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Guardant Health

Second Quarter 2022 Financial Results Call

August 4, 2022

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PRESENTATION

Operator

Hello and welcome to today's Guardant Health Second Quarter 2022 Financial Results. My name is Bailey and I will be your moderator for today's call.

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I would now like to pass the conference over to our host, Alex Kleban. Alex, please go ahead.

Alex Kleban

Thank you. Earlier today, Guardant Health released financial results for the quarter ended June 30, 2022. Joining me today from Guardant are Helmy Eltoukhy, co-CEO, AmirAli Talasaz, co-CEO, and Mike Bell, Chief Financial Officer.

Before we begin, I'd like to remind you that during this call Management will make 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, 2021, and in its other filings with the Securities and Exchange Commission.

This call will also include a discussion of certain financial measures that are not calculated in accordance with GAAP. Reconciliation to the most directly comparable GAAP financial measure may be found in today's earnings release submitted to the SEC.

Except as required by law, Guardant disclaims any intention or obligation to update or revise any financial projections or forward-looking statements whether because of new information, future events or otherwise. This conference call contains time-sensitive information and is accurate only as of the live broadcast, August 4, 2022.

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

Helmy Eltoukhy

Thanks Alex. Good afternoon and thank you for joining our second quarter 2022 earnings call.

I will begin the call today by providing an update on our progress across oncology including quarterly trends, reimbursement and upcoming product launches. I will then turn the call over to AmirAli for an update on the ECLIPSE timeline, the Shield LBT launch and multi-cancer screening. And, finally, Mike will provide a more detailed look at our financials and guidance for 2022.

At Guardant, we are dedicated to helping patients across all stages of cancer live longer and healthier lives with the data provided from our powerful blood tests. In line with this commitment, I would like to start off with a patient story.

In 2018, a woman in her 50s was diagnosed with advanced stage rectal cancer. Following her diagnosis she received radiation, surgery and adjuvant chemotherapy, and responded very well to treatment. About three years following her initial diagnosis she began to experience some new pain in her hip. Her oncologist ran a number of tests in search of the cause, including a colonoscopy, CT scans, bloodwork and a full urology workup. All test results were normal. Perplexed, her oncologist decided to order Guardant Reveal. Guardant Reveal detected ctDNA which indicated an increased risk of recurrence. This result from Reveal led them to order a bone scan, something uncommon for rectal cancer as it rarely spreads to the bone. The bone scan detected a lesion in her hip bone of less than 3 mm and a PET scan confirmed the malignancy in the bone. Because the lesion size is so small, radiation therapy was directed at the hip and the patient is now cancer-free. She is receiving chemotherapy as a precaution, and is back to living a pain-free life.

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This patient's story is a great example of how Guardant Reveal can detect ctDNA years after resection when accessing tissue can be difficult.

Now, turning to our performance on Slide 3. We ended the second quarter with record revenue of $109 million, up 19% over the prior year quarter. Within this, Precision Oncology grew by 27% thanks to continued traction with oncologists. Clinical test volume reached 29,300, up 40%, and Biopharma volume reached 6,000, up 65%, all on a year-over-year basis.

Moving on to Slide 4, our team continues to extend our leadership in liquid biopsy through our high-performance tests and commitment to customer service. Diving into the underlying Q2 dynamics, volume growth was strong, but a bit below our original forecast as we continue to navigate macro headwinds. We started the quarter very nicely, but saw periods of softness throughout May and June when we had anticipated stable growth throughout the quarter. Put simply, we expected a stronger recovery from COVID-related disruptions and we see similar lingering effects across other sector indicators we monitor.

That said, there were a number of positive takeaways during Q2 that bode well for accelerating growth for the remainder of the year.

Our business continues to gain strength in both breadth and depth as we again reached a record number of ordering oncologists. These oncologists are ordering about 30% more Guardant tests on average versus this time last year.

Since last year we also saw a large increase in the number of oncologists ordering multiple Guardant products in addition to Guardant360. This is driven by very strong growth in new products including Reveal, TissueNext and Response.

And finally, we continue to lead the industry in terms of share of voice with our customers.

Turning to Slide 5 and what should help us accelerate our clinical volumes in the second half. So far in July we have seen volume pick back up nicely in the early weeks. In addition, we are very excited by a number of critical tailwinds that will start to have an impact on the remainder of the year. Starting with MRD, we are pleased to announce that we have received reimbursement for Guardant Reveal from MolDX. As we disclosed earlier this week, it will be the first blood-only MRD assay to be reimbursed by Medicare for patients with Stage II or III colorectal cancer. We believe this gives us an excellent tailwind to gain even stronger volume momentum in the second half.

