollment of our ECLIPSE colorectal cancer screening trial and expand into other cancer types, addressing an estimated $50 billion screening opportunity. We also significantly strengthened our balance sheet with two capital raises during the year, ending 2020 with $2 billion in cash. With this capital, we are well positioned to aggressively invest in 2021 and beyond, which will more firmly secure and open up a massive opportunity to transform cancer care for millions of patients.

With that, I will now turn the call over to AmirAli for more detail on our biopharma business and our pipeline activities.

AmirAli Talasaz: Thanks, Helmy. Starting with our biopharma business, sample volume in fourth quarter of 2020 was 4,841 tests, 23% below the prior year period. However, volume were up 58% from the third quarter of 2020, reflecting partial recovery from COVID, but more so the year end rush for sample

analysis. Developed services and other revenue grew 148% to $13.6 million, reflecting our growing pipeline of CDx partnerships and prospective studies. We are pleased with our progress in pharma testing volumes and growing CDx partnerships. However, in the first half of the year, we expect the impact of COVID to continue to be felt with slower trial enrollment, delaying sample volumes, as well as CDx development services.

We are seeing significant interest in our companion diagnostic business following FDA approval of Guardant360 as a companion diagnostic for osimertinib. We are pleased to announce that we have submitted supplemental PMAs for our collaboration with Janssen with Amivantamab and with Amgen for Sotorasib. The selection of Guardant360 CDx as the frontline liquid biopsy device of choice in these two programs demonstrates the growing confidence of biopharma in our IVD offering.

FDA granted priority review or breakthrough therapy designation for these therapies, and we expect accelerated review by the agency. We believe liquid biopsy test can add additional clinical benefit to cancer patients beyond just treatment selection. We have over 40 publications that demonstrate that a second liquid biopsy test a few weeks after treatment initiation can segment responders versus non-responders across multiple tumor types and multiple classes of therapies.

These are exciting days for liquid biopsy, and it's clear that as more of these tools become part of clinical practice such usage will usher in even more applications, many that we cannot even imagine today.

Now turning to our LUNAR program. As Helmy mentioned, last week we were excited to announce the launch of Guardant Reveal, the first blood only liquid biopsy test for the detection of residual and recurrent disease. With a simple blood draw, this test improves the management of early stage colorectal cancer patients by detecting ctDNA in blood after surgery to identify patients with residual disease who may benefit most from adjuvant therapy and by detecting recurrence months earlier.

Guardant Reveal is in a class of its own with industry leading sensitivity and specificity, an average turnaround time of only seven days compared to other tests that require tissue biopsy and also have turnaround times of four to eight weeks. CEA, which is the current standard of care, has a sensitivity of 69% with 64% specificity in the survey line setting versus 91% sensitivity with 100% specificity for Guardant Reveal. This level of performance has been achieved through analysis of over 400 kb of genome spanning across thousands of regions that may contain somatic mutation or methylation signals from CRC.

It is vital that oncologists have better tools to quickly identify those high risk patients who may benefit from

escalation or de-escalation of treatment. The platform technology we use for our MRD test is based on the integrated analysis of somatic genomic and methylation changes, which have potential for detecting tumor types with high level somatic mutations or reach differential methylation patterns. Besides CRC, we have exciting feasibility data in other cancer types like lung and bladder, which gives us confidence that our blood only MRD test will continue to have market leading performance as we expand Guardant Reveal to multi-cancer types in the near future.

Turning to ECLIPSE, we continued to see robust patient enrollment throughout the fourth quarter. We have now over 150 sites actively enrolling patients. Overall we are pleased with our progress and are on track to complete enrollment in 2021. If successful, ECLIPSE will play a pivotal role in regulatory approval and reimbursement of our liquid biopsy screening tests. We are starting to plan our next screening clinical trial in other cancer types and expect to share more updates about this in the latter part of 2021.

With that, I will turn the call over to Mike for more detail of our financials. Mike?

Mike Bell: Thanks, AmirAli. Total revenue for the fourth quarter of 2020 was $78.3 million, up 25% from $62.9 million in the prior year quarter. This growth was driven by a year over

year increase in both precision oncology testing revenue and development services and other revenue.

Total precision oncology testing revenue for the fourth quarter was $64.7 million, a growth of 13% compared to $57.4 million in the prior year quarter. Precision oncology revenue from clinical tests in the fourth quarter was $45.9 million, up 47% from $31.3 million for the prior year quarter.

Fourth quarter clinical test volume was 17,353, up 14% from the prior year quarter. The chemical test average selling price was $2,643 in the fourth quarter of 2020, up from $2,049 in the prior year period. The 29% increase in the clinical test ASP over the prior year quarter was principally due to expanded Medicare coverage of non-lung cancer tests which commenced in March 2020, and our success in gaining private pay coverage of our tests. Although clinical test volume increased sequentially by two percent in the fourth quarter compared to the third quarter of 2020. Clinical test revenue of $45.9 million, decreased by $2.4 million compared to $48.3 million in the third quarter of 2020. This was primarily due to quarter-over-quarter fluctuations in the revenue recognized from cash collected for tests performed in the prior periods, which in the fourth quarter of 2020 was three million lower than in the third quarter of 2020.

