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Guardant Health

Second Quarter 2021 Earnings Call

August 5, 2021

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PRESENTATION

Operator

Good afternoon. Thank you for standing by. Welcome to the Guardant Health Second Quarter 2021 Earnings Conference Call.

Please be advised, today's conference is being recorded.

I would now like to turn today's conference over to Carrie Mendivil, Investor Relations.

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Carrie Mendivil

Thank you.

Earlier today, Guardant Health released financial results for the quarter ended June 30, 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 today from Guardant are Helmy Eltoukhy, AmirAli Talasaz and Mike Bell.

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 discuss 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, August 5, 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 Second Quarter 2021 earnings call.

Our mission at Guardant has always been to ensure patients have access to innovative oncology products. Today, the vision is clearer than ever and I have never been more excited about the opportunity ahead of us. This afternoon, we announced a new leadership structure which will allow us to aggressively move and scale into new areas of growth across the continuum of cancer care.

We have created two focus areas within Guardant - oncology and screening. AmirAli and I will serves as Co-CEOs with AmirAli leading our screening efforts and me leading oncology. We believe this leadership structure will provide the focus and strategic attention required to continue as the liquid biopsy leader in oncology, while aggressively pursuing the massive opportunity in cancer screening. This structure will also allow for scalability to address new areas across healthcare beyond screening in oncology.

Everything we do at Guardant is motivated by our commitment to serve patients. We are dedicated to bring the absolute best products to market that'll provide clinically actionable information to inform patient care. We believe that this new focused leadership structure will allow us to more rapidly address the unmet need to serve patients. And in line with these commitments, I will start off today with a patient story.

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Last March, a 68-year old woman was diagnosed with colorectal cancer. Shortly after her diagnosis, surgery was performed followed by adjuvant therapy. in follow-up, her oncologist detected elevated levels of CEA, which she scanned negative for evidence of disease. At another follow-up, just over a year after the initial diagnosis, her oncologist ordered a Guardant Reveal test, which showed she was ctDNA negative. Guardant Reveal directly measures tumor-derived DNA in the blood while CEA has its own specific biomarker and can be elevated multiple cancer types; for example, in smokers and in patients with various benign diseases. Guardant Reveal has a sensitivity of 91% compared to CEA test with a sensitivity of 69%. With a higher sensitivity than CEA in the surveillance setting, Guardant Reveal showed the patient was not actively progressing.

This story highlights how Guardant Reveal can provide confidence and reliability in recurrence testing for cancer.

Now, turning to our second quarter performance. Revenue grew 39% to approximately $92 million. Second quarter clinical volumes grew to 20,830 tests, representing 52% growth over the prior-year period and up 13% from the first quarter of this year. While patient visits and office (inaudible) are still not fully back to pre-COVID levels, we are pleased with how well our commercial team is continuing to execute in this environment and still achieve healthy volumes. International clinical volumes were impacted by the resurgence of COVID cases, especially in countries where the vaccination rates remain low.

During the second quarter, we saw strong growth in U.S. clinical volumes, as oncology offices gradually reopened throughout the quarter. However, in recent weeks, we have seen a reduction in oncology office visits and sales force access in the United States and across our global business, which may have an adverse impact for the remainder of the year. Although we have started to see some impact globally, we have not seen much yet in the United States. We are monitoring the situation closely as it evolves.

Our portfolio is growing quickly and we have launched a record number of new products and product upgrades in the last year alone. But we are nowhere close to done. Two of these new product launches were announced in the second quarter - Guardant360 TissueNext and Guardant360 Response. Both products expand the trusted Guardant360 portfolio to offer oncologists end-to-end testing solutions. TissueNext supplement our blood-first approach. Our TissueNext tests provides the integrated solution for oncologists to use liquid first ahead of tissue ensuring patients receive guideline complete testing with the fastest turnaround times. An oncologist orders an integrated product and begins with a Guardant360 liquid biopsy test. If there is no biomarker detected, he or she is able to quickly refresh (phon) the tissue with TissueNext.

This integrated approach has a significantly higher biomarker detection rate than tissue alone. In the ECLIPSE study, in non-small cell lung cancer, CGP liquid testing using Guardant360 identified 81% of patients with informative test results and tissue testing found informative biomarkers in the remaining 19% of patients. On the other hand, standard of care tissue testing alone identified just 57% of the patients with informative test results in this study. This study is one of many that highlight that the blood-first TissueNext approach offers a clinically superior paradigm. The early response to TissueNext has been very encouraging. The reimbursement path for tissues is well defined and we expect to submit the technical assessment application to MolDX this year. We believe this offering will serve as a stepping stone for those who continue to rely solely on tissue testing to move towards a blood-first testing paradigm.

Guardant360 Response is the first commercially available blood only liquid biopsy test. It detects changes in ctDNA levels to provide oncologists an early indication of a patient's response to treatment, such as targeted or immunotherapies. Our comprehensive product portfolio essentially enables our oncologists to perform profiling for treatment selection in both blood and tissue as well as response monitoring.

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Feedback for both new products is very positive. We do not expect either products to be a significant revenue contributor in the near term as we work to establish reimbursement.

Turning to our recurrence monitoring opportunity with Guardant Reveal. We are pleased by the encouraging feedback and reception from oncologists. Based on the early success we are seeing in the market around Reveal, we have expanded this dedicated commercial team. More than 9,000 oncologists have ordered a Guardant360 test and we are leveraging these existing customers as well as our relationship with KOLs for their launch of Reveal. Beyond CRC, (inaudible) in great advances in other cancer types with the compelling data on bladder, lung and now breast as well.

