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Guardant Health

First Quarter 2021 Earnings Call

May 6, 2021

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Guardant Health Q1 2021 Earnings Call. All lines are currently in a listen-only-mode. After the speaker's presentation, there will be a question-and-answer session.

As a reminder, today's conference is being recorded.

It is now my pleasure to hand the conference over to Carrie Mendivil from Investor Relations.

Carrie Mendivil

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Thank you. Earlier today, Guardant Health released financial results for the quarter ended March 31, 2021. If you have not received this news release or if you'd like to be added to the company's distribution list, please send an email to investors@guardanthealth.com.

Joining me to today from Guardant is Helmy Eltoukhy, Chief Executive Officer, and 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 of the Company's Annual Report on Form 10-K for the year ended December 31, 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 with generally accepted accounting principles. Reconciliations 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, May 6, 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 first quarter 2021 earnings call. Everything we do at Guardant is motivated by our commitment to serve patients. In line with our patient-first commitment, I will start off our call today with a patient story.

Six years ago a 64-year-old man was diagnosed with metastatic colorectal adenocarcinoma and went through numerous therapy regimens and surgeries. In the spring of 2020, his cancer recurred and his new oncologist ordered a Guardant360 test. A BRAF V660E mutation was identified. It is estimated that this mutation occurs in approximately 8% to 10% of colorectal cancers. By identifying this actionable mutation, he was able to begin treatment with a combination of target therapies of encorafenib plus panitumumab only recently approved by the FDA. Fortunately, the patient responded to this targeted therapy, but as we know, tumors are constantly evolving. After about six months, the patient was showing signs of progression. His oncologist ordered another Guardant360 test with our expanded panel that includes tumor mutational burden or TMB. This second Guardant360 test identified the patient's tumor as TMB high. A few months earlier, the FDA had approved pembrolizumab for patients with TMB high tumors of 10 mutations per megabase and above. This finding opened up another therapeutic avenue for this patient.

This story highlights how genomic profiling using Guardant 360 can keep up with evolution of a tumor and identify ongoing therapeutic options.

Turning to our first quarter performance, we started the year strong with revenue growing 17% to approximately $79 million.

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I am really proud of our team for their continued hard work this quarter which translated to solid growth in our clinical business as well as progress across our product pipeline. As expected, we continue to see residual COVID impact at the beginning of the year, but over the course of the quarter, as physician offices started to reopen, business improved further. Even with the persistent presence of COVID headwinds, clinical volume grew 21% to record levels of 18,390 tests. We continue to extend our position a liquid biopsy leader for therapy selection and there is still a vast amount of greenfield opportunity ahead in this market. The underlying fundamentals of our clinical business are very strong and we continue to see growth in both new physician adds and repeat orders. Even with the residual impact from COVID that we anticipate this year, we expect our clinical volume to grow more than 40% over 2020.

We also made important progress on the reimbursement front. At the end of March CMS confirmed that our Guardant360 CDx test meets the criteria for advanced diagnostic laboratory tests or ADLT status, which is reserved for FDA approved tests as well as for innovative product that provides novel clinical information that cannot be obtained by any other method. With ADLT status, Guardant360 CDx will be reimbursed at a rate of $5,000 for all Medicare patients, in line with our internal expectations.

Now moving on to our recurrent monitoring opportunity with Guardant Reveal, we are very pleased with the tremendous enthusiasm we are hearing from oncologists since its launch in mid-February. As a reminder, Reveal is the first blood-only liquid biopsy test for the detection of residual and recurrent disease. With a simple blood draw, the test improves disease management of early stage colorectal cancer patients by detecting ctDNA in blood after surgery to identify patients with a residual disease who may benefit most from adjuvant therapy and by detecting recurrence months earlier than current standard of care. We believe Guardant Reveal is truly in a class of its own with industry-leading sensitivity and specificity, and an average turnaround time of only seven days compared to other tests that require a tissue biopsy and have turnaround times of four to eight weeks.

Much as you saw with the launch of Guardant360, a blood-only solution addresses the significant logistical challenges posed by tissue in this setting.

Today, the standard of care is CEA, a blood test where you get your results a few days later. Importantly, Guardant Reveal fits into an oncologists workflow in the exact same way as CEA is used but give them extraordinarily better performance. CEA has a sensitivity of 69% with 64% specificity in the surveillance setting, versus 91% sensitivity with 100% specificity for Guardant Reveal. So, they are getting the better product market fit with the benefits of improved performance.

It is still early but we are seeing strong uptick from both new users as well as customers that have been using other products on the market, and benefiting from the deep relationships we have within the oncology community.

From the onset, we have said that it takes more than just great technology to drive durable, long-term adoption of new products. This type of sustained growth requires seamless integration into clinical workflows, demonstrated clinical utility, regulatory approval and broad reimbursement.

As for our work with Guardant360, we are committed to achieving excellence in each of these to ensure that our product drives superior values to the market and maximizes (inaudible) for patients. We are making great progress on the reimbursement front and are confident we will have Medicare reimbursement in place for Guardant Reveal by end of 2021.

At the beginning of April, the New York State Department of Health Clinical Laboratory Evaluation Program, or CLEP, approved Guardant Reveal for the detection and monitoring of MRD in patients with early stage cancer. This approval is an important proof point for Reveal and builds on our commitment to

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improving care for all cancer patients by expanding access to our tests through compliance with the appropriate clinical laboratory regulations.