Precision oncology revenue from biopharma testing in the fourth quarter totaled $18.8 million, down 28% from $26.2 million for the prior year quarter, though sequentially up 57% from $12 million in the third quarter of 2020.

Fourth quarter biopharma tests totaled 4,841, down 23% from the prior year quarter. However, sequential test volume was up 58% in the third quarter of 2020 due to a partial recovery from the COVID and the usual year end seasonality. Biopharma test ASP was $3,892, down slightly from $4,142 in the prior year period due to changes in the mix of tests performed. Development services and other revenue in the fourth quarter totaled $13.6 million up 148% from the prior year quarter.

Gross profit for the fourth quarter of 2020 was $49.9 million, compared to a gross profit of $41.1 million in the same period of the prior year. Gross margin in the fourth quarter was 64%, compared to 65% during the fourth quarter of 2019. We expect our gross margins to continue to be in the mid-60s range for the foreseeable future as we launch new products such as Guardant Reveal, which will take time to gain reimbursement coverage from Medicare and from private payers.

Total operating expenses for the fourth quarter of 2020 were $141.1 million, a 110% increase from $67.0 million in the fourth quarter of 2019. This change was driven by an increase of $51.3 million in stock based compensation expense primarily

related to market based restricted stock units granted to the company's founders in May 2020, as well as our continued investment in developing and commercializing new products and services and in scaling our operations.

In 2021 we expect stock based compensation expense to be between $170 and $180 million for the full year. In addition, we expect operating expenses to accelerate in 2021 as we continue to invest in our leader program, ECLIPSE study, and other development activities as well as launch new products and expand our commercial organization in both the U.S. and internationally.

Net loss attributable to Guardant Health's common stockholders was $93.7 million or $0.94 per share for the fourth quarter of 2020, compared to $25.2 million or $0.27 per share in the fourth quarter of 2019. Adjusted EBITDA was a loss of $29.8 million in the fourth quarter of 2020, compared to a $17.1 million loss in the fourth quarter of 2019. As a reminder, we define adjusted EBITDA as net loss attributable to Guardant Health adjusted for stock based compensation, interest, income tax, depreciation, amortization, other income and net expense, non-controlling interest, contingent consideration, and acquisition related expenses.

Turning now to the full year 2020. Total revenue was $286.7 million, a 34% increase from $214.4 million in 2019. Precision

oncology revenue increased 31% to $236.3 million, and was comprised of clinical testing revenue of $171.8 million, which grew 70% year over year and biopharma testing revenue of $64.5 million, which declined 19% year over year.

Despite the adverse impact of COVID, clinical test volumes for the year grew to 62,254, up 27% year over year from 49,926 tests. The average revenue recognized for clinical tests in 2020 rose 34% from the prior year, primarily as a result of the expanded Medicare coverage of non-lung cancer test which commenced in March 2020, and our success in gaining private pay coverage of our tests.

Clinical revenue for the year ended December 31, 2020 also included $11.9 million in revenue for payments from Medicare from peers to samples processed in prior years compared to $6.8 million in revenue in 2019. The company does not expect to continue to receive payments of required revenue for these specific appeals in 2021.

Biopharma testing volume was also impacted by COVID in 2020 and despite the partial recovery in the fourth quarter, declined 23% year over year to 15,983 tests. Development services and other revenue grew 49% to $50.4 million in 2020, reflecting our growing pipeline of CDx partnerships and prospective studies. Net loss attributable to Guardant Health common stockholders was $253.8 million compared to $75.7 million in 2019. Net loss per

share was $2.60 in 2020 as compared to $0.84 in 2019. Adjusted EBITDA was a loss of $85.2 million in 2020 compared to a loss of $53.3 million in 2019. We ended 2020 with $2 billion in cash, cash equivalent, and marketable securities.

Now turning to our revenue outlook for the full year 2021. Despite the fact that we are still in the midst of a global COVID pandemic, we view the fundamental drivers of our business to be very strong, and as such expect 2021 revenue to be between $360 and $370 million, representing growth of approximately 27% of the 2020 at the midpoint of the range. We expect clinical sample volume for 2021 to be greater than 90,000 tests, which represents growth of at least 42% over 2020.

Embedded in our outlook are a few key assumptions around reimbursement. Firstly, we anticipate that the upcoming billing code change to Guardant360 CDx in April to an ADLT PLA code may have a short term impact on private payer reimbursement, which could offset any positive impact we received from an increased ADLT reimbursement rate from Medicare. Secondly, although we are excited about the launch of new tests such as Guardant Reveal, it will take time to receive Medicare coverage and subsequent private payer coverage. An offset we do not expect the 2021 revenue to be material for these new tests.