We are also in the advanced stages of preparing for our Reveal multi-cancer launch, which will make Reveal available for use in breast and lung in addition to colorectal cancers. We have been making great progress and are targeting a second half launch.

Finally, we are on track for completing our announced Epic EMR integration in the second half of this year, which should serve as an important catalyst for our business across a variety of our products.

Moving on to Biopharma on Slide 6, we delivered 6,000 tests in the second quarter, representing 65% growth year-over-year. To date, we have partnered with more than 130 biopharma companies as we continue to grow and diversify our customer base. This was evident at ASCO where the power of the full Guardant platform facilitated strong customer engagement.

Furthermore, we are pleased to announce we have successfully launched our Smart Liquid Biopsy assay and early assets for research use. We have signed a number of agreements and started processing customer samples at the end of Q2. With a healthy pipeline of discussions, including for Smart Liquid Biopsy, we believe we have a strong set-up heading into the back half of the year.

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Moving on to Slide 7, outside of the United States we continue to make progress in our strategy of achieving global scale with a focus on large core markets. Most notably for this quarter, in Europe our partner lab in Vall d'Hebron in Spain is now open for business.

In EMEA, we completed our planned purchase of a Guardant Health AMEA joint venture. Focusing in on Japan, we received regulatory approval of Guardant360 CDX earlier this year and expect to receive reimbursement later this year. And in China, we signed a strategic partnership with Adicon, one of the largest lab companies in China, to offer CGP to biopharma customers. All of this takes us another step closer to ensuring all cancer patients across the globe receive access to our technology.

I will now turn the call over to AmirAli to provide an update on our screening program.

AmirAli Talasaz

Thanks, Helmy.

Starting with an update on ECLIPSE on Slide 8, since our last earnings call in early May, we made good progress with our central pathology review process and continue to find and confirm more CRCs. We've also continued ECLIPSE enrollment to ensure we have more than enough CRC cases for our PMA study and to further build our bio bank for future research and development.

With where we are today, we are now just one CRC away from our target range of 60 to 70, which will put us in a position to control the timing of when we unblind this study.

In parallel, we have already started drawing ECLIPSE samples in the lab and are making good progress in generating the data. Based on the rate of CRC confirmation in the last few months, we expect ECLIPSE will read out sometime in the fourth quarter of this year with the exact timing depending on identification of the last few CRCs.

We are also making good progress with our analytical study and other deliverables required for PMA submission. We are pursuing a modular submission to FDA and have already submitted our earlier modules, which the agency has started to review. As a result, even with a fourth quarter ECLIPSE readout we believe we are on track to complete our PMA submission by the end of the year.

Assuming a successful review and approval by FDA, we are confident we can secure ADLT status and achieve favorable Medicare pricing. ADLT pricing is based on a well established process and initially depends on the list charge and then the panel market base rate. Over the long term, we believe we can achieve an overall ASP of over $500 across all payers.

Following FDA approval, we expect to be included in American Cancer Society or ACS guidelines. The recommendations by ACS are followed by a number of states due to the state level requirement for payers to cover ACS recommended colorectal screening tests. Our best estimate is that there are about 15 states that could follow ACS guidelines, covering about 20% to 25% of the population.

A major milestone for our test would be inclusion in USPSTF guidelines with favorable grading. We have worked hard to understand the process behind USPSTF decisions based on expert opinions and guidance from former task force members.

We believe, as long as our blood test gets FDA approval with established performance even at the level of FIT tests, USPSTF will include our test as a new modality for colon cancer screening. Under the current USPSTF structure, we expect guideline recommendation in 2026.

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It is known the current USPSTF five-year update cycle is not matching rapid developments in biomedical research and new technologies, and can lead to a significant lag in the adoption of new promising screening technologies such as Shield. We are pleased by inclusion of report language in both House and Senate appropriations bills that urges the USPSTF to utilize its early topic update process and review new screening technologies upon FDA approval. In addition to the momentum from appropriators, we are also encouraged by recent letters to United States Department of Human Health Services from the Energy and Commerce democratic leaders and Senator Marsha Blackburn which raises important questions about the USPSTF process and demonstrates congressional interests in addressing this issue.

