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Guardant Health

Third Quarter 2020 Earnings Call

November 5, 2020

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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Guardant Health Q3 2020 Earnings Call. At this time all participants are in a listen-only-mode. After the speaker's presentation, there will be a question-and-answer session. To ask a question during the session, you need to press star, one on your telephone. If you wish to withdraw your question, press the pound key.

I would now like to turn the conference over to your speaker today, Carrie Mendivil with Investor Relations. You may begin.

Carrie Mendivil

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Thank you. Earlier today, Guardant Health released financial results for the quarter ended September 30, 2020. 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, Co-Founder and Chief Executive Officer, and AmirAli Talasaz, Co-Founder & President, and Derek Bertocci, 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, 2019, and in its other filings with the Securities and Exchange Commission. 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 that is accurate only as of the live broadcast, November 5, 2020.

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

Helmy Eltoukhy

Thanks, Carrie. Good afternoon, and thank you for joining our third quarter 2020 earnings call. During the quarter we continued to make substantial progress across our business, driven by our commitment to serve patients. Consistent with these values, I will start off our call with a patient story.

A 44-year-old non-smoker was diagnosed with Stage 4 adenocarcinoma, type of non-small cell lung cancer. His oncologist originally ordered a limited panel (inaudible) test, but he was confirmed negative for EGFR ALK, ROSI and PDL1, so his oncologist selected chemotherapy plus pembrolizumab for first-line IO treatment, despite not having complete biomarker testing. However, the patient failed to respond to treatment and was being considered for hospice. Fortunately, his oncologist then decided to try liquid biopsy for a complete genomic assessment of his tumor and order a Guardant360 test. We quickly identified a BRAF mutation. Based on this result, the oncologist was able to put him on a corresponding targeted therapy, a combination of dabrafenib and trametinib for treatment.

His story demonstrates the importance of the precision oncology paradigm. It underscores the challenge of using tissue to get guideline-complete genotyping and how our liquid biopsy platform is uniquely qualified to address the needs of patients at all progression time points.

Turning to our business, we ended the third quarter with $74.6 million of revenue, growing 23% over the third quarter of 2019. Clinical volumes for Guardant360 grew to 16,950 tests, a 28% increase compared to the third quarter of 2019 and a 24% increase compared to the second quarter of 2020, returning back to the levels we saw in mid-March, pre-pandemic.

I am proud of the Guardant team to continue to successfully serve our customers despite the challenging backdrop. However, over recent weeks, there has been a resurgence of COVID cases in some regions across the United States. We are seeing some early signs indicating that this resurgence will adversely affect clinical volumes as renewed or continued up as closures are resulting in overall reduced in-person cancer patient visits and limited access.

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During the quarter, FDA approval of Guardant360 CDx helped us achieve a key catalyst for adoption of comprehensive genomic profiling in patients with any solid tumor cancer and as a companion diagnostic to identify non-small cell lung cancer patients with EGFR alterations who may benefit from treatment with Tagrisso. This approval is a landmark decision, demonstrating the value liquid biopsy delivers to oncologists and, more importantly, to the patients they treat.

We applaud the FDA further and collaborative review process and for approving the first comprehensive genomic profiling liquid biopsy test. FDA approval of the Guardant360 CDx assay was based on multiple studies comprising more than 5,000 samples and represents what we believe to be one of the most rigorous validations of the clinical and analytical performance of a liquid biopsy test.

Following FDA approval, we launched two versions of Guardant360 in September. The first product Guardant360 CDx is the FDA approved version of our assay. We are confident that our FDA approval will help to accelerate wider adoption of guideline recommended genomic profiling and increase the number of advanced cancer patients who receive potentially life-changing treatments. Specifically, we expect FDA approval to strengthen reimbursement by advancing conversations with private payers and further improving Medicare pricing; extend momentum for a companion diagnostics business; and advance the use of Guardant360 with physicians who have been slow to adopt comprehensive genomic profiling over the medium to long term.

The second product, we launched is the next generation version of our Guardant360 laboratory developed test, or LDT, that doubles down on our commitment to continue innovating in this space and offer additional biomarkers to our customers, as they become relevant. This exciting new version provides even higher performance than previous versions of Guardant360. It includes additional homologous repair deficiency genes in an effort to keep up with the continued expansion in the PARP inhibitor space, NTRK2 and NTRK3 fusions, and a best-in-class tumor mutational burden or TMB score, which was recently approved in tissue as a biomarker for pembrolizumab for solid tumor patients who have progressed following prior treatment.

Our blood-based TMB assay is highly differentiated and built upon deep sequencing of two mega bases of genomic content. It uniquely integrates information about tumor shedding levels, somatic driver alterations, and chip mutations to provide a robust TMB score that can help identify more patients than other TMB tests. This product offering allows us to address the barrier of confidence in liquid biopsy among some late adopters with an FDA approval and opportunity to provide enhanced features to those customers who are regularly using liquid biopsy in clinical practice.

Overall, I could not be more proud of the Guardant team for the progress made this year. It's hard to believe it was only a little over two years ago when we became a public company and broadly presented our vision to address the continuum of cancer care for screening, to recurrence monitoring, to therapy selection, with a portfolio of practice changing products. There is clearly a growing appreciation of this vision and a growing realization of the potential of liquid biopsy to truly transform the field of oncology.