As Helmy and AmirAli both mentioned, we are still experiencing COVID related impacts across our clinical and

biopharma businesses and we anticipate that these impacts will continue in the first half of the year. Specifically, in the first quarter of 2021 we expect to see a reduction in biopharma volume compared to the seasonally high fourth quarter of 2020.

Furthermore, as I mentioned earlier, we do not expect to record revenue in 2021 for Medicare payers for samples processed in prior years, which in the fourth quarter of 2020 totaled 4.6 million. As a result of these factors, we expect revenue in the first quarter of 2021 to be sequentially lower than in the fourth quarter of 2020. However, as we move beyond some of the COVID headwinds including transitions in the first half of 2021, we expect revenue growth to accelerate back above 30% by the end of the year.

At this point, I would like to turn the call back to Helmy for closing comments.

Helmy Eltoukhy: Thanks, Mike. Before closing, I want to again thank our team at Guardant for the dedication and effort they have shown, particularly over the past few quarters. I believe that 2021 will be an unprecedented year for Guardant as we are bringing to fruition the vision we had when we founded the company of significantly improving outcomes across the entire continuum of cancer care. Indeed, this will be a pivotal year in terms of the number of product launches and the planned breadth of our product portfolio.

I'm confident that these product launches will serve as drivers for strong growth in 2022 and beyond. These new products also mark an important inflection point as we begin to transform Guardant from the leading liquid biopsy company to the leading cancer testing company.

With that we will now open it up to questions.

Operator: As a reminder, if you would like to ask a question you will need to press star one on your telephone. That is star one on your telephone if you wish to ask a question.

Your first question comes from the line of Brian Weinstein with William Blair.

Brian Weinstein: Hi, hey guys. Thanks for taking the questions. A lot to get into here, but, you know, we've heard a lot of companies this earnings season talk about significant investments going into 2021 given all of the new products that are out there. I'm curious if you can talk about the specific investments that you are making.

I heard in the prepared comments, Mike had made some comments about OpEx going up. But more specifically, can you talk about where those investments are going and give us some idea around those, specifically around things like preparing for the CRC launch. Which, you know, is still a little bit of ways but something that you have to, you know, start to be thinking about. Or commercial efforts for the MRD assay as you think

about scaling that up or anywhere else. I'm just curious where you think the key areas are for investment this year.

AmirAli Talasaz: Hey Brian, nice to talk to you again. Yeah, we're making investments across our organization. I'll start and then let maybe Mike fill it in. But certainly, it's focused on our pipeline activities and R&D in terms of investing, you know, certainly in these new products and new trials that, you know, we have kind of some R&D for new programs we have and certainly scaling up the commercial side of the organization. Obviously, these new products aren't going to sell themselves. We're expanding into other parts of oncology and also starting to think about as we race down the finish line of the close, really the commercial planning stages for that program.

Mike Bell: Yeah. Maybe just to add, Brian, yeah. For this, yeah, particular year of investment, as you mentioned. And when we look at the operating expense, yeah, we think that's going to ramp up as we make new investments. Something like an increase of, you know, $150 to $180 million increase over the year compared to 2020. So, yeah, that's what we're looking at for this year coming.

Brian Weinstein: Got it. Thank you. And then, as it relates to Reveal, can you talk more about kind of the basis of competition here? How it may be different than other products in

oncology-based diagnostics and if you think that having G360 already in the market clinically is something that provides you any kind of clinical advantage when talking to clinicians. Thanks.

Helmy Eltoukhy: Maybe AmirAli can take that one.

AmirAli Talasaz: Yeah, sure. So one thing, actually, we are just a couple of weeks into this commercial activity around Guardant Reveal. But so far, I can tell you it's super good. Very excited with the enthusiasm that we are seeing really many of our KOLs and technology enthusiastic and early adopters that we are targeting at this stage are overlapping.

We decided to put people we interacted with for Guardant360. They have kind of pretty good respect for the quality of the product and services that they've got from Guardant Health throughout the years. Here, I made--I'm actually very happy with the fact that we are a blood-only test that does not really depend on having access to tumor tissue and also with pretty markedly in performance.

So while logistically it's much better, turnaround time is much better. It doesn't kind of, you know, sacrifice of the clinical sense if you can specificity for their patients. Really, the way they are comparing us with is with CEA, a standard of care that's not a retail conversation that we are having with the doctors at this time. And the delta between

Reveal and CEA is very obvious. You know, performance of 64, 69 versus 90, 100 is, I think, a very big delta that generates a lot of good excitement.

Operator: Your next question comes from the line of Tycho Peterson from JPMorgan.