Turning to Slide 9 and our Shield LDT, I am excited to share that the launch of our Shield LDT is off to a great start. Market feedback and initial uptake are head of our original expectations. Our core (inaudible) is that simple blood-based testing will drive a higher compliance rate than stool-based testing, and contribute significantly in boosting overall screening compliance to over 85% in the next 10 years. In our first 1,000 ordered samples, we observed over 90% adherence rate. Simply, this is a ratio of the number of blood tests received in our lab to the number of tests ordered by physicians. This real-world adherence rate is much higher than reported numbers for colonoscopies and stool tests.

We are also launching clinical studies with some health systems this year to generate additional clinical evidence for favorable adherence rates for blood-based CRC screening.

Another advantage of higher adherence rates is significant increase in sales and marketing efficiencies, by converting a higher fraction of ordered samples to billable cases. We believe this higher commercial efficiency will enhance the operating margins for our tests relative to what historically has been seen for stool-based tests.

Turning to Slide 10, the long-term forecasted adoption of our blood test depends on CRC sensitivity readout from ECLIPSE study. We study the adoption for sensitivities ranging from 92% – Cologuard sensitivity – to 75%, which is about the minimum sensitivity required by NCD for Medicare coverage. We expect a very robust adoption for an assay even with sensitivity around 85%. We are forecasting over 10 million tests per year in 10 years for such assay with annual revenue opportunities well over $5 billion.

Even at CRC sensitivities of about 75%, there is still a significant opportunity for blood-based CRC screening tests. Under such a scenario, at 10 years out we are forecasting about 3 million to 4 million tests per year with an annual profitable opportunity of about $2 billion.

In our research, we have not seen any notable dependency to advanced adenoma sensitivity in the current PCP market. As a reminder, our previously reported CRC sensitivities and case controlled studies ranged from high 80s to low 90s in detecting early stage CRC cohorts.

Turning to Slide 11, our vision for early detection has always been to build a multi-cancer screening brand. We strategically selected CRC as our lead and anchor indication, but not the only indication. Unlike stool-based tests that can just detect CRC, blood-based tests will go well beyond this single indication. We are planning to upgrade our Shield LDT test to also screen for lung cancer in high risk individuals in 2023. Previously, we have reported that our blood tests can detect 87% of early stage lung cancers in a case control study.

In midterm, our blood tests will be upgraded to a broad multi-cancer test screening with a large panel of indications. By adding new indications to our blood-based screen test, the resulting life year gain should further improve.

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We are confident about our strategy in building highly sensitive, widely accessible blood based multi-cancer screening tests with high patient compliance.

These are exciting times for us at Guardant, waiting to see ECLIPSE data, then further expanding our test to multi-cancer screening, while working in parallel to get FDA approval and building wide access to our tests.

With that, I will now turn the call over to Mike for more detail on our financials and outlook for 2022.

Mike Bell

Thank you, AmirAli.

Turning to Slide 12, total revenue in the second quarter of 2022 was $109.1 million, up 19% from $92.1 million in the prior year quarter.

Total Precision Oncology testing revenue for the second quarter was $92.1 million, with growth of 27% compared to $72.6 million in the prior year quarter. This increase was driven by year-over-year growth in both clinical and biopharma sample volumes.

Precision Oncology revenue from clinical tests was $70.5 million, up 15% from $61.1 million for the prior year quarter. Note that in the second quarter of 2021 clinical revenue included a $9.6 million true-up representing cash received for tests performed in prior periods where the total cash received for those tests exceeded the total revenue that had previously been recognized. Because our ability to estimate revenue has improved, the second quarter of 2022 included only $1.6 million of cash true-up relating to prior period tests. Excluding this cash based revenue recognition impact, the underlying clinical revenue growth was 34%. Second quarter clinical test volume was 29,300, which is an increase of 40% from the same period of the prior year. As well as strong Guardant360 growth, our new products – Reveal, TissueNext and Response – again contributed for the growth for the quarter. For the remainder of the year we expect volume growth to gain momentum as both Reveal and TissueNext have now received reimbursement coverage for MolDX.

For the second quarter of 2022, the ASP for Guardant 360 was in the $2,600 to $2,700 range, which is consistent with the last few quarters, and the blended clinical ASP was approximately $2,400. The blended clinical ASP will continue to be influenced by both the volume mix of Guardant360 new products, as well as the reimbursement for new products.

Precision Oncology revenue from biopharma tests in the second quarter totaled $21.6 million, up 87% from $11.6 million for the prior year quarter.