Since our IPO, we have made incredible progress establishing liquid biopsy as a vital clinical tool for therapy selection in advanced cancer patients. Achievement of several key milestones, including securing reimbursement, have made the $6 billion addressable market attainable, as comprehensive genomic profiling become standard of care. We've also made significant progress with our LUNAR programs, aggressively addressing the even larger opportunities in the recurrence monitoring and screening populations. These programs are initially focused on colorectal cancer, which will serve as a beachhead for expansion of monitoring and screening for multiple cancer types. I'm confident from recent data that our LUNAR-1 assay for recurrence monitoring is best-in-class from both a performance and clinical workflow perspective. I'm also encouraged by the breakneck speed with which our team is executing ECLIPSE, our colorectal screening trial, and that if successful, will address significant unmet need.

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

AmirAli Talasaz

Thanks, Helmy. Starting with our biopharma business, as Helmy mentioned, during the quarter, we reached a critical milestone for our CDx business with FDA approval of Guardant360 CDx. Since FDA approval in mid-August, our CDx discussions have accelerated and we believe our first approval will pave the way for A new companion diagnostic partnerships.

We have another strong quarter for Development Services and Others revenue, growing 63% to $14.2 million led by increasing CDx services. Under sample testing front, biopharma sample volume of 3,071 tests was 42% below the prior year period, but grew 9% from the second quarter of 2020 due to the expansion of our customer base.

Our robust CDx pipeline demonstrates that our biopharma partners are recognizing the value of CGP to accelerate clinical trial enrollment. To that end, a new study published in Nature and Medicine, led by the National Cancer Center Hospital East, NCCHE in Japan, demonstrated that the Guardant360 liquid biopsy is not only concordant to tissue genotyping, but also accelerates clinical trial enrollment, detects more actionable alterations, and achieves similar treatment response rate and progression free survival in patients with advanced gastrointestinal cancer.

Patient with advanced gastrointestinal cancer, including gastric and colorectal cancer were matched to novel therapies that target the specific biomarkers identified. Compared to tissue genotyping, the Guardant360 sped up screening by threefold and improved trial enrollment rates by 132%.

We are also making great progress with GuardantINFORM, our re-enrolled (phon) clinical genomic platform, which we launched in June to help accelerate research and development of the next generation of cancer therapeutics. GuardantINFORM, combined with a robust genomic data from each Guardant360 test with the identified clinical information for each patient. Our biopharma partners are finding significant value in longitudinal real world evidence, which gives insight into how patients are treated based on their mutation profile, as well as patterns of drug response, resistance and tumor evolution. We are excited by the number of deals we have signed to date and by the number of active discussions that are going with additional customers.

Now, turning to our LUNAR program. Since our inception, we have been committed to commercializing tests across the continuum of cancer care that will offer a superior clinical utility, means they offer physicians actionable information for patient care. Similar to the beachhead approach we took with Guardant360 to establish clinical utility non-small cell lung cancer, we are using a focus strategy for establishing clinical utility of our LUNAR assays in colorectal cancer, in spite of the broad applicability of our LUNAR technology to multiple cancer types.

Turning to ECLIPSE, we are continuing to see robust patient enrollment. We have now nearly 150 sites that are onboarded and actively enrolling patients. Overall, we are very pleased with our progress and are on track to complete enrollment within the 24 month timeframe announced last November.

We applaud the recent decision from USPSTF to expand their recommended screening guidelines to 45 to 49 age population. This aligns with the enrollment criteria of ECLIPSE, which was designed to assess performance in that age group.

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We are also pleased with the recent draft NCD proposed by CMS for blood-based CRC screening. The data we have previously presented indicates that the performance of our LUNAR-2 assay exceeds the minimum requirements in the draft NCD, and we are optimistic that the results of ECLIPSE trial will confirm that our assay meets those requirements. This development of this draft proposal reaffirms our choice of CRC as a beachhead of our early detection program.

Finally, during the quarter, FDA granted emergency use authorization of Guardant-19 for use in detection of SARS-CoV-2. The test is being offered to Guardant Health employees and select partner organizations. While we are leveraging our expertise in liquid biopsy testing, and are proud of the contribution that we are making in battling the pandemic, serving cancer patients remain our top focus.

With that, I will now turn the call over to Derek Bertocci for more information and details on our financials. Derek?

Derek Bertocci

Thanks, AmirAli. Revenue for the third quarter of 2020 totaled $74.6 million, up 23% from $60.8 million in the prior year quarter. The increase was driven by an increase in precision oncology testing revenues, resulting from significant increases in clinical sample volume and average selling price, or ASP, per test, as well as higher development services and other revenue.

Total precision oncology testing revenue for the third quarter was $60.4 million comprised of $48.4 million from clinical tests and $12 million from biopharmaceutical tests.

Precision oncology revenue from clinical tests included $4.3 million in revenue received from Medicare for samples processed in 2019. Given the age of the samples associated with this revenue, we do not believe it to be indicative of ordinary course of operations.

Third quarter clinical precision oncology volume totaled 16,950 tests, up to 28% from the prior year quarter, and up 24% from the second quarter of 2020 which was especially impacted by the COVID-19 pandemic.

Clinical precision oncology ASP was $2,852 in the third quarter of 2020, up 23% from $2,319 in the prior year period. The 23% increase in clinical ASP over the prior year quarter was due principally to the reimbursement from Medicare for testing of non-lung cancer samples in addition to lung samples starting in March 2020.