Tycho Peterson: Hey, thanks. A similar line of question on the tissue launch. Just curious, you know, A, what you think the market was really missing between, you know, foundation care and some of the others. You know, if you could probably, you know, confirm specific launch timelines and how you're thinking about, you know, share capture and then also the FDA approval pathway?

AmirAli Talasaz: Yeah, no thanks. Thanks, Tycho, for the question. It's something we obviously have, you know, thought about for some time. You know, it was really a matter of when, not if. And when we look at the tissue space, I think we were still, you know, quite surprised at, you know, how much of a challenge ordering these tissue tests, you know, continues to be.

If you think about it, the end to end time from a physician's point of view is three to four weeks. You know, I know a lot of them say they're, you know, 10 days, 14 days. But in terms of the tissue acquisition actually getting the results back, it really takes three to four weeks which is a nonstarter in terms of the time to treatment decision and urgency that an

oncologist has in the frontline setting. And so we realized that if we push the reins into our owns hands of CGP and really catalyzing the market, that, you know, if we developed our own tissue test we could really integrate that with our current offerings and provide a user experience, a customer experience that is completely differentiated in terms of getting more markers faster and quicker and more completely.

And, you know, that's really the experience that we expect to be able to provide to physicians. So in--so the way we think about it is that in the base case, we'll be able to catalyze faster adoption of a blood-first paradigm in the market and I think in the--both case, we'll certainly be able to take a considerable share from some of the existing players.

But some of the challenges, I think, that exist are that, you know, there's still a large percentage of patients, you know, over 50% of patients that aren't genotyped comprehensively and even more that aren't genotyped in the online setting before the trigger is pulled for treatment. And that's the challenge, and that's an unmet need we think we can squarely address with a--with this tissue offering. We haven't released timelines at this point in terms of the products but stay tuned.

Tycho Peterson: Okay, that's helpful. And then on G360, just curious how we should think about the mix, you know, between G360 and the LBT?

AmirAli Talasaz: Yeah. So I think you can imagine that, you know, both 360 CDx and 360 LBT is gonna have their own life cycle management. You know, CDx most probably is going to get updated as a IVD grade device and with less frequency than Guardant360 LBT as a, you know, peer grade device.

I think the LBT in our portfolio would really enable us to be nimble and add newly upcoming biomarkers and the clinical practice around the pharma trial practice actually faster into our offerings. And CDx would be--go through the revisions with, you know, lower frequency as I mentioned. But both of them are gonna get operated, you know, for the foreseeable future.

Tycho Peterson: Okay. Last one, just curious, you know, as we think about the ECLIPSE study kind of getting, you know, wrapped up later this year. Any comments you guys can make on, you know, follow-on studies for, you know, lung, breast, some other indications?

AmirAli Talasaz: Yeah, sure. Actually, we are pretty excited about this topic, you know. The--I think--when was it? Like, starting two years ago when we talked about our ambitions around early cancer screening, even before that, we talked about four cancer types that at the time there were four strains. CRC was one of them. The other one was lung cancer, breast cancer, and ovarian cancer. Eventually, I think some pilot data for some of the cancer types earlier.

And we made some progress for some of these cancer types. So, we believe the platform technology that we have that integrates the genomic biomarkers with epigenomic and on the epigenomic side, methylation plus all the structural changes as a result of fragmentation pattern changes. It's super-duper powerful to find cancers in various stages of disease and we are happy we saw the feasibility data that we've seen in other cancer types that I think it's really the prime time that after we really get ECLIPSE to a hopefully, you know, the last innings of it, we start talking and doing some clinical trials around other cancer types. The future of our donor program would be a multi-cancer screening program. But CRC continue to be our lead indication in this marketplace.

Tycho Peterson: Okay, that's helpful. Thank you.

Operator: Your next question comes from the line of Doug Shankle from Cowen.

Doug Shankle: Hey, good afternoon guys. Thank you for taking my questions. I want to start with a high level question, and then I want to come back and talk about something specifically on Guardant Reveal.

So first, the high level question. You know, I think it's fair to say that you guys established yourself as, you know, early on one of the adults in the room when it comes to developing liquid biopsy tests in a responsible way. You know,

you quickly got a seat at the table early with the FDA and CMS and groups like AACR. You know, this put you in a position to not just launch G360, but to do it successfully with clinical and regulatory rigor that resembles, you know, what those of us who grew up in biopharma saw there but didn't see often in the early days of diagnostics.

That said, you know, the market's getting more crowded as menus from competitors seem to be evolving in a way where, you know, it looks like there's gonna be four to five companies down the line that look quite similar in terms of what they offer, what their menu looks like. And I think that's gonna happen in the next four to five years, if not sooner. That's long been our view, but it--you know, I think the pace of moving towards that is accelerating. I mean, even you guys as come up a couple of times on this call launched a tissue product and the MRD product is, you know, coming to market a lot more quickly than we anticipated.