Biopharma volume was strong with second quarter samples totaling 6,000, which was up 65% from the prior year quarter. Biopharma sample ASP in the second quarter was approximately $3,600, up 14% from the prior year period, but in line with the prior quarter due to a similar product mix.

Development Services and Other revenue in the second quarter totaled $17.1 million, down 12% from the prior year quarter. Although we had a positive impact for the milestone revenue related to our Adicon Lab partnership, which we signed in the second quarter of 2022, and while we continue to see strong demand for our development services, we still expect that our 2022 Development Services and Other revenue will continue to be lower than prior year as several companion diagnostic projects were successfully completed in the second half of 2021 and new projects will take time to ramp up.

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Gross profit for the second quarter of 2022 was $72.4 million compared to a gross profit of $62.2 million in the same period of the prior year. Gross margin percentage continues to be in the mid 60s, being 66% for the second quarter of 2022 compared to 68% in the prior year quarter.

Operating expenses for the second quarter of 2022 were $202.7 million, an increase of 27% compared to $159.8 million in the second quarter of 2021.

Net loss was $229.4 million or $2.25 per share for the second quarter 2022, compared to $97.6 million or $0.96 per share in the second quarter of 2021. Net loss includes a one-off charge of $99.8 million related to the purchase of the approximately 50% of the Guardant Health AMEA joint venture that we did not own. As a reminder, in June 2022 we paid $177.8 million to acquire the Guardant Health AMEA equity interest held by Softbank and its affiliates. As a result, in incurred a charge of $99.8 million to the controlling interest liability line in the income statement, which represents the difference between the liability we were carrying on the balance sheet of $78.0 million and the final purchase price of $177.8 million.

Moving on to non-GAAP financial measures on Slide 13, non-GAAP operating expenses exclude stock-based compensation and related employer payroll tax payments, acquisition-related expenses, amortization of intangibles and contingent consideration.

Non-GAAP operating expenses for the second quarter of 2022 were $176.2 million, a 41% increase from the $124.7 million in the prior year quarter. This increase was driven by the investments made over the past 12 months across both our oncology and screening businesses, primarily in our commercial infrastructure and the continued development of our product pipelines and clinical data. Throughout 2022, we will continue to invest in progressing our strong pipeline of oncology products, as well as in generating clinical data to support their reimbursement. For screening, 2022 investment will be focused on the commercialization of our Shield LDT test, completing the data readout from ECLIPSE, the PMA submission for our CRC device, and the continued development of our multi-cancer screening tests.

Non-GAAP net loss was $101.8 million or $1.00 per share for the second quarter of 2022, compared to $61.4 million or $0.61 per share for the second quarter of 2021.

Adjusted EBITDA was a loss of $94.3 million in the second quarter of 2022 compared to a $56.4 million loss in the second quarter of 2021. We define Adjusted EBITDA as non-GAAP net loss adjusted for interest, income tax, depreciation, amortization, and other income and expense.

Turning to the balance sheet, we ended the second quarter of 2022 with approximately $1.2 billion in cash, cash equivalents and marketable securities.

Before moving on to our current year guidance, I would like to take a bit of time to discuss our liquidity and capital allocation on Slide 14.

At Guardant, we have always taken a measured approach to our investment and have ultimately been focused on the path to profitability. As we look ahead to how the business will develop and the investments needed to support the significant long-term growth opportunities, we look at both the future oncology business and screening business.

For oncology, we currently have strong volume growth which is fueled by our core Guardant360 tests as well as new products, very good gross margins in the mid 60s and have built out a sizable commercial and operational infrastructure. Going forward, we will continue to invest in areas that we believe will drive sustainable long term growth such as MRD, Smart Liquid Biopsy and developing the clinical data to support utilization and reimbursement.

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Given the strength of our current business, and our investment approach, we expect the oncology business will reach cashflow breakeven in approximately two years.

For screening, we are currently in heavy investment phase with the Shield LDT launch underway to be followed by a milestone-driven commercial ramp up, and with our multi-cancer screening development assets. Underpinning this, we have a fair amount of infrastructure investment that is necessary as we scale our operations.

Taking into account all these dynamics, we believe that we can reach cashflow breakeven one to two years after Shield inclusion in the USPSTF guidelines for CRC screening.

We are in a fortunate position to have sufficient cash on our balance sheet to fund the business for the foreseeable future, and we will continue to actively manage our capital allocation with a goal to long-term profitability.