As a result of the evolution of coverage for the testing of Medicare patients, when change is encouraged and permitted, we have submitted appeals and revised claims for samples processed in prior years. In the third quarter of 2020, we recorded $4.3 million of revenue for payments from Medicare from appeals and revised claims for samples processed in the prior year. In the third quarter of 2019, we recorded $5.5 million of revenue from Medicare appeals. Excluding the impact of revenue from Medicare appeals. Clinical ASP in the third quarter was approximately $2,600 per sample, down from approximately $2,700 per sample in the second quarter. The decline was due principally to commercial payers with whom we are a non-covered provider beginning to provide lower payments for tests.

Precision oncology revenue from biopharmaceutical tests in the third quarter totaled $12 million, down 44% from $21.4 million for the prior year quarter, but up 6% from $11.4 million in the second quarter of 2020. Third quarter pharma precision oncology volume totaled 3071 tests, down 42% for the entire year quarter, but up 9% from the second quarter of 2020, due mainly to additional customer programs. ASP was $3,919, down 3% from $4,052 in the prior year period. The ASP was driven mainly by changes in the

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proportion of total biopharmaceutical tests using the GuardantOMNI test, which has a higher selling price than the Guardant360 test.

Development Services and Other revenue in the third quarter totaled $14.2 million, up 63% from the prior year quarter. The increase from the prior year was primarily due to companion diagnostic revenue.

Gross profit for the third quarter of 2020 was $53.4 million, compared to a gross profit of $42.3 million in the same period of prior year.

Gross margin in the third quarter was 72% as compared to 70% during the third quarter of 2019. The increase in gross margin compared to the third quarter of 2019 was primarily due to the increase in clinical precision oncology sample volumes, as well as to the higher clinical precision oncology ASP.

Total operating expenses for the third quarter of 2020 were $127.6 million, a 113% increase from $59.8 million in the third quarter of 2019. R&D expenses for the third quarter of 2020 were $36.2 million compared to $24.6 million in the third quarter of 2019. The increase was primarily attributable to increased spend to support our LUNAR programs, including the ECLIPSE clinical trial, our FDA submission for Guardant360 CDx, and other research and development programs.

Sales and marketing expenses for the third quarter of 2020 were $25.1 million compared to $18.8 million in the third quarter of 2019. The increase was due to growth in sales and marketing staff, plus spend on programs to increase education and awareness about liquid biopsy.

General and administrative expenses for the third quarter were $66.3 million compared to $16.4 million in the third quarter of 2019. G&A expenses for the third quarter of 2020 included $50.1 million in stock-based compensation or SBC, including expense related to market based restricted stock units granted to the Company's founders on May 26, 2020, as compared to $1.7 million in SBC in the third quarter of 2019. The remaining increase in G&A expense is $1.5 million, which was primarily due to additional staff to support the growth of the Company, legal expenses, and the cost of compliance with requirements of being a large accelerated public filer with the SEC.

Net loss attributable to Guardant Health common stockholders was $77.7 million or $0.78 per share for the third quarter of 2020 compared to $12.8 million or $0.14 per share in the third quarter of 2019. We ended the third quarter of 2020 with slightly over $1 billion in cash, cash equivalents and marketable securities.

Beginning in the second quarter of 2020, we added disclosure of Adjusted EBITDA, a non-GAAP financial measure, to our financial reporting, to assist management and investors in evaluating the performance of our core business. By removing the impact of income or expenses attributable to material non-cash items, specifically stock-based compensation and fair value measurements due to the subjectivity, management judgment, and market fluctuations involved around these amounts. We exclude certain other items because we believe that these income or expenses do not reflect expected future operating expenses. Additionally, certain items are inconsistent amounts and frequency, making it difficult to perform the meaningful evaluation of our current or past operating performance. You will find a detailed presentation of non-GAAP adjusted EBITDA and a full reconciliation to GAAP net loss attributable to Guardant Health common stockholders in our Q3 2020 press release results and quarterly 10-Q filed with the SEC.

Our use of Adjusted EBITDA as a non-GAAP financial measure is not intended to be considered in isolation from, a substitute for, or as superior to the corresponding financial measure prepared in accordance with GAAP.

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Non-GAAP Adjusted EBITDA was a loss of $14.6 million in the third quarter of 2020 compared to a $9 million loss in the third quarter of 2019.

The impact of COVID-19 created headwinds for the oncology space during the third quarter, and due to its unpredictable evolution, we do not believe that we can reasonably estimate the magnitude or duration of specific impacts on our business. Accordingly, we're not reinstating financial guidance at this time.

Where we sit today, we believe the effects from COVID are likely to continue to impact the oncology space in the near term. As Helmy mentioned, there has been a resurgence of COVID cases in some regions across the U.S., and we are seeing signs indicating that this resurgence will adversely affect clinical volumes. While we have been successful in continuing to serve our customers in this environment, we expect that clinical volumes for the fourth quarter will only grow modestly in the low single digits compared to the third quarter 2020 given this resurgence.

Regarding our biopharma business, we expect that biopharma sample volumes will continue to grow in Q4 at rate similar to Q3. We expect Development Services revenue to remain strong and be comparable to Q3.

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

Helmy Eltoukhy

Thank you, Derek. Before closing, I want to again thank our team at Guardant for the dedication and effort they have shown, particularly over the last few months. I believe we have a truly unique opportunity at Guardant to expand unprecedented access to cancers' molecular information throughout all stages of the disease.

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

Operator

At this time I'd like to remind everyone in order to ask a question, please press star and the number one on your telephone keypad.

Your first question comes from the line of Puneet Souda from SVB. Your line is open.