I am so excited about what is ahead for Guardant and believe 2021 will be a pivotal year for us as we expand our product portfolio and invest across our business to build the foundation for complete cancer testing across the continuum of care.

Looking ahead in our therapy selection business, we will continue to expand the utility of Guardant360 with additional approvals, clinical data and broaden use of the test in the molecular response and monitoring settings.

There have been more than 40 publications to date that highlight the utility of Guardant360 in this setting. We have generated data across multiple tumor types including lung, breast, gastric and bladder cancers, and multiple classes of therapies including immunotherapies that demonstrate a second Guardant360 test a few weeks after treatment initiation can segment responders versus nonresponders.

To that end, a new study recently published in JPO Precision Oncology shows that Guardant360 provides an early indication of treatment response to pembrolizumab based immunotherapy by detecting molecular response as measured by changes in circulating tumor DNA levels early on. This study adds to the growing body of evidence showing that our Guardant360 test can effectively measure molecular response, giving clinicians an earlier indication of whether to continue or stop treatment, to explore other therapeutic regimens, or to enroll the patient in a clinical trial.

Monitoring molecular response is an important application of our technology platform that will soon usher in a new era of adaptive management of treatment and disease, all within the reach of any oncologist using a simple blood draw.

We are also looking forward to the upcoming launch of our first tissue product which we believe will address the unmet need that persists in the therapy selection market today due to the challenges with many of the existing tissue offerings.

In recurrence monitoring, we will continue to drive the adoption of Guardant Reveal, just as we did with Guardant360 several years ago, ushering in a new era of precision oncology for earlier stage patients.

And finally in screening, we expect to complete enrolment of our ECLIPSE trial before the end of the year and to begin work on our expansion into other cancer diagnoses. To support our ambitious vision, we are continuing to grow our incredible team. I am excited to welcome Dr. Craig Eagle, who recently joined Guardant as our new Chief Medical Officer. Craig most recently served as Vice President of Medical Affairs Oncology for Genentech, where he oversaw the medical programs across the oncology portfolio. Craig has a wealth of experience driving medical affairs, clinical development and clinical trial operations at leading pharmaceutical companies and he will undoubtedly make a great impact as we continue to develop and commercialize best-in-class products and (inaudible) the company for the future.

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

AmirAli Talasaz

Thanks, Helmy. Our biopharma business as a whole is roughly back in line with the pre-COVID levels and we are pleased with the progress we have made in Q1.

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Looking at biopharma samples, as expected volumes for the first quarter were sequentially down from Q4 levels but higher than the COVID trough we saw in Q2 and Q3 of 2020. Biopharma sample volumes was 3,522 tests for the first quarter, a decline of 33% from the prior year period.

We continue to serve a growing number of biopharma customers with more than 70 partnerships currently underway. We are supporting an increasing number of studies and we have a robust pipeline of discussions for future collaborations.

However, while clinical trials are picking back up, enrolling patient volumes are still depressed compared to pre-COVID levels, continuing to impact both prospective and retrospective sample volumes.

Looking at Development Services, we continue to see strong interest in our companion diagnostic business following FDA approval of Guardant360 in 2020. Development Services revenue for the first quarter 2021 grew more than 100% to $14.9 million.

Last week we announced a strategy collaboration with Daiichi Sankyo to pursue regulatory approval and commercialization of Guardant360 CDx as a companion diagnostic for Enhertu, a HER2-directed antibody-drug conjugate being studied in the treatment of patients with advanced metastatic non-small cell lung cancer.

This further strengthened the importance of comprehensive profiling as more and more biomarkers are being pursued in this disease.

We are also investing in our global companion diagnostic footprint as part of our mission to make CGP broadly available to patients around the world. To that end, we recently received our (inaudible) certification for the EU and submitted our initial PMDA filing in Japan. Our platform continues to generate data that further demonstrates the clinical utility of our product portfolio.

At AACR, Amgen presented a clinical study that demonstrated how our Guardant360 CDx was effective at selecting patients with KRAS G12C who may benefit from treatment with sotorasib. This mutation exists in 1 out of every 8 patients with non-small cell lung cancer, so there is a critical need to improve access to high-quality diagnostics and more routine biomarker screening.

Now, turning to Guardant Reveal, before its launch ctDNA based tests developed to detect MRD mainly required tumor tissue to identify patient-specific tumor mutations. A new study led by Massachusetts General Hospital Cancer Center which was published in Clinical Cancer Research demonstrated that Guardant's Reveal identifies patients most likely to recur with high clinical accuracy. The integration of cancer-specific epigenomic and genomic signatures allows Guardant Reveal to detect minimal residual disease in early stage colorectal cancers with industry-leading performance and without the need to tumor tissue. In the primary landmark analysis, 84 blood samples were taken from the curative intent patient population one month after completion of (inaudible). In the subset of patients with at least one year of clinical follow-up, all patients with detectable ctDNA recurred. Guardant Reveal's sensitivity and specificity were 55.6% and 100%, respectively, for this single time point. By incorporating longitudinal surveillance samples, sensitivity improved to 91%. Tissue-dependent MR details have previously reported sensitivities of 40% to 50% with a single post surgical blood draw. Interestingly, integrating epigenomic signatures increased test sensitivity by 36% versus just using genomic alteration alone.