Now, turning to our revenue outlook for the full year 2022 on Slide 15.

We continue to expect to be between $460 million and $470 million, representing growth of approximately 24% over 2021 at the midpoint. This is unchanged overall, but with some moving parts between the lines.

Reflecting the first half performance, we now expect clinical oncology sample volume for 2022 to grow by approximately 45% compared with the previous guidance of over 50%, and we continue to expect biopharma volume to grow by at least 30%.

Despite the revision to our clinical volume growth expectations, we expect Precision Oncology testing revenue to grow by approximately 35% over the prior year, as we expect second half tailwinds from arrear (phon) Medicare reimbursement and the continued strength of our Biopharma business.

Finally, we continue to expect Development Services and Other revenue will be at least $50 million in 2022.

Please note that while we are highly encouraged by the strong reception to the launch of our screening LDT test, we are not expecting significant revenue contributions from it this year.

Moving to Slide 16, we are continuing to make great strides across our business, obtaining reimbursement for our new products, broadening our product portfolio with our Shield LDT test, and expanding our reach into the cancer screening market. We are aggressively pursuing the best opportunities ahead, and we are confident that we will be a leader in cancer across the continuum of care.

At this point, we will now open it up to questions.

Operator

Thank you.

The first question today comes from the line of Puneet Souda from SVB Securities. Please go ahead, your line is now open.

Puneet Souda

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Okay, great Thanks. AmirAli and Helmy, thanks for taking the questions. First one, just a couple on ECLIPSE. Maybe if I can squeeze in one for MRD as well. AmirAli, you said timeline is now expected in the fourth quarter. Wondering if you could give a view if October is still part of that timing that you can hit. I know you talked about September/October initially, so just wanted to confirm that the pathology services and challenges are all resolved at this point. And do you think you need to reach the 70 targets for CRC in order to power the study, or maybe let's say 65 is good enough, or even low 60s?

Then sort of lastly on ECLIPSE, maybe could you talk a little bit about the interval. I think that's a major question, sort of what gives you a confidence that the three-year interval would be maintained under FDA and then when it is covered by commercial payers potentially, and if there is any impact from advanced adenoma performance there?

For Helmy, if I could get pricing on the MRD Reveal that would be great. Thank you so much.

AmirAli Talasaz

Thanks for your question, Puneet. Let's maybe go through them one by one.

In terms of the timing, October is still a possibility. What we mentioned in the last earnings call is our team has a very good confidence it would be in the second half, likely (inaudible) September/October. We continue to have very high confidence that the readout would be in basically the fourth quarter before we (inaudible) for sure, and October still is a possibility.

Really, the exact timing is a function of the timing of finding these low number of events. Our study is already powered for a sensitivity test. Our target is (inaudible). Effectively we are in full control in terms of when we want to unblind the study. There are multiple factors that go into really the decision about clicking the button and effectively unblinding the study. Some of it is for continuing to raise the bar for (inaudible) blood-based test that (inaudible) provability bar for other blood tests down the road.

We are going to have a good balance of where we are, when we are planning these CRCs and we would make the decision, but all these stuff it's kind of matter of the weeks that we are talking about. It's going to be in the fourth quarter we are going to have the readout; we have full control over it.

In terms of interval testing, as a manufacturer our recommendation is going to be our blood test to be used every one to three years. Medicare pricing is set for our test after we get (inaudible) well established ADLT pricing. The framework and process, which has nothing to do with interval testing, that is our belief. That's the reason we set our cash pay price at $895, and our list price is even a little bit over that.

We have very good confidence about our pricing strategy and the negotiations that we are going to have with CMS. Not negotiation, the process that we are going to go through with CMS, post FDA approval and post getting the ADLT status.

MRD pricing?

Helmy Eltoukhy

Nothing to disclose at this time, but it's something we're working through and I'm sure we'll announce it soon. We'll be able to also pursue ADLT status as well in the coming quarters, so that's still a route that is very much open to us.

Puneet Souda

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Thanks, guys.

Operator

Thank you. The next question today comes from the line of Jack Meehan from Nephron Research. Please go ahead, your line is now open.

Jack Meehan

Thank you. Good afternoon. Wanted to focus on reimbursement strategy for Guardant Reveal, notably there's been a little bit of a debate around whether Guardant can pursue ADLT status for Reveal, whether you're first in category with blood, or whether you're second in category when it comes to MRD overall. Just was curious if you've gotten any indication around your eligibility for ADLT status from Medicare.