So my question is, you know, how should we expect Guardant to differentiate over the long term when, you know, you and four or five other companies have a menu that goes from multi-cancer and single cancer screening to therapy selection in blood and tissue, to monitoring? You know, how--what's going to differentiate Guardant from others in the long term?

AmirAli Talasaz: That's a great question, Doug, and one that, you know, obviously we spent a lot of time on thinking as a company.

You know, it's not just one dimension that differentiates us. You know, even in therapy selection when we launched, you know, there are probably, you know, a couple dozen companies in the lipid biopsy space and so you know, on the surface, you could say that, you know, there's always been competition, that there's always been a crowded field. But in reality, it's really the quality, the, you know, the level of performance of these products, the level of clinical evidence that supports them, really the customer service channel, the white glove service that we provide, you know, billion in reimbursement.

It really takes, you know, five or six different dimensions to really change a standard of care, you know, change clinical practice in health care, as you all know. And we believe that we are second to none in each one of those as I mentioned, not just in therapy selection, but really taking that same approach to these new products that we are launching as well. And so yeah, I know we--we're actually, I think, pleasantly surprised by how much differentiation still continues to exist with 360 versus, you know, every other product that has been launched that's out there and it's no different with the Reveal.

You know, on the surface you can say, oh, there's a bunch of companies working on MRD. But, you know, Reveal now is really the only, what we believe, true liquid biopsy in the market that's tissue independent, that, you know, really has the advantage of liquid without any disadvantage in terms of performance, on customer service and customer experience. And so if you think about it, you know, they're the one company that really does spend that entire continuum of care, that has a very strong channel in oncology market.

Over 9,000 oncologists have ordered our test and so it's probably a broad reimbursement for, you know, products like Guardant360. And so we're, I think, very pleased with how the market is shaping. The last thing I'll say is that competition's important because it defines markets, it brings awareness to new products, and, you know, I think it really allows, you know, physicians to understand kind of--and clients and customers to understand really the use cases and, you know, what good looks like. It's hard to really have differentiation in terms of the performance of our products and the performance of our services without a backdrop to compare it to.

Doug Shankle: Thanks for all of that. That's helpful and interesting. And now for the Reveal-specific question. You know, in your recent presentations and press release, I think you indicated that Reveal has a sensitivity of 91%. You talked about

that in your prepared remarks today as well. I believe this improvement is at least in part attributable to the fact that on top of methylation markers, you've now added genomic alteration assessment to the assay. I may be oversimplifying or maybe misstating this, but, you know, assuming I'm going down the right path I'm just wondering if the addition of these additional markers, which seemed to be important to improving performance have led to any other compromises as part of the assay.

Specifically, I'd love to just hear if you think you need to--if basically you require a larger sample size to accommodate the additional markers on this assay. And then a, you know, probably a more simple question, and I know it's early, but I believe that most would assert that there is an inherent advantage to using a non-bespoke test versus a tumor-informed test if there are not other compromises required. I know that's your belief. Are you hearing anything in terms of early market reaction or market research that is consistent with that view? Thank you.

AmirAli Talasaz: Thanks, Doug. Regarding the core platform technology for Reveal, maybe starting with that 91% sensitivity that I mentioned in the script. Actually, that's the sensitivity in the surveillance in a one year trying to detect early

relapse, which is the maturity of actually the opportunity in the CRC setting.

Now this is the exact same assay that we are using in our clinical trials for COBRA and Stand Up To Cancer insight, except some process improvement happened for scalability of this device, you know, for, you know, potential huge uptake of this device in the years to come. So it's not the process and operational infrastructure has included for a device, but the assay and impacted performances very, very similar to what we are doing in our interventional studies, COBRA, Stand Up To Cancer and some other studies. But yeah, the core platform is based on combining and integrating multi-mode of information from the same cell-free DNA fragment. Which in this case, we are combining somatic end stage non-methylations for--in MRD setting.

Reactions of KOLs and the target list that we had, you know, still it's--as I mentioned, it's early. We are in the second week of this commercial launch, but all the conversation so far has been very, very positive. And I think this is really resonating with customers that we target to so far that a blood only assay can really help their practice tremendously and really, they are comparing their performances with other blood only standard of care assay like, you know, CEA.

And they're seeing that the performance and the promise, there's a big delta in terms of performance on promise here and that generates a lot of excitement. Having said that, you know, we think it's gonna take some time for adoption of this test. You know, multiple conversation needs to happen and, you know, in order for this thing to get--this test get adopted. But we are super pleased with the early reaction of the market to what we put out there.

Doug Shankle: Thank you for that. And just one thing I may have missed in that answer. In terms of the sample size requirement, nothing different with the current version, recognizing that it's pretty consistent with what you were doing as part of that other study?

AmirAli Talasaz: Yeah, it's the same. Actually, we--the number of blood tubes, if you may, in terms of sample types, it's the same number of blood tubes that we are getting for our clinical trials. So it's exactly the same. It's more--we made it more scalable on some of the infrastructure and operation aspects of it, but the device is the same device.