Also, CEA tests, the standard of care in colorectal cancer, did not predict recurrence in this patient cohort.

We believe that Guardant Reveal can be a powerful decision-making tool for oncologists managing patients with early stage colorectal cancer. In addition, our blood-only approach offers a more streamlined workflow and faster turnaround time for clinical decision-making.

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We remain committed to generating clinical utility evidence based on prospective interventional studies. We are pleased with our progress in multiple studies, including COBRA, Stand-up to Cancer and PEGASUS trials. We continue to believe that demonstrated clinical utilities will be the critical component to drive long-term and deep adoption in this space.

Turning to screening and our ECLIPSE trial. We continued to see robust baseline enrolment throughout the first quarter. We now have over 180 sites enrolling patients. Overall we are pleased with our progress and we remain on track to complete enrollment by the end of this year.

As we prepare for the readout of ECLIPSE, we are beginning to establish a commercial team engaging industry groups and lay the foundation for commercial organization to focus on this (inaudible) opportunity ahead. In parallel, we are considering to develop screening data for CRC internally and look forward to presenting data from our largest early stage patient cohort to date at ASCO in early June. We are also looking further ahead to the opportunities beyond CRC. We are starting to plan our next screening clinical study in other cancer types and expect to share more updates about this in the latter part of 2021.

With that, I will now turn the call over to Mike for more details on our financials.

Mike Bell

Thanks, AmirAli. Total revenue for the first quarter of 2021 was $78.7 million, up 17% from $67.5 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 first quarter was $63.7 million, a growth of 6% compared to $60.2 million in the prior year quarter. Precision Oncology Revenue from clinical testing in the first quarter was $49.8 million, up 31% from $38 million for the prior-year quarter. First quarter clinical test volume of 18.390, up 21% from the prior-year quarter. The clinical test average selling price was $2,710 in the first quarter of 2021, up from $2,489 in the prior-year period.

First quarter 2021 clinical test revenue includes approximately $5 million recognized from cash collected for Guardant360 tests performed in prior periods.

There are several factors that will impact the ASP of Guardant360 for the remainder of 2021. Firstly, we will have a positive impact from the new ADLT Medicare reimbursement rate of $5,000 for Guardant360 CDx. As a reminder, the $5,000 Medicare rate took effect on April 1, 2021 and will continue until January 3, 2022, at which time the rate will change to the median private payer rate. However, we continue to anticipate that the April 1 change to ADLT billing code may have a short-term impact on the processing and payment of Guardant360 CDx claims by non-contracted private payers, which could offset the positive impact we receive from the increased ADLT Medicare reimbursement.

In addition, we expect the impact on ASP caused by prior period cash collections to start to reduce in the second half of the year as our revenue recognition becomes more weighted towards tests performed in the current period.

On the whole, we expect the ASPs for Guardant360 to average approximately $2,600 for 2021.

Note that it will take time to receive Medicare and private payer reimbursement coverage for newly launched clinical tests such as Guardant Reveal. As a result, we expect minimal revenue for these newly launched tests in 2021 which in turn, and depending on volume, could impact the overall clinical ASP.

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Precision Oncology revenue from biopharma tests in the first quarter totaled $13.9 million, down 38% from $22.3 million in the prior-year quarter. First quarter biopharma tests totaled 3,522, down 33% from the prior-year quarter. As previously mentioned, biopharma volume is now back above the lows we saw in the second and third quarter of 2020, but we are still facing headwinds with respect to clinical trial patient volumes.

Biopharma test ASP was $3,944, down 7% from $4,230 in the prior-year period, primarily due to changes in the mix of tests performed.

Development Services and Other revenue continued to be a strong growth driver, and in the first quarter totaled $14.9 million, up 106% from the prior-year quarter.

Gross profit for the first quarter of 2021 was $49.9 million compared to a gross profit of $47.0 million in the same period of the prior year. Gross margin was in line with our expectations and in the first quarter was 63% compared to 70% during the first quarter of 2020.

Operating expenses for the first quarter of 2021 were $157.8 million, a 93% increase compared to $81.9 million in the first quarter of 2020.

Non-GAAP operating expenses exclude stock-based compensation and related employer payroll tax payments, acquisition related expenses, amortization and intangible assets, and changes in fair value consideration. Non-GAAP operating expenses for the first quarter of 2021 were $100.7 million, a 53% increase from $65.9 million in the first quarter of 2020. As mentioned during our last earnings call, we expect operating expenses to continue to accelerate in 2021 as we invest in our LUNAR program, the (inaudible) study and other development activities, as well as launch new products and expand our commercial organization both in the U.S. and internationally.

Net loss was $109.7 million or $1.09 per share for the first quarter of 2021 compared to $27.7 million or $0.29 per share in the first quarter of 2020. Non-GAAP net loss was $49.4 million or $0.49 per share for the first quarter of 2021 compared to $15.4 million or $0.16 per share for the first quarter of 2020.

Adjusted EBITDA was a loss of $45.4 million in the first quarter of 2021 compared to a $15.5 million loss in the first quarter of 2020. We define Adjusted EBITDA as non-GAAP net loss adjusted for interest, income tax, depreciation, amortization and other income (inaudible).

We ended the first quarter of 2021 with $1.9 billion in cash, cash equivalents and marketable securities.