Moving on to biopharma. Biopharma volumes grew to 3,653 tests, up 30% year-over-year and up 4% from the first quarter. We continue to experience some pressure in biopharma sample volumes given the lag in many of the samples coming to us for analysis due to slower enrollment during COVID peaks. Q2 development services and other revenue was approximately $19.5 million, up 27% year-over-year. We are pleased by the growth of our overall pharma business and continue to serve an increasing number of biopharma customers with more than 80 active partnerships. As our biopharma business matures, we expect growth to be underpinned by sample volumes including new product introductions, for example, multi-indication Reveal, as well as companion diagnostics.

This quarter, we announced two new companion diagnostic approvals with Janssen and Amgen Both for use in advanced non-small cell lung. The FDA has approved the Guardant360 CDx test as the first and only liquid biopsy companion diagnostic for comprehensive genomic profiling to identify patients with locally advanced or metastatic non-small cell lung cancer who harbor the KRAS G12C mutation and who may benefit from Amgen's LUMAKRAS, or who harbor an EGFR exon 20 insertion mutation who may benefit from Janssen's RYBREVANT.

Moving on to GuardantINFORM, our real world evidence platform, featuring an extensive clinical genomic liquid biopsy data set of advanced cancer patients. We have signed more than a dozen biopharma collaborations for GuardantINFORM since its launch, just over a year ago. We are pleased with the success and growing interest from our biopharma partners in this offering.

At Guardant, our sights are set not only in providing solutions for patients with advanced and early stage cancer, but early cancer detection as well. We are focused in establishing ourselves as a best-in-class company in these large markets while maintaining a culture of fast execution as the organization continues to scale.

Since founding Guardant, AmirAli and I have always had a strong partnership and we've been laying the groundwork for these two focused areas of oncology and screening for quite some time. This Co-CEO leadership structure is a continuation of our current strategy and supports the evolution of our business. We are scaling the team to support the growth of both businesses and recently brought on Chris Freeman as our new Chief Commercial Officer of Oncology. We expect to bring on several more key leaders in the near future and have started building a dedicated commercial organization for our screening business. Having leadership teams dedicated to each opportunity will give us the focus and velocity to rapidly scale in each of these areas to drive both near-term and long-term success.

We have also continued to invest in our governance and made recent changes in addition to our Board of Directors. I will now be serving as Chairman of the Board and AmirAli will continue to serve on the Board as a Director. We believe this rotation in responsibility adds a fresh perspective and is in line with our overall focus to scale our organization.

In addition, Meghan Joyce has been appointed to our Board of Directors. Meghan is the Chief Operating Officer and Executive Vice President of Platform at Oscar Health, a high growth health tech and health

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insurance company, where she leads operations, technology, clinical, marketing, and new business lines. Prior to joining Oscar Health, Meghan had several leadership roles at Uber, most recently as Regional General Manager of the United States and Canada. Her expertise in scaling high growth organizations will be invaluable to our next phase of growth. We look forward to her contributions and guidance.

We are committed to continue to develop a portfolio of breakthrough products across all stages of cancer and ensure these innovations are not only available but readily accessible for all patients. We look forward to continuing to expand our product portfolio, attract and develop top talent, and improve patient outcomes as we conquer cancer with data across the continuum of care.

I will now turn the call over to AmirAli.

AmirAli Talasaz

Thanks, Helmy.

I want to start by echoing Helmy's excitement for what is ahead of Guardant. Early cancer screening has a potential to significantly transform patient outcomes. The successful readouts of our ECLIPSE trial will potentially open up a $20 billion screening opportunity in colorectal cancer, and future studies will open up opportunities in additional cancer types, paving the way towards a total addressable screening market of more than $50 billion.

We are confident that we will become the leader in screening, not just in CRC, but across many cancer types.

That said, it is clear that this opportunity requires a dedicated and focused effort. I'm thrilled to assume the role of Co-CEO as we position ourselves for the launch of our screening business. We are encouraged by the progress in the CRC indication and this is just the first of many indications we will pursue for screening.

I'm excited to announce that we have recently enrolled the 10,000 patients in our ECLIPSE trial. I'm proud of the progress our clinical team made in running this study during the pandemic, when enrollment in many clinical trials were heavily impacted. Now, based on the CRC prevalence that we see in ECLIPSE so far, we plan to enroll an additional 3,000 patients in this study for a total of 13,000 to ensure we reach the required number of CRC positive patients. We are confident that we will have total enrollment completed by November of this year, the same 24 month timeframe that we announced when we launched the ECLIPSE study.

In parallel to running ECLIPSE, we are also making great progress building our commercial infrastructure to launch our screening product. I'm pleased to announce that we are planning to launch the LDT version of our CRC screening assay in the first half of 2022 and we expect to launch the IBD (phon) version of the assay in 2023, pending successful FDA review and approval.

The initial version of our screening test will be for CRC and we expect over time more indications will be added to the assay. We have presented data and are continuing to see good technical performance in detecting early stage lung, bladder, pancreatic and a few other cancer types in pilot cohort studies.