Helmy Eltoukhy: Yeah, just because, you know, the genomics simultaneously doesn't reach the (INAUDIBLE) input quite (INAUDIBLE).

Doug Shankle: Okay. All right. Thank you very much.

Operator: Your next question comes from the line of Puneet Souda from SVB Leerink.

Puneet Souda: All right, great. Thanks, Helmy and AmirAli. First question I have is on guidance. You're projecting 90,000 in terms of test volumes here, which feels pretty robust. But the revenue growth for the full year is coming in slightly lower than what we had anticipated. And so I just want to hear--and the, you know, you're pointing out biopharma volume reduction in the first quarter and Medicare appeals also not being included.

So I completely hear you on that. But just wondering, maybe could you give us a view of where you stand in terms of the demand that's coming through for biopharma services, OMNI, G360 currently? And what is the demand outlook from biopharma in throughout the year? Because as I view it, not only you'll see a demand from those products, but you also see demand from the recurrence monitoring product and potentially some other products that you could potentially launch. So I just want to get a sense on how should we view the biopharma growth?

Helmy Eltoukhy: I'll let Mike take this.

Mike Bell: Yeah, Puneet. You know, I think when we look at the biopharma growth, I mean, we think that's gonna be strong. We think it'll be, you know, low double-digit growth. So carrying on that sort of robust performance. I think, you know, you mentioned that bit of a difference, even though we talk

about strong clinical volume, maybe a bit of a difference from the numbers that you had. And I think the main driver there is on the clinical ASP.

You know, we saw the ASP being around 2,600 in the fourth quarter and that's probably likely to be the ASP throughout 2021. I laid out some assumptions on reimbursements around new products and not expecting reimbursement for those and no material revenue for those and also, potentially, the issues with private payers as we switch CDx to an ADLT PLA code. So I think, really, the discrepancy is not coming from biopharma volume which we, again, we think is strongest more on the ASP assumptions that are out there.

Puneet Souda: Okay, that's very helpful. And then, on the ECLIPSE study. Helmy, it appears the enrollment is progressing well. Wondering if we should expect anything, any other data sets that were smaller cohorts and whatnot. And maybe AACR, you have DDW coming up as well and at ASCO. Could you maybe just elaborate, you know, potential for any data sets--smaller data sets there? And again, if you could just maybe clarify on the timing of the readout here for ECLIPSE because I think that's highly anticipated among investors.

Helmy Eltoukhy: I'll go with AmirAli.

AmirAli Talasaz: Yeah, sure. So, in terms of the upcoming data you could imagine like, you know, major congresses we are

now continuing to provide some additional data. And in fact, our collaborators are going to contribute a lot of data. You know, we gave access to our device to a bunch of, you know, collaborators to assess the performance of our straining assay in different cohorts.

Having said that, all those cohorts is kind of in a biobank setting, and there are similarities between the type of data we showed before versus what is going to get presented. But I think so far, all the data are positive and, you know, more to come in different congresses. But in terms of a data set similar to what we expect from ECLIPSE, which is prospective screening of 10,000 patients, you know, we are not gonna have such data until we really get it from ECLIPSE. So we need to be still patient for that study to finish.

Puneet Souda: Okay. And then, lastly. And then--yeah, go ahead.

AmirAli Talasaz: Yes. Please repeat the second part of your question. I missed the (INAUDIBLE).

Puneet Souda: Yeah. I mean, it was just in terms of the, you know, sort of the timeline for ECLIPSE. And given the, you know, the growth, you know, the robust enrollment that you're seeing here?

AmirAli Talasaz: Yeah. So, so far, actually, we are expecting that the study would finish by the timeline that we

always mentioned. So through COVID we had ebb and flow, up and downs. But overall I think we are on track to finish this study on the timelines that we always mentioned. So, so far, so good. We'll see how it continues during the remainder of the next few months.

Puneet Souda: Okay, great. And last one, if I could squeeze in, on MRD and recurrence monitoring. Obviously, you have had data here in CRC. But when we look at another competitor in the space, you know, there is--there are slightly more publications, more data sets that have come out. Obviously, Guardant is focused on building a strong clinical evidence for its products and is usually the first one to do so. So maybe just, you know, if you could, you know, elaborate for us the efforts that you are doing on recurrence monitoring with the CRC and maybe indications beyond that, an eye or a lung or breast, that could potentially yield, you know, further data sets and clinical evidence that helps a physician look at the assay more closely. Thank you.

AmirAli Talasaz: Absolutely. So there are several ISTs that actually are finished. There are several other ones which are ongoing and, you know, we have the manuscript that, you know, the data that we are talking about in terms of performance of Reveal is coming from a collaboration with one of our major partners, major cancer centers in the United States. So there is

a manuscript under review that hopefully, basically we get published.

Operator: Your next question comes from the line of Tejas Savant from Morgan Stanley.