Now turning to our revenue outlook for the full-year 2021. We are pleased with our solid start to the year and believe the fundamental drivers of our business to be very strong. However, we are not yet through the global COVID pandemic. As Helmy mentioned, we are still seeing COVID impacts in our clinical business as some physician offices remain closed.

Related to our biopharma business, while clinical trials are picking back up, patient volumes are still depressed compared to pre-COVID levels, continuing to impact both prospective and retrospective sample volumes.

Given this backdrop, we continue to expect revenue to be between $360 million to $370 million, representing growth of approximately 27% over 2020 at the midpoint of the range.

We also expect clinical sample volume for 2021 to be greater than 90,000 tests, which represents growth of at least 42% over 2020.

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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 thank our team for their incredible work to bring to fruition the vision we had when we founded Guardant of significantly improving outcomes across the entire continuum of cancer care.

2021 will be a pivotal year for us as we expand our product portfolio and invest across our business to open up the massive opportunity to transform cancer care for millions of patients. 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.

I am so excited about what is ahead for Guardant and look forward to updating you on our progress.

With that, we will now open it up to questions.

Operator

We do ask that analysts limit their questions to one question and a follow-up. We'll pause for just a moment to compile the Q&A roster.

Your first question comes from the line of Puneet Souda with SVB Leerink.

Puneet Souda

Hi, Helmy and AmirAli. Thanks for taking the questions. First one is on the guide.

You're obviously maintaining your guide as before so just wanted to get a sense from you what you are seeing in the channel and from the sales reps. Maybe can you give us a sense of what percent of the reps are actually in person and detailing the G360 and other products versus still online? Obviously vaccinations have ramped up, patients are coming back to the clinic, obviously not at the same levels as before. The pandemic is still here.

ADLT reimbursement appears to be improving, though I appreciate what Michael is saying, but you also have FDA approval and that should be helping, so just wanted to get a better understanding of that 90,000 test. What is sort of driving that conservatism, and if you can just walk us through is that something that you are just waiting for a little bit more time to get a better sense of that, or anything else you can provide on that would be very helpful.

Helmy Eltoukhy

Good question. I'll maybe start and let Mike jump in.

I think the first part of the year obviously a lot of physician offices were still closed, the pandemic was still raging in January. I would say that towards the end of the quarter in March, though, we started seeing I think resolution of a lot of the offices starting to open back up. We're seeing it's now over 30% to 40% of visits now in person, so things are certainly going the right direction, and I think we're pleased with the progress.

I think what we have baked in is resolution of some of the negatives, the headwinds of COVID, especially with respect to physician office visits and so on by the second half of the year. And it's frankly why we

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believe we have a very robust guide in terms of (inaudible) in our view from where we were last year and I think it's baked in our optimism and cautious optimism that essentially that our teams will continue to do their magic and hopefully protect these more kind of compromised individuals in the metastatic cancer space.

I would say that I think what is still uncertain is exactly how fast COVID continues to go down the right path in terms of resolution of those headwinds, as well as some of the uncertainty around the transition our ADLT status. I think we're seeing, I think, positive momentum there so far in terms of getting payments from Medicare at the higher rate of $5,000, but obviously it's going to take some time to play out in terms of really the impact on the non-covered private payers that are likely to impact ASPs for the remainder of the year.

Michael Bell

Helmy, maybe just (inaudible) in the last earnings call we laid out a bunch of assumptions with respect to the guidance, ADLT, COVID impact and those assumptions are playing out as we expected, so yeah, we're very confident with the guidance that we've put out, and I think when we get past these uncertain items we'll have a much clearer picture for the remainder of the year.

Puneet Souda

Okay. That's helpful.

On ECLIPSE, just wanted to clarify. You mentioned enrollment completion by year end I know, I believe I think in past you had said sometime around October. That would align with the October 2019 timeline when you started this trial. You had about 150-plus sites before; now you have more than 180 sites so it suggests that the enrollment is ticking up. Just wanted to get a sense of is this still the same timeline or is it moving a little bit? It would suggest the timeline should move up rather than later.

Then in terms of the screening data for CRC that you mentioned at ASCO, just wanted to get a sense of AmirAli on that, that if I heard that correctly, that large cohort, how big is that cohort and is that still very much a case-controlled study, or this is more an average risk?

AmirAli Talasaz

Regarding timeline, Puneet, for ECLIPSE last patient enrollment, still we are on track to finish it up (inaudible) in the 24 months, so the timeline as you mentioned is actually where we think we are going to have that last patient in. That's going to be before the end of the year.

We are going to monitor the field and see if we are going to have some up and downs, but we feel very confident that it would finish by the timeline that we always mentioned throughout this. (inaudible) with all the ups and downs we had due to COVID, which we are very excited about.

In terms of the ASCO data, actually it's a pretty interesting cohort, cohorts. It's the largest cohort data that we are showing. Still, it's not like a prospective screening cohort that we are giving in ECLIPSE. Really, ECLIPSE is one of a kind and we have to just wait to see what readout we're going to get from ECLIPSE, but systematically we are removing some of the technical risk in terms of some potential variation, different cohorts, potential variation in terms of type of patients that they were in the cohort, so please (inaudible) with that data and we are going to (inaudible) in ASCO pretty soon.

Puneet Souda

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Okay, that's super helpful.