Helmy Eltoukhy

That's a great question, Jack, to have that route open to us. This is a first of its kind test, the only true liquid biopsy in the space. (Inaudible) there's a significant (inaudible), anywhere from 20 to even (inaudible) certain indications that don't have tissue available, and even the ones that have tissue, it's very difficult to get. So, this is a breakthrough test. It's a watershed moment for the field in terms of (inaudible), and ADLT status is (inaudible).

Jack Meehan

Awesome. Then also, is there any additional color you can provide around the logistics of how Medicare will reimburse from a test? Will it be one test? A bundle of tests? Through what period of time? Then there was this reference to a three-month window after resection; just comment how was that chosen,

Helmy Eltoukhy

That's a great question. It's based on the data we submitted in initial dossier. This is really in the setting, this is for a bundle of tests that will be reimbursed, so it will essentially be for serial monitoring in that post setting. So the first test could be performed any time within that three month window, you would have essentially a string of tests that would follow for a large interval of time.

Jack Meehan

Thank you Helmy.

Operator

Thank you. Our next question comes from the line of Mark Massaro from BTIG. Please go ahead. Your line is now open.

Mark Massaro

Hey guys, thank you very much for the questions and congrats on the progress. Maybe two questions. The first is there was some confusion about the MRD Medicare reimbursement that came in. Can you just clarify if that can be used in both the adjuvant window – call it the first six months of the patient journey — and then also in the recurrence monitoring setting as well for repeat timepoints?

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Then my second question, I just wanted to clarify, are you pursuing ADLT status for the CRC screening test as an LDT, or are you planning to apply for that after you get FDA approval?

Helmy Eltoukhy

It's a great question. I'll start with the MRD one.

This is for the adjuvant setting for that initial period after intervention. For monitoring those (inaudible), that time period can extend out for a considerable amount of time, but for the patients that are multiple years away, let's say, from a intervention, we are continuing to have discussions with Medicare, additional data to pursue some of those additional (inaudible) as well as obviously indications outside of CRC (inaudible).

AmirAli Talasaz

Regarding ADLT status for the CRC Shield LDT test, our current plan is to wait for FDA approval, secure CMS coverage and then apply for ADLT status. Obviously we need to have Medicare coverage first before you apply for ADLT, and based on criteria that we have (inaudible) FDA approvability is a requirement. So, our current plan is to go through it in sequence of FDA approval, then quickly CMS coverage, and then we submit our package for ADLT status.

Mark Massaro

Perfect. Thank you.

Operator

The next question today comes from the line of Brian Weinstein from William Blair. Please go ahead, your line is now open.

Brian Weinstein

Hey guys. Thanks for taking questions. Just wanted to talk to you about the core business a little bit here. You mentioned the volume growth was below forecast. You talked about May and June being a little bit weaker. Can you just reiterate kind of what was going on specifically, what you thought was weaker? Was that an industry thing? There is obviously some new competitive products that are out in the market. Was there some competitive headwinds that were going on? What does it look like again in July, and I guess we're early August but it doesn't count, but just through the first part of the third quarter. Thanks.

Helmy Eltoukhy

Great question. We saw, obviously, very strong growth regardless, both in the core business with 360 and new products as well, very robust. But as we mentioned, we had a very strong April and then a weaker May and June. What we saw in the field in general was that still lingering effects in terms of COVID. There was Omicron. A lot of hospitals had staff shortages and so on, so I think depression in the overall space.

We're not seeing anything new from a competitive front that would worry us, and in fact as we mentioned it has been very strong and we've seen things (inaudible) confident that the underlying metrics we mentioned in terms of depth and breadth continuing to increase (inaudible) essentially be the second half of the year and we think we can close some of the gap based on the progress we're making.

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Brian Weinstein

Okay. Then you said that you expect with the CRC product that you expect ACS guidelines. Is that based off of conversations that you've had already with ACS guidelines, or is that based off of precedent that we saw with Cologuard?

AmirAli Talasaz

That's our expectation based on some of the history, (inaudible) we've been engaged with (inaudible) conversation with some stakeholders and even there is some kind of potential that if there is a strong pivotal study readout coming out that shows really a very favorable outcome for blood-based testing, there is even a probability of seeing some guideline (inaudible) before FDA approval. But post FDA approval, based on what we heard so far, there is a good level of confidence by us that American Cancer Society based on the frequency guideline recommendation and changes that they make they would recommend such tests, again, assuming ECLIPSE data would be as we expect it to.