Part of our strategy is to invest in addressing areas for emerging trends that are synergistic to our efforts in screening. To that end, we have recently partnered with Lunit, a company focused on AI-powered radiology and pathology solutions, with the vision of streamlining the screening journey for patients. We believe that a multimodal and integrated screening paradigm can offer tremendous value to the

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healthcare system and patients. This is an important aspect of our overall strategy and we will continue looking for strategic opportunities over the coming quarters.

Turning to clinical data. At this year's ASCO annual meeting, we presented about 20 abstracts covering our full suite of products. I would like to highlight a few of these abstracts today.

In an MRD study, (inaudible) CSF in (inaudible) metastic CRC patients, Guardant Reveal was used to analyze post procedure ctDNA in serial blood samples in 46 patients. Positive predictive value of positive post procedure ctDNA to predict recurrence was 96%, and an average ctDNA was detected 28 weeks before radiographic recurrence, mean of 17 versus 45 weeks, respectively.

Pfizer also presented data leveraging Guardant360 to assess ctDNA dynamics as a predictor of early (phon) response. In newly diagnostic advanced non-small cell lung cancer patients treated with lorlatinib, Guardant360 was able to discern molecule responders from non-responders four weeks after their start of therapy and molecule responders had significantly longer progression-free survival.

We also reported clinical outcomes from patients in the NILE study. Patients who received target therapy based on their Guardant360 result had comparable outcomes to those treated based on history results. Importantly, time to treatment in ctDNA cohort was significantly shorter compared to the tissue cohort - 18 versus 32 days, respectively.

Lastly, in another abstract covering early stage cancer management using cancer-specific genomic and ethnogenomic signals we showed the performance of our liquid assay for detecting the presence of ctDNA in early stage non-small cell lung cancer and bladder cancer patients. The assay performance was tested using 175 pre-treatment clinical samples from patients with early stage disease in 171 self-declared healthy donors. Sensitivity for non-small cell lung cancer was 70%, Stage 1, 56%, Stage 2, 80%, and Stage 3, 83%, and sensitivity for bladder cancer was 51%, in non-muscle invasive, 36%, in muscle invasive, 69%, with 95% specificity.

These abstracts demonstrate the value and utility of liquid biopsy across the continuum of cancer care.

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

Mike Bell

Thanks, AmirAli.

Total revenue for the second quarter of 2021 was $92.1 million, up 39% from $66.3 million in the prior-year quarter. This growth was driven by a year-over-year increase in both our Precision Oncology Testing revenue and our Development Services and Other Revenue.

Total Precision Oncology Testing revenue for the second quarter was $72.6 million, a growth of 42% compared to $51.0 million in the prior-year quarter. Precision Oncology Revenue from clinical testing in the second quarter was $61.9 million, up 54 % from $39.6 million for the prior-year quarter. Second quarter clinical test volume, which primarily consists of the Guardant360 test, was 20.830, which is an increase of 52% from the prior-year quarter.

In the second quarter of 2021, (inaudible) estimated ASP for Guardant360 CDx and LDT tests was approximately $2,600, which was in line with our expectations following the April 1 increase to $5,000 of the Medicare reimbursement rate for Guardant360 CDx and the partial offset from potential payment delays or denials of the new Guardant360 CDx ADLT code from private payers.

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For the remainder of 2021, we expect the estimated ASP for Guardant360 CDx and LDT tests to continue to average approximately $2,600. Note that the clinical revenue recognized in the second quarter of 2021 consisted of accrued revenue for tests performed in the period based on the estimated ASP, as well as cash collected for tests performed in prior periods, where the cash collected was greater than the previously accrued revenue. As our ability to estimate the ASP for Guardant360 continues to improve, this while growing historical collection data, we expect clinical testing revenue for the second half of 2021 to be primarily derived from accrued revenue for tests performed in the period based on estimated ASPs. And therefore, the amount of revenue recognized from cash collected for tests performed in prior periods will be significantly lower than in the first half of 2021.

Precision Oncology revenue from biopharma tests in the second quarter totaled $11.6 million, up 2% from $11.4 million from the prior-year quarter. Second quarter biopharma tests totaled 3,653, up 30% from the prior-year quarter.

Biopharma test ASP was $3,153, down 22% from $12,054 in the prior-year period, primarily due to the mix between our OMNI and 360 tests.

Development Services and Other revenue continued to be a strong growth driver, and in the second quarter totaled $19.5 million, up 27% from the prior-year quarter. Development Services revenue included milestone payments for the two FDA companion diagnostic approvals we received in the second quarter of 2021.

Gross profit for the second quarter of 2021 was $62.2 million compared to a gross profit of $43.9 million in the same period of the prior year. Gross margin was in line with our expectations and in the second quarter was 68% compared to 66% during the second quarter of 2020.

Operating expenses for the second quarter of 2021 were $159.8 million, an increase of 62% compared to $98.5 million in the second quarter of 2020.

Non-GAAP operating expenses exclude stock-based compensation and related employer payroll tax payments, acquisition-related expenses, amortization of intangible assets, and changes in fair value of contingent consideration. Non-GAAP operating expenses for the second quarter of 2021 were $124.7 million, a 71% increase from $72.9 million in the second quarter of 2020. We expect operating expenses to continue to accelerate in 2021 as we invest in our LUNAR program, the ECLIPSE study and other development activities, as well as expand our commercial organization both in our oncology business, where we have launched several new products so far this year and in our screening business as we prepare for the planned launch of the LDT version of our CRC screening assay in the first half of 2022.