Helmy Eltoukhy

(Inaudible).

Another thing about the timeline for ECLIPSE, I think we are very pleased with the progress there. We've been able to maintain our initial timeline to 24 months since we started the trial and I think that's a testament to the level of kind of resilience and level of execution that the team has had.

We are seeing other trials and delays from whether they were initially (inaudible), and so I think it puts us in a similar position.

Puneet Souda

Okay, great. Then last one, if I could just squeeze in. In terms of the Reveal data and the CCR paper, obviously a really good paper. Is that clinical utility data good enough for reimbursement or are there other data sets that you would want to add here before getting the reimbursement from Medicare by the year end? And wondering if there are any indication—as far as indication expansion that you are thinking about Reveal? Thanks so much.

AmirAli Talasaz

We are very pleased with that paper. It was a collaboration which we had with (inaudible) and there are some additional ISTs (phon) that we are doing in the same space as CRC which the data is getting—it's basically cooking and we are going to show the data at the right time.

In terms of reimbursement, we are pleased (inaudible) conversation we had with some of the major payers in the field. Is that something which, you know, would convince all the major national payers to cover this test? No. If you thought would be the case, we wouldn't do the clinical utility studies that we have started since almost now a year and half, two years ago. We think the readout of some of those studies would be the intact long-term adoption, commercial adoption of the test and long-term reimbursement by many payers, and that's why we prioritize those activities over this commercial launch.

But still, we are seeing some interesting and exciting signals from some of the conversations we have, so please stay tuned so hopefully we have some good information this year in future.

Puneet Souda

Great. Thank you.

Helmy Eltoukhy

You asked about indications. Very quickly, for a while we talked about our platform technology as definitely way beyond CRC. CRC is our lead indication, not the only indication. We have been working in a few other cancer types and we are pleased with the progress that we've seen in really multi-cancer setting which has some implication, MRD side and some implication on the screening side. We are pleased with the progress on those fronts.

Puneet Souda

Great. Thanks, guys.

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Operator

The next question will come from the line of Dan Arias with Stifel.

Dan Arias

Good afternoon, guys. Thanks. Helmy, just maybe a couple on some other clinical trial questions.

Just on ECLIPSE, that's obviously going to be a pretty high profile data set. Would you need—would you feel the need to unveil that at a meeting or can that kind of be ad hoc when it's ready to be put in front of people?

Helmy Eltoukhy

I think we'll see what makes sense. It depends on the timing. Obviously if the timing works out I think it could be unveiled at a trial, but it's obviously a very sensitive data set but would likely need to shared in a timely fashion. We'll make sure that gets out there.

Dan Arias

Okay. Then maybe on the MRD side, Stand Up to Cancer and COBRA, I think the primary completion date for Stand Up to Cancer is listed as February of '22 and then COBRA is summer of '22. Do you think we might get an interim look at data from either of those before those dates? Or is that more or less the timing that we should think about when it comes to just sort of seeing results and having something to evaluate?

AmirAli Talasaz

Those are the timelines for the enrollment. This is a multiyear trial in terms of figuring out the clinical endpoints that we have in those studies. Some of those (inaudible) end of overall survival, so it's going to take a few years for some of those studies to have a solid readout on the clinical endpoint while the enrollment was finished, and close to the timeline that we have stated.

It's going to take us some time to really get some good return out of those investments, but as I indicated before, we believe those are very key for the progress I think the whole MRD field needs to make to really open up this big opportunity that we are excited about.

Dan Arias

Okay, sorry. One last quick one for Mike. Mike, are you able to say what percentage of private payers are actually billing using the miscellaneous code right now?

Mike Bell

No, Dan. We don't really break out the codes that we use, so if you're trying to get out how that ADLT impacts the private payers, I think all we're saying is that those non-contracted payers really the sort of negative short-term impact of that will offset this positive Medicare rate at $5,000.

Dan Arias

Okay. That was in fact what I was trying to do. So, thanks.

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Operator

The next question will come from the line of Derik De Bruin with Bank of America.

Ivy Ma

Hi. Thank you for taking my question. This is Ivy on for Derik today. First I want to start with Reveal. Just wondered if you could share a bit more about the uptake so far, and also what kind of revenue growth trajectory you are looking for and can we look to the G360 (inaudible)? I know it's still early but would appreciate any comment on that.

Helmy Eltoukhy

We are very pleased with what we are seeing so far with Reveal. I think it's meeting all of our expectations in terms of having a product that really has the right product market fit. There's really just no other product like it in the market today, both from performance and from really just the ease of use for blood-only test.

We are seeing physicians using CEA and others that are using other ctDNA tests out there very easily switch to using Guardant Reveal, so it's—I think we couldn't be more pleased.

I would say that in terms of kind of the ramp that you should expect, we have much deeper relationships today than we had seven years ago when we launched Guardant360 and I think part of the success we have is the credibility we've built and the deep relationships we've built with the oncology community in those seven years now, and so I think we're leveraging a lot of that and we're very, I think cautiously optimistic in terms of the continued uptake of Guardant Reveal for the remainder of the year and beyond.