Brian Weinstein

Okay. That makes sense. Thank you.

Operator

Thank you. The next question today comes from the line of Kyle Mikson from Canaccord. Please go ahead. Your line is now open.

Kyle Mikson

Hey guys, thanks for the questions. Congrats on the quarter. I have I guess one question but multi parts. For AmirAli, you said over 90% adherence from the first sample was impressive; it's just one sample size, though. Maybe how has adherence trended recently? Then who are the early users of the test? Like by age group, I guess. Curious, obviously, commercial private payers, if they're reacting in any way.

Then for Helmy, congrats on the Reveal reimbursement. Could you just talk about why that took so long and why you're confident that reimbursement for the future indications is not going to be like similarly delayed? It was delayed by at least six months. Thanks.

AmirAli Talasaz

Thank you for your question. (Inaudible) confirmation, like stuff that looked kind of (inaudible) and now you're seeing patients really prefer blood tests and adherence using blood tests would be high. In over 1,000 samples, hundreds of ordering physicians across (inaudible) very few (inaudible). So almost steady adherence week to week, and it's continuing to stay. In fact, our adherence that we are seeing is even much higher than I'm quoting but we don't want to get off our skis too quickly and get too excited. But based on the trend that we are seeing I think really blood can show very high adherence.

The type of accounts are—obviously we are targeting early adopters at this stage. Again, this is metric adherence is a metric that we are kind of continuing to monitor and see what's going to happen. Please note, the adherence that we are talking about, like at Guardant we don't have huge patient navigation kind of programs and significant amount of investment there to make sure patients really submit the samples. This is the reality of what's happening, really as strong (inaudible) patients and physicians (inaudible). We are very excited about it.

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Helmy Eltoukhy

In terms of delays with MRD, this is a really novel new test, very (inaudible) in the space. There was definitely some back and forth, I think learnings and education required in terms of really diving into the details and work. How could you possibly detect recurrence without having tissue? So, we're very confident now that we've gotten over that. We have come to a place where there's good confidence in (inaudible) understand how it works and so now I think we'll be mostly limited just by the speed of clinical validity data and clinically getting that out into the publication space.

Kyle Mikson

Great. Thanks guys.

Operator

Thank you. The next question today comes from the line of Matt Sykes from Goldman Sachs. Please go ahead. Your line is now open.

Matthew Sykes

Thanks for taking my questions. A number of my questions have been asked so maybe I'll just keep it to one and make it pretty high level. Just say we look back like a year and a half ago, I think there was a view that given all of the funding environment that it was becoming potentially a crowded field in terms of overall liquid biopsy with a number of private companies coming into the space. Just given the changes in the funding environment, how are you guys thinking about the competitive environment? I know you're obviously focused on achieving your goals, but in terms of how you're looking at the competitive landscape a few years out and what potential impact could this funding environment actually have on the competitive landscape for liquid biopsy in your view?

Helmy Eltoukhy

I would say that obviously we're monitoring kind of the space. It's really interesting to see some of the developments. That said, it continues to be a hot space. There continues to be money that's diving in (inaudible) dollars that have been raised over the last few quarters that continue to be invested. So, we're taking kind of the pedal to the metal, at least in terms of our internal programs. We've always been very disciplined in terms of how we operate the business and we're going to continue to be so in this environment, but we're not necessarily going to take—we're not going to slow things down in terms of development of the work we're doing. But I think there's going to be some opportunities as well as things progress in terms of technologies, consolidation.

We feel very well poised and well positioned, and what the next few quarters could mean for the liquid biopsy space in general.

Matthew Sykes

Thank you very much.

Operator

Thank you. The next question today comes from the line of Tejas Savant from Morgan Stanley. Please go ahead. Your line is now open.

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Neil

This is Neil on for Tejas. I just have two quick ones. Now that the lab in Spain is fully operational, any color on early traction here? Then with full operational ownership of the AMEA joint venture, how should be thinking about planned investments to support the scale up in Japan? I know you mentioned that you anticipated reimbursement in Japan by year end, but any extra color on when we could expect to see some updates there?

Helmy Eltoukhy

Great question. Very excited about the progress we're making internationally. I think probably too early to say (inaudible) they're a little bit early, just getting the first few samples out. They're super excited. It's really a first of its kind laboratory in the Europe and certainly in Spain, and so that's going to give a lot more access to our technology there. We have similar work being done in the U.K. and we're excited about that.