Net loss was $97.6 million or $0.96 per share for the second quarter of 2021 compared to $54.6 million or $0.57 per share in the second quarter of 2020. Non-GAAP net loss was $61.4 million or $0.61 per share for the second quarter of 2021 compared to $23.5 million or $0.25 per share for the second quarter of 2020.

Adjusted EBITDA was a loss of $56.4 million in the second quarter of 2021 compared to a $25.1 million loss in the second quarter of 2020. We define Adjusted EBITDA as non-GAAP net loss adjusted for interest, income tax, depreciation, amortization and other income and expense.

We ended the second quarter of 2021 with $1.8 billion in cash, cash equivalents and marketable securities.

Now turning to our revenue outlook for the full-year 2021. While we feel bullish about the trajectory of our business and against our record revenue this quarter, we want to be cautious given the uncertainty

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around the impact of COVID-19 and in particular, the Delta variant, on oncology office visits, clinical study enrollment and sales force access in the U.S. and across our global business. Therefore, we are maintaining our guidance of $360 million to $379 million, representing growth of approximately 27% over 2020 at the midpoint of the range.

We continue to expect clinical sample volumes for 2021 to be greater than 90,000 tests, representing growth of at least 42% over 2020.

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 this quarter as we work to establish ourselves as the leader in cancer across the continuum of care.

We have made great strides this year as we continue to expand our product portfolio and establish our solutions as best-in-class in cancer testing. We are looking forward to bringing the strong momentum into the second half of the year.

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

Operator

Thank you. Our first question will comes from the line of Tycho Peterson with J.P. Morgan.

Julia

Hi, good afternoon. This is Julia on for Tycho. To start off, maybe you can spend a little bit more time on the new leadership structure. Obviously, we all understand that the screening is a different animal for oncology in terms of reimbursement timeline, go-to-market channel, etc. Would this leadership structure change—like what specific operational changes can we expect for the cancer screening business, especially in terms of resource allocation and financial reporting? I know you touched on commercial team expansion as a major part of it, but are there any meaningful changes in the office outlook or the long-term strategy we should be thinking about? I think you mentioned in the beginning that there are potential opportunities beyond screening and oncology. So just wondering if you could elaborate a little bit more what specific opportunities you could be seeing.

Helmy Eltoukhy

(Audio interference) on the screening side. But this really a combination of changes and the evolution of the organization that is ongoing for the last several years and I think it really is a testament to the confidence we have in our own screening (inaudible) separate businesses. And then (inaudible) of the future that we want to set up.

I'm going to let AmirAli talk a little bit about the screening side of things.

AmirAli Talasaz

Yes, thank you, Helmy. So I'm thrilled with this additional responsibility and I believe it would generate actually additional focus, additional share of attention for both of us to run oncology and screening while

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there are a bunch of corporate matters that are beyond these two businesses that we are going to continue (inaudible), but always be very close partners and still operate under one Guardant entity business operation that we have, plus wanted to make sure we have more focus and dedication across the different business lines (inaudible)

Helmy Eltoukhy

I think in terms of the second part of your question, I think this structure also allows for scalability beyond the areas that we're targeting today. We're not making obviously any announcements on those areas, but we do know that our platform really has the legs and I think the capabilities of addressing other areas of healthcare, but more to come in the future.

Julia

All right. I guess, we'll stay tuned. And then separately, I have a question on the G360 Response test. Just curious, since you already have Reveal, what's the rationale for launching Response as a separate test instead of having a single quantitative MRD test? And then a related note, I've got several clients asking this. Does the Response test cause any cannibalization on G360?

Helmy Eltoukhy

The Response is really, I think, a very well targeted product. If you think about therapeutic response, most targeted and immune therapies are really targeted towards advanced cancer patients than on markets. So, you're really conflating two different animals that don't belong - MRD and therapeutic response.

So this is absolutely the right product for the field. We're seeing really a lot of excitement in terms of the launch of the test. We have a wealth of data. We have 40 publication of it that fully support the science and the clinical utility and clinical (inaudible) of this application. It's really part and parcel to, I think, what we laid the groundwork for, now, I think over five years ago in terms of our tumor response map. You make a decision, a physician makes a decision in terms of which treatment to put a advanced cancer patient on for many reasons the current standard of care is less than stellar in terms of determining and understanding whether that patient will respond or not, especially to therapies like immunotherapies. And the Guardant Response can come in and just a few weeks later essentially that test is able to help with adjudication determination that that patient is indeed responding or not.

So, fantastic product, but sits squarely in kind of the unmet need that exists today in advanced cancer patient market. So we actually see it as an amplification of our current products, not a cannibalization in any way.

Julia

Great. Thank you.

Operator

Our next question comes from the line of Doug Schenkel with Cowen & Company.

Doug Schenkel

Hey, good afternoon. Thanks for taking my questions. Just going back to the leadership structure change, clearly, the opportunities are large here and complex. Even acknowledging that, this leadership change is—it's a bit unusual, especially in the space. Again, I know the opportunities are big, but we could get on

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the list of bigger Board diversified growth companies in life science tools and diagnostics, and none of them have this structure. This includes very successful companies, like Thermo, (inaudible) or Agilent, just to name three, and I could probably name 15 or 30 more.