Ivy Ma

Great. Thank you. Then, wanted you to touch on LUNAR-2. Can I get your opinion on your targeted performance on LUNAR-2 and your opinion what kind of ECLIPSE data you would need to sort of have a faster ramp up versus the other (inaudible) option out there in terms of CRC screening, aka Cologuard? Also, on the commercialization side, I realize it's still early to talk about the plans, but wanted to see what you think in terms of launching it as an LDT versus going for the full FDA approval approach. Thank you.

AmirAli Talasaz

Depending on the performance, I think the indication of (inaudible) could be impacted and (inaudible) in terms of getting successful national CMS coverage, it looks like really reasonable for us. Effectively, it meets our sensitivities of performance is a bit, maybe a little bit more than that.

Then the next kind of target number is numbers by stool-based testing. We believe actually liquid biopsy and blood have the opportunity to meet or exceed the numbers by stool-based testing, but we have to see. We have to see actually what we are going to get in ECLIPSE. When you look at all the data that we've seen so far and we've put out there, we are within striking distance of having a performance that is very comparable and competitive, or potentially even could be better than stool-based testing, but we have to see what ECLIPSE (inaudible) in this kind of screening trial. There are still a bunch of risks left there, but we feel very confident based on everything that we know about liquid biopsy that liquid biopsy would play a major role in screening, especially in this lead indication that we are targeting in colon cancer.

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In terms of commercial buildout, we are continuing to do investment on that front and we are building the team. We are building it up now. We have a bunch of senior executives that we have added to our screening core and we are continuing the recruiting and buildout of the team to be ready for potential launches of our screening tests down the road.

Ivy Ma

Great. That's very helpful.

Last question. Apologize if I missed it in the prepared remarks, but did you talk about the volumes on both clinical and biopharma in April you've seen so far, or just the exit rate? Thank you.

Helmy Eltoukhy

We haven't mentioned kind of what volumes are but I can say that we're pleased with how things are going. Certainly things picked up quite a bit in March and I think we're continuing on that trajectory.

Ivy Ma

Great. Thank you.

Operator

The next question will come from the line of Tejas Savant with Morgan Stanley.

Tejas Savant

Hey, guys. Good evening. Just a couple of follow-ups here on Reveal.

First, Helmy or perhaps AmirAli, can you just elaborate what the lead time was versus imaging for the assay in the MGH paper? Then second, in terms of the failure rates for the assay, is that something that is sort of—we should expect a significant improvement upon given that the paper was based on an older version, or how much more optimizing is there for you guys to do there to get those rates down?

AmirAli Talasaz

Yes, maybe I'll take that question.

For Guardant Reveal, in that paper—I think it's interesting what we are doing in that field, so but that paper actually, the thought process we did in collaboration with MGH. We were getting volumes of 1 mL to 4 mL from different patients and in terms of cell free DNA even (inaudible) 4 nanogram in a bunch of samples. So in different kind of settings we had kind of exclusion QCs for that study for some of the patients actually they never followed through with follow-up imaging or they didn't come twice to the blood testing. We have some exclusion around this.

I have shared with you what we are seeing now commercially in our clinical lab across many tests that we've done during the last couple of months. Our QNS rate or failure rate or cancellation rate, whatever way you look at it, has been less than 1%, so we believe in the quality of the (inaudible), and that's the experience we are seeing on the commercial side in our clinical lab, less than 1% failure or QNS (inaudible).

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Regarding the lead time to the imaging, I think that's really a function of the cohort and the specific practice in that cancer center, how frequently the patients is getting imaged. I don't want to say something wrong but I believe that lead time was at least four months, but this is something which is related to the practice and how often the patients are getting screened.

I think maybe an indication to look at is the clinical sensitivity and the specificity in relevant indications which we believe we need to look at landmark timepoints and the surveillance timepoints differently. We are going with standard of care definition for landmark timepoints, which there is interest we can talk about it.

But based (inaudible) that we cut the data, although it relatively small cohort we believe we have a leading or promise in the field, even without the need of tumor tissue. That's our belief.

Tejas Savant

Got it. Super helpful, AmirAli.

Then one quick follow-up for me. In the past you've mentioned and so have some of your peers just around the fact that background noise from surgery prevents liquid biopsy use for the first few weeks. From a real (inaudible) standpoint, how much of a difference does a tumor-agnostic approach make relative to a tumor-informed approach in terms of when the actual monitoring of the patient actually begins? Is that even a fair question? I'd love to hear your perspective on that?

AmirAli Talasaz

Yes, sure. Actually, there are a bunch of literature around this, now we know the science much better than earlier data liquid biopsy both for Reveal and Guardant360 in terms of post any kind of intervention, like invasive intervention, we are recommending that blood draws happen at least four weeks after that intervention is my best (inaudible). We have some publication even two weeks after surgery or two weeks after invasive procedures, but what we specifically recommend is four weeks after this invasive procedures and then you can look at molecule response right in terms of treatment efficacy and also if you want to look at MRDs in adjuvant setting or any kind of landmark timepoints, still we can get solid information with very high clinical accuracy.

Tejas Savant

Got it. Super helpful.

Then one final one from me on GuardantINFORM. Can you just share an update there on the conversations you're having since the platform went live, and perhaps any sort of marquee deals that have come about thanks to that launch?

Helmy Eltoukhy

We've been very pleased with that. It's quite a big pipeline now of conversations and frankly many deals that we've signed there with pharma companies.

I think it's just like anything there is education and virtualization required but we think this is going to be I think a very significant—a relatively significant part of the business in the future.