Puneet Souda

Hi, Helmy. Thanks for the question. So first one, on clinical volumes. Clinical volumes didn't decline as much for you during the COVID lows of the second quarter as compared to the some of the other diagnostic peers, so we weren't expecting a major recovery for you in the third quarter here, given that backdrop. But just trying to understand some of the comments that you made around COVID resurgence/ I understand the conservatism there but is there anything else that we need to keep in mind? You know, after all, the value of G360 liquid has been the ease of access and it's a blood-based test and accessible to the patients in their home setting with the phlebotomist, so I'm just trying to understand how to frame that, given the second wave of COVID that's coming here.

Then on G360 LDT, if you can help us understand if that's going to be meaningful next quarter. Obviously you're having some unique features here with TMB and a number of additional genes?

Helmy Eltoukhy

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Great questions. In terms of the COVID in terms of the clinical volume, the efficiency of being able to service and detail physician offices in a remote and virtual environment is just not the same as being in-person. I think we saw a very quick recovery to pre-COVID levels because of the agility of our teams on both Medical Affairs and our Commercial teams, of really being able to convert to this new normal, this new environment of being able to detail and service our clients and our customers and physicians through this new virtual means.

That being said, I think it's challenging. We're seeing record numbers of COVID cases. I mentioned before that cancer patients have about a 30% mortality rate due to COVID, so they are a population that is heavily in danger, that needs to be sheltered in place. We are seeing very good utilization of mobile phlebotomy and some of the other services that help in this environment, and I think it's why we're continuing to see growth in this environment. We saw 28% year-over-year growth in terms of clinical volume.

I think if you think about what the backdrop looks like in oncology, patients visits are still depressed from pre-COVID times**. T**hey're still at around 90% of where they were. The top of the funnel is still depressed, there is still headwinds there. I think those headwinds are going to increase.

We're seeing some regions that will do well, where we see growth and all of a sudden where there is resurgence of COVID there are more office closures, and there's more care been taken by the physicians in those practices. We feel very good about how we're managing in this environment, but that being said, COVID is still very real and is still a very large concern in this environment.

In terms of…

Puneet Souda

On G360—and then if I could actually wrap it up into another question—FDA approval of G360 was great to see. Can you just walk us through the G360 version to LDT. What is the regulatory pathway there as well?

Helmy Eltoukhy

I think as we alluded to on the call, we now have this framework where we have a FDA approved product with Guardant360 CDx. That product has best-in-class turnaround time. It's an amazing tool, wealth of clinical evidence supporting it in terms of one of the most rigorously validated tests, liquid biopsy tests out there, and it's something that is extremely useful for the first line setting, and very useful for onboarding physicians who maybe aren't used to using CGP in a day in day out basis. We see that as a very important piece of our product portfolio.

That being said, the field is continuing to evolve very rapidly. New biomarkers are being added, there are new clinical trials. So, continuing having an LDT test like our next generation Guardant360 which we launched at the same time, is going to be important for us to remain really best-in-class in terms of biomarkers that are available to test for in terms of our physicians and for their patients.

Guardant360 LDT is a commitment to continuing to move fast in this field and we're seeing very nice engagement on both sides. There are early adopters out there that want look for new biomarkers and look for essentially next generation types of clinical trials, as well as thinking about the progression setting where we may need to look at some extended options for those patients.

We see having these two products really complement—they complement each other and help really segment the market in a way that drives value for both types of physicians.

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Puneet Souda

That's very helpful. The last one, if I could ask, Helmy, on multi cancer screening. You're a leading company in the space in liquid biopsy, and just wanted to get your thoughts on how Guardant views the multi cancer screening opportunity in the light of the two large pre-revenue transactions that have happened in the space?

Helmy Eltoukhy

AmirAli, do you want to take this?

AmirAli Talasaz

Yes, sure. (Inaudible) our lead indication is CRC. We think we are far away, all other kind of players who are trying to build blood-based CRC screening assays. The performance says that we clearly increased compliance in that space, compliance to screening. The same core platform technology, in fact, is applicable to other cancer types, so for different kinds of settings, we have looked at other cancer types like breast cancer and lung cancer. But on the clinical utility side of it, you're starting from CRC and generating evidence on that side and building the regulatory and reimbursement pathway to our lead indication, but you could imagine in terms of the lifecycle of our LUNAR-2 assay, other cancer types would be added to it since the whole platform is compatible to multi-cancer screening.

Puneet Souda

Okay, great. Thank you.

Operator

Tycho Peterson from JPMorgan, your line is open.

Tycho Peterson

Thanks. Helmy, I'll start with the FDA approval for G360 CDx. Can you just talk on the expected pace of private payer coverage expansion and how much volume lift in ASP improvement we can expect from the approval?

Helmy Eltoukhy

Great question. We're definitely seeing a pickup in terms of conversations with private payers. I think there's a lot of momentum there. Certain private payers view FDA approval as one of the last milestones, in terms of really getting over the hump in terms of reimbursement. Those conversations are happening, and we're seeing progress there.

I would say that I think in this quarter, we added—this last quarter, we added over 10 million covered lives so we continuing to make very good progress on that front.

In terms of improvement in ASP, there are a couple of I think different components to that, especially on the Medicare side. The indication for our FDA approved product is wider in terms of Medicare population. It's a test that can be used in the first line setting, and so rather than just 85% of our Medicare volume being covered under the LCD, we believe that we can be in the 90% to 95% range for the NCD that we now are covered by for Guardant360 CDx.

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Then longer term, we think in the next few quarters, we'll be able to qualify for ADLT status with a unique code and we think, at least on the Medicare side, that should move up our payment rate from $3,500 to something that would likely be over $4,000. We're very, I think optimistic about continued improvement in ASP over the medium to longer term.