So, recognizing part of leading a company is being decisive and nimble and ultimately having one person at the helm, what precedent can you point to that supported this decision? How did the Board make a decision that this was the right thing to do when no one else in the space has? And often, and this is really important, co-CEO structures lead to eventual single CEO structures. Usually, these are temporary when we've seen them in other areas. Helmy, this seems like it could be a sign that you're likely to leave the CEO role at some point relatively soon. Are you committed to this current role through 2022? This seems very, very important, given how many clinical readouts and how many product launches you plan for that time period.

Helmy Eltoukhy

Yes, (inaudible). I'm not going anywhere and I'm firmly committed to Guardant as is AmirAli. It'd be crazy to leave when we have so much opportunity to address so many patients. I don't see another opportunity, frankly, in existence that could really match for me having (inaudible). I think this is really an acknowledgement of how much focus, how much mind share it really takes to win, to succeed in these ambitious areas we're addressing. I mean, we're addressing three areas of oncology that have been grandstanding challenges for—outstanding challenges for decades, and it takes a really singular focus to really open up these huge TAMs that exist in each one - $20 billion, $30 billion TAMs, $50 billion TAMs - and we're (inaudible) some of the companies we listed. I don't think they're necessarily solving some of these complex challenges we're addressing here. No one thought that liquid biopsy was a viable technology when we started Guardant, and there is a lot in terms of how we succeeded in the past, but it's about bucking the trend and doing what is right for the business and is what is right for patients regardless of tradition or what has been done in the past.

Doug Schenkel

Okay. Super helpful, and I appreciate you giving us a little bit more on the thinking behind this. Now maybe just for a couple more near-term questions. I'm sorry if I missed this in your prepared remarks. I understand that guidance factors in the reality of the environment we're in, that there is still some uncertainty as it relates to what's going on with COVID and specifically the Delta variant. And recognizing that, I'm wondering if you can say anything about what you saw over the course of the quarter and what you've seen in the early part of the second half of the year in terms of ordering activity and your ability for the sales force to actually get in and detail clinical practices.

Helmy Eltoukhy

Yes, I think as we mentioned in our remarks, we actually saw improvement during the quarter. We saw offices opening up. We saw more access, which I think is part of the driver in terms of the strong quarter that we had in Q2. I think what we've started to see, especially in the last two days, is some of these offices starting to restrict access, starting to close back up and that's not surprising given where really the number of cases are per day now in the United States and how fast things are rising. So, it's certainly something that, despite the strong progress we're seeing, the momentum we're seeing, we wanted to be I think cautious in terms of the second half of the year, because we're still in the summer months and who knows what would happen, especially in the winter (audio interference)

Mike Bell

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Well, maybe just also to reframe (phon) what we did see a little bit of impact was in the international business. Of course, that's not the large piece of our business, but we saw impact. Again, I think we see continued uncertainty internationally as well. So, again, just another reason why we've maintained the guidance (audio interference)

Operator

Thank you. Our next question is going to come from the line of Tejas Savant with Morgan Stanley.

Edmond

Hey, good afternoon guys. Thanks for taking the time. This is Edmond on for Tejas. The first question I had was on MRD. Given the data around the tumor informed and tumor agnostic assays, Helmy, can you provide us with some quantitative color on how the mind share battle is progressing? I guess in a simpler term, is there any way you can give us some information on how many of your new ordering physicians for BPL (phon) and Response (audio interference) in using other MRD tests?

Helmy Eltoukhy

Yes. I think we continue to see good traction. Very logistically it's straightforward tests that really fits in to how physicians currently order tests like CEA and how they practice medicine. It's something that I think the (audio interference) by the traction we've seen with Reveal. We continue to be pleased. There are a number of KOLs who I think have talked publicly in various forums in both in the U.S. and internationally about the challenges with tissue acquisition, even in the early stage cancer settings and how having a really tissue independent approach is one that, I think, really simplifies some of the—addresses some of those challenges that exist.

In terms of—it's obviously hard getting back numbers, but we really do not see a lot of pushback. Whether or not physicians have been existing or new users to these tests is a test. So we're very pleased by the traction that Reveal is seeing, by the reception that we're seeing with really a whole class of physicians that we've been in front of.

Edmond

Got it. And I'm sorry if I missed this, but can you remind me on the timeline for the investment and the plans to launch and indications beyond CRC?

Helmy Eltoukhy

So I think we mentioned before that reimbursement by end of the year for—at least from the Medicare side. Private payer, I think, will take some time as some of the utility studies readout most likely.

In terms of multiple indications, it's something that should happen relatively soon. We have (audio interference) data that we've presented at ASCO that shows, I think, the progress we've made and the excellent results that we're seeing with the platform beyond CRC. We presented data in bladder and lung that's very compelling. I think we've mentioned in the prepared remarks data on breast as well. So it's (audio interference) in the coming quarters.

Edmond

Got it. One last one for me on ECLIPSE. Maybe, Amir, you guys have showed data on cancer patient populations at ASCO and, first, is this still right to think about readout timing (phon) for early next year?

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Second, in terms of the (inaudible) the ECLIPSE will (inaudible), how should we think about this in terms of the cancer patient population data presented at ASCO?

AmirAli Talasaz

Yes. So, as we mentioned in the script, we expect that we will finish the enrollment by November. There was no timeframe that we had from the beginning with (audio interference) announced that we have in this setting (phon) (audio interference) pandemic and very pleased with that given with additional 3,000 patients.