Tejas Savant

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Got it. Super helpful. Thanks guys.

Operator

The next question will come from the line of Brian Weinstein with William Blair.

Brian Weinstein

Hey, guys. Thanks for taking the questions. I want to jump on the ECLIPSE train that everybody seems to be on today for some reason.

When we do see that data—and I know it's still a little ways away—are we expecting to see just the top line data? Are we going to see data by stage? Are we going to see advanced adenoma data in there? Can you just give us an idea of kind of what the construct will look like when we do see something?

AmirAli Talasaz

Yes. In terms of phasing of the data, we have to see when we get the reports, which one of the data we can (inaudible) clinicaltrial.org, you are going to see some of the primary endpoints that we have in that study and also secondary endpoints that actually highlight some of the data that you would generate. Effectively it would be clinical (inaudible) specificity, some advanced adenoma performance. We are going to actually have stage information for the patients. We are going to have that information. Also, it's just a matter of the timing of when we are going to get access to that information from the (inaudible) of the patient, but all this will be analyzed to my best knowledge.

We are going to share all the information that we are going to see.

Brian Weinstein

Got it, okay.

Then how many—we've seen others that are in the broader precision oncology space spend significant assets—spend significant dollars on adding assets, be it technology or other hard assets that are available. We really haven't seen you do that yet. I'm curious what you think that says. Are you guys more discriminate about what you are looking for? Are you typically not willing to pay up, or do you just really not think that you need to do it? Not that there's a gun to anybody's head, but just it's an observation that you guys have kind of not gone down that path as much as—really, at all, versus others that are being pretty aggressive on adding technology. So, kind of your broader thoughts on M&A and what that says about you. What you guys are looking at.

Helmy Eltoukhy

That's a great question.

I mean we've very much I think pro M&A where it makes sense. We have a team that is actively nursing deals and reviewing deals, but I think we're in an enviable position in terms of the pipeline that we have and the platform we have within Guardant.

When we do pull the trigger on certain investments, they're going to be investments that make sense and we have a high bar for that given where we are internally in terms of our development platform. But that being said, you know, I do think M&A is healthy; it brings in new talent, new technology, diversifies the pipeline, so it will be an important aspect of our business going forward.

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Brian Weinstein

Okay. And can I sneak in for Mike? It's just on the ADLT stuff. With respect to the weighted median here, is any reason to think that that 130% kind of target that CMS has set as it relates to the ADLT pricing, that there would be any kind of an issue there? Are you kind of thinking that you guys are going to be in that—I think it's like 3800 bucks or something or better on the weighted median? Just as I'm thinking about '22 pricing.

Mike Bell

Yes, Brian. I would say we're pretty confident that this 130% won't negatively impact it. I think when we're contracting it's usually above the $4,000 mark, and so I think when we looked at the numbers, although we've not seen any of the payments start to come through yet from the private payers for the ADLT rate, I think as we look at it we're pretty confident that we won't fall below that level.

Brian Weinstein

Okay, great. Thank you, guys.

Helmy Eltoukhy

Thanks.

Operator

The next question will come from the line of Patrick Donnelly with Citi.

Patrick Donnelly

Great. Thanks, guys. Obviously a lot of ground covered, so maybe I'll just keep it to one.

Helmy, you talked a little bit more about the investment and the global footprint this call. You talked about different approvals in the EU and Japan. Can you just talk about the global strategy? Obviously early days but how important that is and what we should be able to look out for in terms of traction over the next 6 to 12 months?

Helmy Eltoukhy

I think we're beginning to really ramp up our investment globally. We're making very good progress with our JV in Japan and Asia, as well as Middle East. Japan I believe, we should have our lab up and running sometime later this year. We obviously submitted to PMDA. We're very hopeful that's going to open up really a kind of new ramp and opportunity in terms of testing (inaudible) in Japan.

In Europe, as we've announced, our public-private partnership with Vall D'Hebron in Spain, and so you see that globally we're thinking of a more partnership and decentralized approach which we think is necessary for some of the different regions that we are targeting to really improve access to this type of testing and, frankly, the inflection point is going to be winning of public reimbursement in each and every country, which there's no cookie cutter approach, but we believe the approaches we are taking are really tailored towards each region and what's likely to be the most successful.

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Patrick Donnelly

That's helpful. Thanks, Helmy.

Helmy Eltoukhy

Thanks.

Operator

The next question will come from the line of Jack Meehan with Nephron Research.

Jack Meehan

Thank you. Good afternoon. Wanted to go back to Guardant Reveal. Helmy, I think you mentioned you felt confident about getting Medicare coverage before the end of the year. Can you just talk about what events need to take place for that to happen? Do you need some of these interventional studies to readout? Then, can you talk about how you're thinking they'll approach pricing for the test?

Helmy Eltoukhy

Discussions have been good in terms of working with our Medicare counterparts. (Inaudible) all the data that is necessary, we have in hand already, and so now it's kind of more procedural in terms of some of the back and forth. We're fairly confident by the end of the year we should have both reimbursement and pricing in place.

In terms of details of the pricing, that's still something that we'll share at a later time.

Jack Meehan

Okay. On the biopharma side, you talked about kind of the continued impact on clinical trials from the pandemic. On the CRO side, we're seeing a lot of momentum helping customers catch up. Are you seeing that for the year as well and can you just talk about within the guidance what you're assuming in terms of revenue for the year?