Tycho Peterson

Okay, that's helpful. Then on Omni, the ESMO guidelines now endorse large panels, including the use of a TMB. So, can you talk to how the U.S. guideline conversations are shaping up and whether peer coverage will accelerate or does it largely depends on FDA approval? How should we think about the difference between the enhanced G360 test versus Omni since both can do TMB now?

Helmy Eltoukhy

Can I take this, AmirAli?

AmirAli Talasaz

I will take the last parts in terms of the differentiation of these two products. As Helmy mentioned, Guardant360 LDT is a next generation Guardant360. You can look at it more as the market segmentation, but there are a (inaudible) that FDA approved Guardant360 CDx would be a better fit for their clinical use cases. It's going to be FDA approval of Guardant360 CDx would accelerate some of the guideline enhancement around that product.

Having said that, there's other part of market sector that really they want to have access to the latest and greatest in terms of biomarker testing and when they think about the lifecycle management of this product portfolio that we are talking about, most probably we can expect we are going to have a lifecycle around Guardant CDx and a lifestyle around Guardant360 LDT. The current version of LDT could be the future generation of CDx, and the next next generation would be the Guardant360 LDT that we are talking about. But, as you know, making some guideline changes will take time.

Helmy Eltoukhy

I think the first part of your question, yes, I mean, I think we see it as a certain positive. TMB is broad sequencing, is an important part of CGP, and certainly there have been some payers that have come onboard, and we see that as a positive development for this space.

Tycho Peterson

Okay. Then lastly, on the clinical studies, I think last quarter you alluded to maybe you could finish enrolling the ECLIPSE study early. Is that something that is still on the table in your view? Also, when should we get an update on LUNAR-1 readout timelines? Thanks.

AmirAli Talasaz

On ECLIPSE, this morning, always we mentioned, we are on track to finish the enrollment on the originally stated timeline of 24 months, which effectively is like November of next year for us. We are very excited with the progress that we made and with some of the additional sites that we brought on, we are even expecting if this resurgence of COVID will generate some maybe short interruption in our trial that we haven't experienced yet. But if it carried some kind of issues, still we would be able to finish the trial on time, so we would be done with it by November of next year, in terms of enrollment.

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On LUNAR-1 our studies are ongoing. The LUNAR-1 studies are multi years and it's going to take some time. We are very excited with conversations that we had with KOLs who are using actually LUNAR-1 assay in their clinical trials in the CRC setting. We've made actually pretty good progress. We believe actually we have the market leading performance in terms of the technical performance and what it's really required in the clinical setting to really have MRD tests embedded in the clinical workflow. We are very excited that one of our partners have submitted a publication that actually highlights the performance of the test that we have relative to the experience that they have. Hopefully, when that paper gets published we can talk about the details at the right time, but we are excited with what we see right now.

Tycho Peterson

Okay, thank you.

Helmy Eltoukhy

Thanks, Tycho.

Operator

Doug Schenkel from Cowen, your line is open.

Doug Schenkel

All right. Good afternoon. Thanks for taking my questions. I want to start by going back to the topic of your FDA approval for G360. I'm just wondering if that has changed the tone of discussions with clinicians, especially in the community where acceptance of newer technologies sometimes just takes a little bit more time.

And sort of related to that regarding, again, FDA approval, Foundation Medicine also got approval over the summer, with FoundationOne Liquid? Has that changed competitive dynamics at all? Or would you kind of look at it differently, and maybe suggest that we kind of think about more FDA approvals in this class being good for all tests, kind of rising tide lifts all boats, just given how much market is left to penetrate?

Helmy Eltoukhy

Great question, Doug. So, in terms of the first part of the question, yeah, we are seeing very nice engagement with I would say the middle majority and laggards in the field. Having an FDA approval, I think lays to rest a lot of the doubt that existed around liquid biopsy. In fact, I think we are seeing record numbers in terms of number of unique physicians ordering the test on a monthly basis. We're seeing, I think, really good metrics in terms of that level of engagement.

That being said, we are in a highly impacted environment with COVID in terms of being in to detail physician offices on a in person basis. A lot of it is virtual. There's just no doubt that there's a reduced conversion and reduced ability to sell in a remote environment, so that's going to continue to impact this space, but I think we've always said that FDA approval is a catalyst over the medium to longer term. A lot of these physicians that have been slow to adopt—and it will take time to get them to use these types of tests, and then finally use it on a kind of every patient type of basis. Those early conversations have been really good.

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And I would agree with the second part of your statement as well, that we see FDA approval, even FDA approval by competitors as really shining a light in terms of the utility of liquid biopsy, that liquid biopsy should be part of the standard of care, really bringing a focus to the conversation. We see that as a overall positive for the space. We see it as clarifying this space as well, in terms of really reducing the noise that exists and really just focusing on those FDA approved products in the space.

But that being said, we're very confident we have what we believe is really a best-in-class product in terms of performance, sensitivity, breadth, and as well as service level. I think we're very bullish and very optimistic in terms of continuing to grow use of Guardant360 and overall CGP in the space.

Doug Schenkel

Thanks for that Helmy. Maybe just one more on a different topic. The CMS proposal on how they are trying to outline a path to reimbursing colorectal cancer liquid biopsy screening tests. I'm just curious at a high level what you think of the proposal, and then more specifically, how this either impacts or doesn't impact your thinking on LUNAR-2 timelines in terms of when you could get reimbursement from CMS?