Right now, further I think after a few months you're going to have the readout of ECLIPSE, as we mentioned, before (inaudible) on track to be ready to run those (inaudible)

In terms of data we were presenting at ASCO, we're very pleased. We continue data generation and additional cohort to get access to additional CRC cohorts, cancer screening cohorts, negative or positive findings. We continue to be pleased with the data and I think we have updated our data across multiple cohorts for a total of over a thousand cases at around 1,300 patients that we showed in ASCO. Data holds up. There is some kind of uniqueness in ECLIPSE in terms of being a prospective screening study - 13,000 patients that we find 67 (inaudible). Nothing can replace that. We continue to always (inaudible). Actually there's binding (phon) of ECLIPSE. But at the end of the day we have to run ECLIPSE and see what we're going to see there. But we feel good about it and I think time will tell. We feel pretty good about it.

Edmond

Got it. Super helpful. Thank you guys.

Operator

Our next question will come from the line of Brian Weinstein from Morgan Stanley.

Brian Weinstein

Hey. I'm sorry (inaudible). It's all good. So, a couple of questions for you guys. Going back to the new leadership structure here, I guess I have another question (inaudible), but just kind of wanted to dig in a little bit here. I get why you want to do this, but I am curious about things like decisions on deployment of capital, decisions on other kind of corporate matters. Who's in charge really? I mean, at the end of the day where does the buck stop on kind of setting that broader strategic decision-making? And as it goes to CEO structure, it's not clear to me kind of who's—who's at the end of the day really held accountable for broader corporate performance?

Helmy Eltoukhy

We've always had a strong partnership between myself and AmirAli since the founding of Guardant. I think it's pretty clear, things around screening, AmirAli will be in charge of, decisions around oncology, I will be in charge of. We're still having a essentially combined leadership structure around other areas and obviously some of those decisions rise to the Board level as well and which is heavily engaged at Guardant.

So, we really see no issues or not a lot of deviation from where things were in terms of this new structure. So we're very confident that a lot of the strategic decisions will continue to be made in the context of one Guardant and really one mindset.

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Brian Weinstein

Okay. And then as it relates to the CRC screening product, the LDT approach we haven't really seen that before. Can you talk about—obviously, you're getting into market a little sooner, but is there any other kind of strategic rationale in terms of data collection or other things that would cause you to kind of go with it, the LDT approach? And then are you—maybe kind of talk about what your updated expectations are for performance of the assay in terms of an early stage detection as well as advanced melanoma (phon) where you think you guys could potentially come in both of those. Thank you.

AmirAli Talasaz

Thank you for asking about the LDT and the rationale behind it. We're still expecting actually (inaudible) this does hopefully (inaudible) positive (phon) review in 2023 and that would be the major commercial push for us. But a couple of years before that, it would be very important for us to going to the market, start shaping the market the way that we believe blood-based screening could add social impact, (inaudible) impact outcomes for patients right away, sharing the experience for the field, integrate our tests with Bright (phon) Health networks, generate experience for people and really add this blood-based screening into a bunch of PCB (phon) workloads and in some RT (phon) accounts. So it's a very strategic move for us.

On the CRC side, I don't believe (inaudible) some of the real world evidence, which maybe add much into—really, I don't see any data yet that real world evidence would (inaudible) in terms of the CRC data. I think ECLIPSE would be very comprehensive by itself (inaudible) other ISPs (phon) that we've done and we're continuing to do our (inaudible). That's incidental findings for other cancer types and generates some evidence for non-CRC findings for us for CRC (inaudible)

So in terms of performance, all the data that is in different cohorts independent during partnerships with different cancer centers and KOLs and PIs, we have published them in different conference presentations. We're going to continue to do so.

You asked about advanced melanoma. That's an area that actually we're looking to (inaudible). While we believe that (inaudible) I think (inaudible) is not required for FDA approval for potential Medicare reimbursement based on the NCD, but we do believe that their response (phon) is important for commercial adoption of the test and expansion of the test (phon). As a result, we're looking to finding surrogate biomarkers and (inaudible) can have a good sense (inaudible). (Inaudible) in the right conference I think we are going to show some performance hopefully there. But it's an area that we have looked at for sometime.

Brian Weinstein

Thank you.

Operator

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

John

Hi. This is John on for Derik. I wanted to ask about the ASPs in the clinical. With all these new product launches, do you see ASP for clinical going up in 2022?

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Mike Bell

Yes, it's Mike here. I think when we look at the clinical ASP and we're very—(inaudible) in their prepared remarks about the ASP for Guardant360. So for Guardant360, CDx and LDT, this quarter there's 2,600 on the back of the ADLT (phon) change and we expect that to be the same for the remainder of the year. Of course, we'll be launching new products and reimbursements are going to take time, so if we take the overall clinical volume and revenue, then the ASP obvious, it's probably going to go down because we're not getting paid for some of the tests. But for Guardant360, it should at least remain where it is. If we can collect from the private payers with the new ADLT code than we previously expected, there's some potential for some upside there.

John

Got you. Thank you. And then you mentioned that the international market, the sequential decline in revenue, that was Delta, but going forward how do you see that growing? And back to domestic, what percentage of the visits are in person? You mentioned last quarter that it was around 34 or 40. I'm wondering how much improvement there's been.