Helmy Eltoukhy

On biopharma or just…

Jack Meehan

Yes. I guess within Precision Oncology for biopharma.

Helmy Eltoukhy

I think we're seeing that trials are picking back up. The CROs are obviously getting back into the swing of things. The challenge is I think patient volumes. Even though the sites are back up, the trials are ticking away, the patient volumes (inaudible) enrollment. There's still been a big shift towards telemedicine. Even though patients can go back in they're not necessarily going in. They're not necessarily traveling the 50, 100, 150 miles that they have to travel to different clinical trial sites, so that's going to have residual impact, certainly first half of the year. And maybe even beyond to some extent. That is the first thing I would say, retrospective and prospective sample volume.

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That being said, I think our Development Services revenue has been very strong. We've had very high growth there and so we're seeing the overall depth and breadth of relationships we have with our pharma customers is continuing to expand. But I think we're assuming I would say in terms of guidance that I think pretty healthy rebound, I would say on the testing side and with respect to resolution for some of these COVID headwinds in the second half of the year.

I don't know if there's anything you want to add to that, Mike.

Mike Bell

I would just say I think our volume this quarter was sequentially lower than Q4. I know we previously signaled that. We had this bolus of samples come in at the end of Q4, but if you look at Q1 now, it's as we said on the call earlier. It's above where we were at the COVID times in Q2 and Q3. We haven't talked about this on a volume basis; if we can recover in the second half of the year, it's something like a low double-digit growth on biopharma.

Jack Meehan

I'll leave it there. Thank you, guys.

Mike Bell

Thank you.

Operator

The final question will come from the line of Doug Schenkel with Cowen.

Doug Schenkel

Hey, good afternoon everybody. Thank you for taking my questions.

Just to talk a little more about Guardant Reveal, first, how would you characterize biopharmaceutical interest in working with you with this assay? Second, with regard to the data in the (inaudible) study in CCR, are there areas where you'd like to see further improvement as you do further optimization work? I'm thinking things like, again not a huge study but the failure rates seen there were a little higher than I think we would have liked.

Then third, there are some, including competitors, that have asserted that there were differences in the study readout on certain metrics relative to those that were published in some of the tumor-informed studies. Things like adjuvant therapy inclusion and the therapy—I'm sorry, and the treatment of inclusive tests. Just based on this, when you head to the market and you're talking to folks in the field, do you have any concerns about how apples-to-apples the results really are relative to others?

AmirAli Talasaz

Sure. So, on the biopharma side, if you look at some of the interesting clinical trials happening in the MRD space, there are not many of them in fact around CRC and that's something that has been impacted—it's not the conversation with biopharma. Our lead indication is CRC but a bunch of other biopharmaceutical interests are in other cancer types. Now that we have some additional data in some other cancer types, you are seeing a bunch of warm-up in conversations around MRD trials with

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biopharma, already some private experimentation is going, some heads-up experimentation (inaudible) see what's going to happen there. But I think that's one of the issues we have with biopharma side in terms of some mismatch of clinical lead indication versus the lead indication necessarily for biopharma trials.

On the Reveal clinical experience, as I mentioned earlier, in our clinical outlook—like in the commercial setting, we have less than 1% failure rate. QNS rate, you know, all that inclusive is just less than 1%. I think interesting since we are hearing in this field is that MGS cohort, you are getting small amounts of plasma volumes, as low as 1 mL, as I mentioned earlier, as low as 4 nanograms of cell-free DNA, so perhaps you have kind of a higher failure rate. In the commercial setting, as I mentioned, we had less than 1%, less than 1%.

In terms of head-to-head comparison, we (inaudible) cohort to make the analysis as close as possible to what's been published by the tumor-informed assays before with the caveat that we believe the landmark timepoints (inaudible) the right clinical definition which is inclusive of any curative intent treatment. It could be surgery. It could be neoadjuvant post surgery, it could be surgery plus adjuvant, so we highlighted that data for (inaudible) landmark cohorts. In the supplemental data, all the data is broken out and (inaudible) break out the data between surgery and adjuvant combination, whatever. What we believe is we are (inaudible) performance and I think over time through other's clinical experience, I think this is going to get further and further confirmed.

Doug Schenkel

Okay. That's super helpful. Thank you for that. I know we're late in the call but maybe if I can just ask one last one, not related to Guardant Reveal. Just thinking about COGS, improvement initiatives over time. Keeping in mind you have a supply agreement with Illumina through 2033, I believe. Noting that, but also acknowledging the fact that others in the space are either evaluating or actively working with or investing in competitive technologies with the intent of reducing COGS over time, do you have the flexibility to work with suppliers other than Illumina over time? If so, is that something that you're actively considering, and what are the characteristics you are looking for?

Helmy Eltoukhy

We have the ability to work with any supplier. We have a good relationship with Illumina in terms of a working relationship. But as I said, we this space continues to evolve we're going to obviously prioritize technologies that give us a little bit of cost advantage and performance advantage. It's like any other part of the reagent and suppliers that we work with. We're always evaluating, find a better way of doing things and lowering our costs.

Doug Schenkel

That's great. All right, thank you very much. Have a good evening.

Operator

With that, this does conclude today's conference call. We thank you for your participation and ask that you please disconnect your line.

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