Tejas Savant: Hey guys, good evening. Thanks for the time here. Helmy and AmirAli, on the tissue biopsy launch, you know, Helmy, you've spoken a couple of times about sort of the importance of reducing the turnaround time there versus the entrenched sort of tissue biopsy competitors.

How much shorter do you think that turnaround time can be, particularly given the fact that a lot of times since the pathologist who takes some time to, you know, draw the sample and send it off to the lab? And how exactly do you plan to sort of, you know, compress that timeline relative to, you know, some of the other competition out there?

Helmy Eltoukhy: That's a great question. I mean, I think I would just, you know, refer you to our liquid biopsy stats. You know, we're averaging about five days on average in terms of turnaround time. And you look at a lot of the other liquid biopsies out there, they're 10, 14 days, you know, sometimes even longer. And that's not even taking into account pathology time on getting tissue access. So there's certainly, I think, a level of automation and operational excellence that we have in

our organization that doesn't seem to be matched, you know, with other products that are out there.

And so clearly, there's a lot of know-how that we can confer and apply to the tissue side of the process. So I'm very confident that, you know, it's not just about, you know, the tissue products on its own. It's also about, you know, how all of these products work together. You know, liquid product, the tissue product, and, you know, I think in having that sort of integrated offering we can provide a customer experience which is more aligned with, you know, what oncologists wants to see. Which is, you know, making sure they get, you know, everything they can in terms of biomarkers tested and their patients as quickly as possible and not missing anything. And we think we'll be able to provide that experience that is at a level that really hasn't been seen in the field to date.

Tejas Savant: Got it, that's helpful. And one quick follow up for Mike. Just in terms of the guide here, how are you--what are you sort of including for OUS expansion? I mean, obviously, you've got the Vall d'Hebron, you know, partnership you announced and the Japan expansion as well. So OUS, and then on the development services front, I mean, obviously, sort of an uptick in 2020 there. How much of a normalization should we expect in that line item in 2021?

Mike Bell: Well, on the OUS, of course, you know, we're not breaking out those numbers. But, you know, we think that's a great opportunity for us and probably an opportunity for upside throughout the year as to how that goes in both Europe and in Asia. On the development services side, yeah, I mean, we've seen this strong--stronger over the last three quarters, actually. And so I think, you know, that will continue through the year. And then we're, you know, we're bullish about the--on the development services revenue that's around 2021.

Tejas Savant: All right, thanks so much, guys.

Operator: Your next question comes from the line of Derik De Bruin from Bank of America.

Derik De Bruin: Hey, thanks for squeezing me in. Just a follow-up on ECLIPSE. Could you just sort of like outline a little bit more, you know, once you sort of get the read out, the potential for commercialization? Just your, you know, your general thoughts on, you know, LBT versus inclusion and guidelines. This is an area we just kept getting a lot of input on from investors. Just basically wanting to understand what your approach is and, you know, do you need to go out and, you know, build a sales force? And has that sort of been built into your plan? Just a little bit more on your commercialization efforts on ECLIPSE would be really helpful. And that's my only question. Thanks.

Helmy Eltoukhy: I can start and the others can patch in. You know, I think we started in November of 2019, which is, I think, about 24 months and so--as what the timeline for enrollment will be, it will take, you know, another little bit of time to process the samples and get the data collated and then get that, you know, submitted to the FDA.

In the meantime, you know, clearly, you know, we're very optimistic about the performance. We released, you know, data already in other cohorts where we have and what we believe is performance that will meet the standards and the minimum threshold that have been outlined in the NCD for Medicare coverage. And so I think we're cautiously optimistic that, you know, ECLIPSE will be able to read out, you know, well above those targets.

And so in the meantime, you know, we are, you know, laying out the foundations for, you know, the commercial channel in the primary care space. That's clearly a very large segment with, you know, numbers, a couple of hundred thousand primary care physicians. And so that's gonna take, you know, considerable investment and we are certainly in the early stages of laying that out and building out the team so that as soon as, you know, the data reads out we're ready to go.

Operator: Your next question comes from the line of Patrick Donnelly with Citi.

Patrick Donnelly: Great, thanks guys. Helmy, maybe one for you just on the guidance. You know, certainly appreciate that your guys' volumes weren't pressured nearly as much as other diagnostic tests during COVID. So the recovery, you're not going to be quite as sharp. Can you just talk through, I guess, the impact you saw as we went through 4Q? And then the level of conservatism that's kind of baked in here as we think about the trajectory as we go through 21, you know, in terms of patients coming back. Again, obviously, the impact wasn't quite as significant given your patient set, but just curious in terms of how you factor that in the volume guidance.