Then kind of the last part—sorry for the long question—but what do you think the most important things are that need to be addressed during the comment period? Thank you.

Helmy Eltoukhy

AmirAli, do you want to take this?

AmirAli Talasaz

We are pretty excited with this broad based CRC screening. It's still in draft form, the proposal. Even without this draft**,** based on conversation we have previously, we feel bullish that post FDA approval of the test, we could get actually some favorite coverage from CMS. But now, actually the guideline is more clear.

I think that the way the draft blood-based CRC screening NCD is written is pretty good. Still we have some comments that we are working on that we would like to see some kind of changes. But in general, it's pretty good in terms of performance matrix that they have, based on all the data that gets presented so far, we feel positive about those performances and we think those are the right bar for having that could make an impact.

We don't expect this would accelerate our reimbursement timeline in a significant way. All would be dependents to the—in the time gap between FDA approval and formal CMS approval. We were expecting that timeline would be short and now with this guidance it could be maybe slightly shorter.

Doug Schenkel

Great. Thank you guys, again.

Helmy Eltoukhy

Thanks, Doug.

Operator

Derik de Bruin from Bank of America, your line is open.

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Derik de Bruin

Hi, good afternoon. The bulk of our incoming questions lately have been around LUNAR-1 and how that test compares to some of the other more personalized TRACERx based methods that are coming in. I mean, other than the workflow advantages, which are clearly obvious in this, can you sort of talk about head-to-head performance, and there's been any studies done, and sort of how the tests—how LUNAR-1 is going to compare to these other tests in terms of how they're going to perform? That's starting to be the real incoming questions that we've gotten from clients.

Helmy Eltoukhy

I would say that—maybe I'll start and the AmirAli can patch in. I think there's a misconception frankly, that something that is tissue informed is necessarily better than something that is a blood only. I think what we're seeing with some of the recent data is we have a very differentiated method by which we're looking very broadly in not just the genomic space, but the epigenomics space. You can see that, most companies that are going towards early detection and trying to detect cancer at its earliest stages are really following a pathway that leads towards epigenomics or methylation or some of these other markers. We feel very confident that we have a very unique approach for the minimum residual disease space, in this in this LUNAR assay we have that looks at both dimensions, the methylation and genomic alteration simultaneously. We really see no deficit or no reduction in sensitivity versus some of these other methods that they're sequencing the tumor, but they're kind of just simply looking at a few mutations in the blood and then tracking them.

We have a very much more, I think rigorous comprehensive approach to looking at residual disease. It has a lot of advantages, both from a biology and a performance point of view, but just as importantly, from a clinical workflow point of view. Being able to actually return result within a week or two, rather than many, many, weeks. Time to treatment, time to making a decision is vitally important in the clinical space and it's no different in the adjuvant setting.

Derik de Bruin

Great…

AmirAli Talasaz

As I mentioned, the other publication review that's basically publication on one of our KOL partners, so we are waiting for that publication. If we come in press, and we can talk about it more, but very excited with what they found. Please stay tuned.

Derik de Bruin

Great. Just one quick follow up. Can you talk a little bit about the biopharma volumes? You said an increase on the quarterly increase between Q3 and Q4. How should we think about that volume picking up, sort of going into next year? I mean, are you still being restrained by samples not being delivered or there's still issues or trials being delayed. Just some sort of color on when you expect the biopharma samples to begin picking up?

Helmy Eltoukhy

You want to take that, AmirAli?

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AmirAli Talasaz

Maybe I start and Derek can maybe patch in.

In terms of actually Q2, we saw huge impact in August and Q3 was modestly better than Q2, and Q4 we are conject to see similar level of progress relative to Q3, modestly we are growing. That is still COVID has some impact in terms of the distraction to our biopharma companies. We have some major programs around some COVID related activities, but also what we are saying is, there is a lifecycle in our partnership with pharma companies that conversations are getting graduated from sample testing to prospective studies, and then CDx development, and for different programs once sample testing gets graduated and goes to, let's say, CDX conversation, we are seeing some kind of shift of revenue from one market to the other market that could generate some kind of up and downs in terms our volume testing, maybe as their…

Derek Bertocci

Just a couple of other comments that I think are helpful. We are encouraged. While we certainly have a deep trough in Q2, we're encouraged by the growth in Q3, what we expect to see continued growth at that rate of growth in Q4. Underlying that, we are encouraged by the broadening of the base of customers who are working with us. There can be, as you know, in the pharma business, individual programs that sort of grow, blossom, and then they complete and then you're filling in with others. What we're happy with is that we're seeing a broadening base of customers, and so in the future we're hoping that those will be to the kind of growth that we saw in the past.

Derik de Bruin

Thank you.

Operator

Brian Weinstein from William Blair, your line is open.

Brian Weinstein

Hey, guys. Thanks for taking the question. Just to go back to a couple questions ago on the CMS draft on CRC, I wanted to see if I heard AmirAli's comment, right? Did you think that that would potentially shorten the timeframe for coverage? Because our readout it was with inclusion now required in one of the guidelines it might actually extend it, so I wanted to make sure I understood the thought process there. Then also, do you think that there's a need for advanced adenoma goalpost to be added to the final document there?

Helmy Eltoukhy

Maybe I'll start. That's actually no different the requirements than kind of statutorily that's required for coverage by CMS in the setting. We don't really see that as a big difference in terms of previous thinking and what was typically required versus what's being proposed. I think this only further gives us confidence in terms of being able to have a timeline that is extremely quick, and I think reaffirms our choice of colorectal cancer as a beachhead for our early detection program.