Mike Bell

Yes. Maybe just on the international, I don't think we said it was sequentially down. What we said is that we saw an impact. I think we were more referring to the impact on the growth than a decline. So we're still, so you know, we're still seeing strong performance internationally, but we've continued to see impact because we're in many different countries and the impact across those countries varies. Again, it may get an impact from our ability to grow the business. But yes, it's not a sequential decline.

Helmy Eltoukhy

Yes. I mean, I think they've improved from the 30%. It probably reached, I think, 50% or more that started opening up and (inaudible) the right traction, but obviously we're seeing things now close back up. I think yesterday there were 150,000 new cases in the U.S. So, clearly, I think there's a lot of justified risk on the part of clinicians given the impact on the cancer patients, advanced cancer patients of this disease.

Operator

Thank you. Our next question will come from the line of Patrick Donnelly with Citi.

Patrick Donnelly

Great. Thanks. AmirAli, I just wanted to follow-up on one of the prior questions there, I think it was Brian talking about the LDT launch. Have you guys kind of carved out a type of population you think will be addressable with this launch? Relative to the overall pie coming with the IBD launch, other companies that have done LDT launches have carved out a tranche where they feel is addressable with the LDT. I'm just curious your guys' perspective on that.

AmirAli Talasaz

Yes. So, (inaudible) population, even for LDT launch with the average risk population. Having said that, we don't expect major adoption before FDA approval. We believe that stamp of FDA approval, we believe, getting multiple coverage policies would continue to help with the adoption of the test, especially on the mainstream adopter. But we believe there's a lot of opportunity with early adopters and people who are really interested. A bunch of stakeholders (phon) we are working with they really want to use our tests

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even sooner than later, so we are kind of responding, to some extent, to some of the market demand too. But now that we are carving out by going just after, let's say high risk patient population, of course, we don't have that strategy at least at this time. We're going to go into markets still with average risk indication with the offering that we have but we (inaudible) the way the market would react to the data package that we're kind of putting in front of them and all the evidence that we have generated during the last few years.

Patrick Donnelly

Okay, that's helpful. And then Helmy, I know you mentioned you've seen some offices closing back up over the last couple of weeks. Do you feel better prepared to weather another, let's say, partial shutdown? Are there learnings from the first time around that will help you guys inflate volumes better if this continues to worsen and offices close up? Just curious if you think the impact this time around would be less given we all learned something from the first time around.

Helmy Eltoukhy

Yes. I mean, I think certainly our ability to (inaudible) offices so we can really build (inaudible) capabilities in that area and built that muscle. I think the question would be more kind of speed of growth and so on and how that could be impacted if obviously—but it all depends on the severity of Delta and there's other variants that come around. Yes, I don't expect kind of what happened in Q2 of last year (inaudible) people got paralyzed and would happen again. I think we're all learning to live I think with the disease and the background to some extent.

Operator

Thank you. Our next question will come from the line of Dan Arias with Stifel.

Dan Arias

Good afternoon guys. Thanks for the questions. AmirAli, on ECLIPSE and just expanding the study to 13,000 enrollees, anything you can touch on there just in terms of the need for that move? You guys aren't the first company to take the population up for a trial like this. So, just kind of curious if it's total overall colorectal cancer patients that you need to increase the number of? Is it related to sub populations by stage, or is something else altogether?

AmirAli Talasaz

(Inaudible), the number of CRC that we need to find in that study. You can think about it more like an event driven study that there are certain number of CRCs we need to find in this patient population that we're screening in our first study to be powered to make the claims that we have as far as (inaudible). So there's a minimum number of CRC patients that we need to find.

When we started this study, based on the prevalence of CRC that (inaudible) at that time, our calculation shows (inaudible) powered study we needed 10,000 patients, and as we enrolled more and more patients and we started actually getting some reports, a number of events that we had we are effectively like fine-tuning the number based on the most recent actual prevalence that we are seeing in the study. That's why the study's going from 10,000 to 13,000 to find the additional CRCs that we need to find. That's the driver of enrolling more patients.

Helmy Eltoukhy

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Yes, but when you see it as—still certainly in line with where we thought things could play out and it's certainly going to conclude in our view within the timelines we initiated when we first started. So, I think we're very pleased by where we are. We couldn't be more thrilled.

Dan Arias

Yes. Okay. Thank you. And then just maybe, Mike, on the mix between OMNI and G360 on the pharma side. What direction do you think that split heads in the coming quarters? Obviously, that's got implication on the ASPs there going forward.

Mike Bell

Yes, in this quarter, we definitely saw it weighted more towards the 360. I think as we look through the remainder of the year, we probably double correct (phon) a little bit and I think our forecast is probably coming back more on the OMNI side. So, we're expecting ASPs to improve a little bit because it was a bit of an outlier in this quarter. But a lot also depends on the pipeline and at this time we'll probably get through the door as well. But that's how we're looking at it.

Dan Arias

Okay. Thank you guys.

Operator

Our next question will come from the line of Matt Sykes with Goldman Sachs.

Dave

Hey guys. This is Dave on for Matt. Congrats on hitting 10,000 patients in ECLIPSE. Very exciting. As well as the LUNAR-2 launch next year. You've been very successful in oncology testing. Screening is an even bigger opportunity, of course. Could you tell us more about your strategy for ramping sales and marketing to reach the hundreds of thousands of TCPs (phon) out there?