Helmy Eltoukhy: Yeah. No, I can start and then maybe Mike can touch(PH) in. So yeah, Q4 was interesting. Obviously, we were just coming off the heels of our launch of our CDx and our LBT and we really saw a nice acceleration in terms of the number of physicians ordering across the volume that we're seeing in terms of, you know, both of those tests. And so it was very encouraging. But as you know, I think the resurgence of COVID was probably greater than most, you know, had really anticipated, you know, at the time or before that time and really caused significant impact in terms of office closures.

I think, you know, well below 20% in terms of in person, you know, visits. Really similar to the height of the pandemic in April and May in terms of access. And so it's a very

challenging environment to be able to sell there. But I think despite that we saw, you know, a very nice, I think, year over year growth in Q4. And so I think it's really a testament to, you know, both the, I think, differentiation of the products as well as, you know, really the resilience of the Guardant team as well as, you know, resilience of these, you know, physician offices that have learned to, I think, deal with patient care in this new environment.

You know, I think baked into the numbers we have for 2021, you know, I think we have considerable growth there in terms of the clinical volume of, you know, 90,000 tests over 2020. And so, you know, I think we are, you know, we are very, you know, bullish in terms of really continued adoption of this testing.

I think the challenges that, you know, are certainly gonna continue in the first half of the year and we expect, you know, as we're seeing, you know, COVID cases decline and hopefully they continue to do so over the next, you know, couple of quarters, that, you know, we're able to see, you know, further acceleration of growth in the back half of the year.

Mike Bell: Yeah. And maybe, Helmy, I mean, just to add, but I think you said it all. But really, baked into our assumption, is COVID. And of course everything is vaccine dependent on how that can roll out. But we're, you know, we built into the numbers, really, a COVID impact in the first half

of the year and then making an assumption that in the second half of the year, you know, that's sort of alleviated. So that's how we're looking at the year, and that's really baked into our numbers. But as Helmy said, you know, we still think if we achieve 90,000 clinical tests in this year, then there'll be a very strong growth.

Patrick Donnelly: That's helpful, guys. Appreciate it.

Operator: Your next question comes from the line of Dan Arias from Stifel.

Dan Arias: Yeah, hi guys. Thanks for getting me in here. Helmy, maybe just one for me on Reveal. Obviously, you guys are looking to get settled here in colorectal cancer first, but just to the point on usage in a broader setting I'm just curious where you are in terms of your thinking about, you know, how quickly clinicians might look to translate confidence in one tumor type to usage in another?

You know, in other words if you build on the ESMO data and if COBRA reads out positively, can that sort of be a gateway to adoption in other cancers? Or do you think that, you know, you kind of have to prove things out tumor type by tumor type?

Helmy Eltoukhy: Yeah, I think we can take parallels from what we did with 360 in terms of really almost singularly focusing on loaning initially. And what we found was that, and by using, you know, a compass that leads us in the direction of

national clinical utilities, that, you know, it really maximizes the kind of the positive reaction of the user experience.

So as these products, you know, find utility, impact decision making in one cancer type. Given that, you know, many physicians are generalists and they're seeing many other cancer types, we found that that kind of, you know, translates into positive, you know, perceptions. And, you know, I think we're seeing a clinical utility in other cancer types as well.

And so, you know, ever since, you know, we've had strong traction in lung cancer. We've seen, you know, growth in other cancer types that has continued to track the growth that we've had in lung. That being said, you know, as we prove out specific cases for, you know, utility and other cancer tests, those can be added drivers for those specific indications. We've seen that, you know, with 360 when we have drug approvals in breast cancer or, you know, in prostate and so on and we've seen considerable step function increases in volume for those specific indications. And so we believe that it will be no different for this product regarding review.

Dan Arias: Okay, thank you.

Operator: Your next question comes from the line of Max Masucci from Canaccord Genuity.

Max Masucci: Hey, thanks for squeezing me in. In the prepared remarks, you spoke about the 65% decline of new

diagnoses of cancer in 2020. Unfortunately, some of these patients may never have the chance to receive a Guardant360 test, but I'd imagine that for those that do, they'll be diagnosed at a later stage. So how are you thinking about this playing out in 2021, probably more in the second half? And is this something you can, you know, act upon proactively and forecast in 2021 or not so much? Thanks.

Helmy Eltoukhy: Yeah. I mean, I think it's difficult to assess exactly how much of a backlog effect or, you know, bolus that would create, you know, just given the different time scales and so on in terms of, you know, diagnoses to metastatic disease and different disease states.

That said, you know, we see that, you know, so many patients still are not comprehensively genotyped, but I think there's still, you know, a lot of room to grow, you know, even outside of, you know, that backlog, whether it persists or not. So, you know, I think that's why, you know, I think we're very bullish in terms of, you know, continued volume increase in terms of, you know, Guardant360 as well as, you know, potentially other products down the line. And so there's--we're still very much in the early innings of adoption of these types of tests.

Max Masucci: Great, thank you.

Operator: There are no further questions at this time. I would like to thank everybody for joining. This concludes today's conference call. You may now disconnect.