In terms of maybe I'll let AmirAli take the second part of the thing. Advanced adenoma.

AmirAli Talasaz

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Advanced adenoma, yes. I think really depends to the clinical application. If you want to increase the compliance rate to screening really like the performance of early CRC detection should be enough. The way that actually we designed the ECLIPSE study, we are going to look at the sensitivity of the Phase 1 in CRC specificity when we look at CRC and advanced adenoma because we are expecting that we are going to detect the [inaudible] *53:0 of the advanced carcinoma cases. But in terms of guidance and requirement for blood-based based on everything we know in this field and the conversation we had with KOLs, having even a blood-based assay that can detect early stage CRC can increase compliance rate in a very significant way. Maybe that performance criteria they have should be sufficient.

Brian Weinstein

Got it. Thank you. Then separately, have you guys looked at or are you interested in the nodule management space, given how deep you are in lung cancer management? Does it make sense for you to enter the discussion there around something maybe post-CT nodule management? We saw a small study or like you were involved in there, but I'm really just not sure how much to make of it because I don't think I've heard you talk about it before?

Helmy Eltoukhy

AmirAli?

AmirAli Talasaz

Maybe look at those as pipeline activities for us. Eventually I think some line data and a few months before we went by—even two years ago, or more than two years ago. The reality of this platform technology is it's really a multi-cancer platform technology. We have seen some performance in a bunch of cancer types already. Still, we have a bunch of work ahead of us. Still, we don't want to distract ourselves on the utility at this time to look at the utility of other cancer types besides CRC.

When you look at it this way that what we are—the platform technology that we have, not only look at genomic markers, but look at epigenomics, look at methylation patterns, fragmentation patterns, which basically the signals could come from multiple sources, from tumor microenvironment, potentially even some signals from immune response. That's what we are assaying with our platform technology, which is a very broad concept and we are excited with some early data that we have, but those are very early. Let's look at those more as pipeline activities for us.

Brian Weinstein

Understood. Thank you.

Helmy Eltoukhy

Thanks, Brian.

Operator

Patrick Donnelly from Citi, your line is open.

Patrick Donnelly

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Thanks. Helmy, maybe one for you, just on the resurgence on the clinical volume side for 4Q. Just trying to figure out I guess how much impact you guys have seen quarter to date already in terms of the October trends versus some level of conservatism baked in? I know even three months ago, you guys had some conservativism for 3Q with the potential second wave. How are you viewing this quarter in terms of the resurgence? How much impact have you seen already and how much are you seeing kind of currently versus the fear of what's to come, I guess, in the next two months or so?

Helmy Eltoukhy

That's a good question. I would say it's really along the lines of what we commented on back in our Q2 earnings call. We're seeing these regional flare-ups. We're seeing impact on a kind of short-term basis, depending on the region and the level of fear that exists. Clearly we're in a much more, I would say, high alert time with the U.S. crossing 100,000 cases per day in terms of new infections. There is I think a well-founded level of, I think, conservatism on the part of the physicians in terms of really trying to make sure that they keep their patients as healthy as possible.

This is not just reflected in our own data. We're seeing in the patient visit data and overall oncology field data that there's a fluctuation there from week to week in terms of in-person patient visits. The field in general has moved very significantly to remote visits. and so all of that reduces the number of opportunities for patient engagement and physician engagement. Virtual calling is just not as effective as being in-person.

But that being said, we are seeing excellent metrics in terms of number of physician adds, in terms of unique physician orders, really, in terms of share of voice in the field. We're very confident that despite these headwinds, we're doing, I think something that is really second to none in terms of the oncology diagnostic space. But it's going to continue to be a challenge. It's not the same type of conversion that we had a year ago, pre COVID.

Patrick Donnelly

That's helpful. Then maybe just to pick up on your last point there, I was kind of wondering how orders tracked for the unique new physician versus existing accounts, to your point, they're just about kind of virtually calling. How do you see the ability to open these new accounts during what was pretty nice recovery in 3Q, did you see that accelerate? How should we expect that to trend in the near future here?

Helmy Eltoukhy

We saw a low in Q2 but that being said, we're back. I wouldn't say we're back to 100%, in terms of new ordering MDS, but very close to that in terms of Q3. We still have the ability to be able to add new physicians. We certainly think that FDA approval is something that has helped, as well. Help us not just engage new physicians but re-engage those that maybe tried us a long time ago and now realize that this is much more validated and something that is worth their time.

Patrick Donnelly

Great. Thanks, Helmy.

Helmy Eltoukhy

Thanks.

Operator

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Tejas Savant from Morgan Stanley, your line is open.

Tejas Savant

Hey, guys. Good evening. Just a couple of ones here, Helmy and AmirAli. First on GuardantINFORM, you've probably got north of 100,000 patients in the clinical genomic database here. Can you update us on some of the work you're doing there to monetize that offering and what the pipeline looks like? Particularly since, you know, it's likely to be a very high margin offering for you.

Helmy Eltoukhy

Yeah, it's good. AmirAli, do you want to take that?

AmirAli Talasaz

Yeah, sure. That's a very exciting business for us. From business perspective also generating lots of new clinical data to show the value of liquid biopsy there, and that we are even more excited in what we're doing in GuardantINFORM looking at the longitudinal real world evidence. One of the unique advantages of liquid biopsy is and the database that we have is multiple lead time points that we have from different patients. You could really see what's happening to a patient as a result of treatments over the course of relatively long period of time, when a patient is getting tested multiple times and that has opened up some interesting opportunities for us.