AmirAli Talasaz

Yes, sure. So, we're talking about a little bit before too. We started actually building the leadership of our commercial channel and screening side a few quarters ago, and now I'm happy that actually we have a couple of layers of that leadership already (inaudible). It's a dedicated leadership on the screening side. At the highest level it was from our internal executives that we had on the oncology side. I think there is a possibility of leading the commercial and for some screening side. A very knowledgeable individual that we are really excited about having him. Now we have next layers of leadership in place too. As we speak, we are building the next layers to be ready for this LDT launch and we believe we are going to have commercial and all operational infrastructure that we need to support this LDT launch in the first half of next year.

Dave

Fantastic. And could you tell us a little bit more about the AI powered pathology partnership you announced for multi-modal screening?

AmirAli Talasaz

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Yes. So the company that we have a partnership with is (inaudible). They're a AI company in radiology and pathology. Very strong team with very heavy experience on AI side, especially on the image processing, and they have already some regulated products in the radiology side. Their sales with the product gives us an improved productivity of radiology and we think different kinds of scans of different kind of scanning modalities. When you think about what would be the future of screening, we believe definitely blood-based assays are very important, but cannot be the only assets there to really streamline screening journey for the patients.

So, we envision obviously a multimodal solution out there that starts with—(inaudible) would be blood-based screening but we need to put some kind of additional solution at the front end and back end to really have a great experience and workflow for patients and providers to really take—open up the opportunities that blood-based screening can offer in the field.

So we're very excited about that partnership. We're going to work with them to see how much we can shape actually the future activities for them to really help us on the screening side.

Operator

Thank you. Our next question will come from the line of Jack Meehan with Nephron.

Jack Meehan

Thank you. Good afternoon. I was wondering if you could comment on how much Guardant Reveal added in the quarter in terms of volumes? And we're waiting on the Medicare final LCD for MRD. Do you think there's a chance for it to be included in that?

Helmy Eltoukhy

Yes, there is a final LCD for CRC and I think the one that's still in draft is the one that expands that and extends that to applications of micro (phon) response as well. So, yes, hopefully going to have them later this year in terms of final utilization but that's obviously up to them in terms of their timelines.

Talk a little bit about the (inaudible)?

Mike Bell

Yes. On the volumes, obviously, we're not splitting out the specific Reveal volumes for competitive reasons, amongst other things. We did say that (inaudible). The vast majority of the (inaudible) volume that we (inaudible) Guardant360. I think what we would say again is that the Reveal launch has gone as well as we could have expected and we're really enthused with it. So the volumes that are coming through the door is as good as we expected and we continue to see them growing. Again, we're not going to be breaking those out specifically.

Jack Meehan

Great. Thank you. And then just one math question. Sorry, juggling a few earnings tonight. Sorry if this is a dumb question. But at $61 million of clinical sales, 20,830 tests, my math was going in $2,900 price point. I know you quoted $2,600. Is there some other dynamic that I missed?

Mike Bell

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Yes. I tried to explain that in the (inaudible) but maybe (inaudible). The way that we recognized revenue in the past there's always been a large sort of cash collection component from samples from previous periods, even if it is revenue. We're moving more and more to having our revenue just purely based on the improved revenue given the samples in that quarter. So, there's still some cash in the Q2 number from prior periods, and that's the reason the math is off a bit.

Operator

Our last question will come from the line of Andrew Cooper with Raymond James.

Andrew Cooper

Hey guys. Thanks for taking me in. A lot's been covered, but maybe just first, when we think about the screening commercial sales force you intend to build and the sort of timeline on the LDT to FDA, can you help us a little bit more to think about, I would say it's early today, but where do you want to be in the first half when you're launching that LDT and then where do you want to be again when we think about the timing for the FDA approval? Just sort of what the stage gate looks would be helpful.

AmirAli Talasaz

So a lot of (inaudible) metrics for us during this LDT period is making sure that actually we can build strategic relationships, get into workloads and really build a bunch of power metrics more than volume metrics, and we would be ready once FDA approval comes. In fact, all the infrastructure and workflow integration that actually we have built during this period of time would take us to the maximum opportunity that blood-based screening can offer much faster than without this LDT experience.

Having said that, we think there's good opportunity with early adopters and really use technology (inaudible) that based on the data that they see in fact they want to get their hands on this device and start using it clinically. But our main goal, as I mentioned, is for this LDT early launch, is to build a bunch of power metrics and make sure we are well integrated into PCP workflows and any network system.

Andrew Cooper

Okay, great. Maybe just one more, if I could. On LUNAR again, just thinking about sort of the multimodality, I just want to make sure kind of thinking about the way you are viewing this appropriately, they've got scope I-O that is more on the immuno-oncology side and then more of the kind of traditional radiography type tools as well. So is this something you envision on the front end with the I-O piece, or maybe the back end in terms of reflexing (phon) from a multi-cancer test? How do we think about where this fits into the Guardant pipeline?

AmirAli Talasaz

I would maybe encourage you to maybe stay tuned a little bit. And you know, we are excited about this partnership and we have our vision of how this multimodal integrated radiology blood testing could really shape the future. Let us go through that process and we would keep you posted about the progress that we make. But I want to tell you that we are very excited about this future and the way screening can get streamlined for the patients in oncology and potentially then other diseases.

Operator

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Thank you. With that, we have no further questions. We would like to thank everyone for participating on today's Guardant Health Second Quarter 2021 Earnings conference call. This concludes today's conference call. You may now disconnect. Thank you.

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