Besides longitudinal real world evidence in terms of single points of data, we've seen a lot of excitement by our biopharma partners. Almost with all biopharma partners that we have, we had some interesting conversation around GuardantINFORM. We have signed bunch of deals and many more deals are in the pipeline of conversation. Still, it’s early for us and we have to go through this process of conversation to really be able to assess the opportunity size for next year better, but it's an exciting area of an emerging business for us.

Tejas Savant

Got it. Then just a couple of ones on LUNAR here. Helmy, just in terms of the implications of the Palmetto draft LCD, would you consider accelerating your plans to submit for other indications beyond colorectal? Particularly, as you know, the space gets a little bit more competitive here, in light of the supportive reimbursement landscape.

Then on LUNAR-2 I mean, this goes back to an earlier question around some of the M&A activity in the space. But in terms of your own commercial channel, build out efforts ahead of launch, are you sort of incrementally more open to considering partnerships in the space versus a go-it-alone strategy as far as that targeting those physicians is concerned?

Helmy Eltoukhy

Great questions. The first one, we've always had a roadmap of starting with initial beachhead cancer, and that's colorectal for LUNAR-1 program. We've made excellent progress there and I think we're very excited with the capabilities of the platform. But that being said, we have research and multiple cancer types. We're very confident from the data we have that we can make a big impact in terms of the field and other cancer types as well, and some of the main cancer types that would benefit from residual disease monitorings or recurrence monitoring.

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We think we have some unique capabilities for the platform and some of those other cancer types that maybe aren't very amenable to some of the more simplistic approaches that are out there. That's certainly something that is in our roadmap and something that certainly is going to be a next step for us.

I would say, in terms of the LUNAR-2 side of things—can you remind me what the question was? Sorry, Tejas.

Tejas Savant

I was just asking around your plans for the commercial channel buildout given that the other partnerships that have just been struck in the space?

Helmy Eltoukhy

We're certainly open to those types of partnerships. We partner with many of our pharma companies on the therapy selection side in terms of the companion diagnostic component of our test and that's going to be no different on the early detection side.

That being said, I think we are in the early stages of planning in terms of the building out that commercial channel. It is a very different commercial channel in terms of the primary care setting. It's one of the reasons we did this recent fundraising a couple quarters ago, to really be able to invest in building out a really differentiated and leading commercial channel in that space and doing so in a way that's aggressive, that is timed with a potential launch of a product in for colorectal screening.

Yes, it's something we're very committed to and we believe that really making sure that we engage all channels. Not just personal promotion, but digital promotion, direct-to-consumer, as well as partnering with other stakeholders, those are all on the table and all going to be components of our commercial framework.

Tejas Savant

Got it. Thanks so much for the color.

Helmy Eltoukhy

Thanks.

Operator

Again, if you'd like to ask a question, please press star and the number one on your telephone keypad.

Your next question comes from the line of Sung Ji Nam from BTIG. Your line is open.

Sung Ji Nam

Hi, thanks for taking the questions. Just a couple of quick ones. Firstly, I was curious, what's the rationale of the enhanced Guardant360 versus I guess more broadly using GuardantOMNI? Are there different use cases? Are there price activity factors involved? Because I've always thought that Omni was kind of the next generation 360?

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Then the follow-up question is totally different. I know, it's a not a core business, but with your contributions from COVID testing this quarter, and do you anticipate meaningful contribution given, I think, the capacity you guys have is pretty sizable in the coming quarters? Thank you.

Helmy Eltoukhy

AmirAli, do you want to take that one?

AmirAli Talasaz

Regarding Guardant360 LDC, the next generation version of it. In the market that we are actually in, not many doctors in fact would enjoy it seeing a lot of information that a 500 gene panel like GuardantOMNI produces, and in fact it could be negative for them. That's on the customer side.

On the reimbursement side, there are definitely some anxiety of using extremely broad panels in terms of potential off-label drug uses for biomarkers that maybe their clinical relevance of those biomarkers at this time, it's not proven yet. We think the next generation Guardant360 for clinical testing the best product is what we put in the market on one side as a tool mega based panel similar to Omni that we have for pharma, and basically does the TNB calling based on that content. Also look at 80 plus genes, which are very clinically relevant, and also we enhance that panel, as Helmy mentioned, on the NTRK side, HRD side to really match all the biomarkers that based on guidelines people are interested to test.

Then COVID, yes, so regarding COVID, actually we—maybe I'll get Derek comment about our COVID revenue in Q3. But since it's not really the focus of our business, we are not really expecting COVID revenue to play a material role in our revenue in Q4 and the quarters to come because really we are laser focused in the oncology area.

Having said that, we are excited about this EUA approval that we got. We really like the offering of the test to Guardant employees and partners and really making our working environment as safe as we can, has been very important for us to keep the productivity level high during this pandemic with **a** state of mind that vast majority of our employees have now that we're doing this testing for Guardant employees.

Also, we open it up to a bunch of partners, but we are not commercially pushing it in a significant way. Derek?

Derek Bertocci

Yes. Sung Ji, we recorded a $1 million worth of revenue for our COVID-19 tests, and we report it in the Development Services line items because we don't want to confuse or combine it with our oncology testing, which is precision oncology testing. That has stayed clean and it's really small, sitting in the Development Services. And as AmirAli suggested, we are not working on it to become a big element and we don't expect it to become a big element.

Sung Ji Nam

Sounds great. Thank you so much.

Helmy Eltoukhy

Thank you.

Operator

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There are no further questions at this time. This concludes today's conference call. You may now disconnect.

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