In terms of joint venture that could be (inaudible), we're very bullish about the upcoming catalyst that we have there. Japan is an extraordinary market in terms of size, number of cancer patients, reimbursement rates. They have great studies on the clinical side, great connections with a lot of the hospitals there. So we think there potentially could be some upside in the years to come in terms of (inaudible) Japanese market once we have reimbursement and once we're fully there.

I think us taking control of that allows us to really have a unified global presence with the pharma companies (inaudible) investing, in terms of really making kind of real on the opportunity we have. Then obviously we just signed and announced a partnership in China as well, which is a very big market opportunity for us, and so I think it's going to justify the investment we're making in that region.

Neil

Thank you.

Operator

The next question today comes from the line of Dan Arias from Stifel. Please go ahead. Your line is now open.

Male Speaker

Hi guys. This is (inaudible) on for Dan Arias.

First for Helmy—sorry to repeat it again—but on the Reveal reimbursement a few questions, so bear with me. What is the timing on when we might see that, and then also when it might be effective? Then will it come under the current umbrella LCD for MRD solid tumor cancer? Then within the coverage decision, is the language you initially expect to cover for serial testing initially, or does that come over time?

Then lastly, are you able to provide any specific studies that Palmetto reviewed to come to their coverage decision? Or is this just comprehensive of the MRD studies you've done to date within colorectal? Thanks.

Helmy Eltoukhy

(Inaudible) give an overview of what the reimbursement (inaudible).

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It's reimbursement for a bundle of tests, so essentially serial monitoring of colorectal cancer patients, Stage II and Stage III in that adjuvant setting. First test is when the first three months after treatment or surgery, that individual and then subsequent testing can extend the time after that. That's reimbursement that is I think now in effect, and we are still in discussions in terms of the look-back period in terms of when that can—when could (inaudible) billing opportunity.

So, it's something that I think is a big, I would say milestone for us, and I think it bodes well for continued indication expansion over time, hopefully. I think that answered most of your question. If there's anything else (inaudible).

Male Speaker

Yes, you did. Is it going to be under the same LCD of MRD testing in general?

Helmy Eltoukhy

Yes. The LCD is a general (inaudible). It applies to this category of tests. (Inaudible).

Male Speaker

Okay, thanks. Then maybe I'll just change gears because a lot has been covered. For AmirAli, the adding to lung to Shield in 2023, could you just give us an idea on what the logistics of that might look like in terms of data, actually launching the test, FDA approval and then all the way up to reimbursement? Thank you.

AmirAli Talasaz

Yes. We are very excited about that. We think that's actually a feature that really takes these blood testing to even the next level, like very exciting. A lot of conversation that in just the field of CRC how much blood can add value, which is significant, and I think when you start adding some other cancer type to it you're having (inaudible) completely. Would you just do a simple stool test that can just detect one thing, or you're going to go and do a highly sensitive, highly compliant test that (inaudible) very relevant stuff.

We are going to operate our (inaudible) in 2023 to be able to look at lung cancer. We have shown data already in case control studies. We are (inaudible) these kinds of studies. We have done a validation study in terms of sample collection since 2017, so it's been a five-year study for us to (inaudible), and as part of the (inaudible), we are going to actually run and touch more (inaudible) study that we've done, the path for LDT upgrade as a registrational study for getting the FDA label. We're doing our Shield lung study in parallel that we started January of this year. We have January of this year, we had the FBI, and it's going to take some time to really finish the enrollment and get the (inaudible) study.

Male Speaker

Thank you, guys.

Operator

Thank you. The next question today comes from the line of David Westenberg from Piper Sandler. Please go ahead. Your line is now open.

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David Westenberg

Great. Hi, thank you for taking the questions. Can we talk about some of the sensitivity metrics in MRD testing and in Guardant Reveal? I mean actually specificity of characteristics. One of the interesting things that we have found in our checks from things like ASCO is that we found people tend to think of about this in context of multiple testing or serial testing, as kind of we just discussed, and at that point a lot of the specificity metrics tend to sort of mount over time. So when we're thinking about specificity and what kind of numbers you need to really have commercial success with oncologists, where do you think we're at?

Helmy Eltoukhy

I think all the data we've shown is in the high 90s, if not close to 100% in terms of the specificity, so we're very confident about the performance of that assay.

Yes, there seems to be a misperception that somehow if you don't have tissue information that you can't get high specificity, and that's—we haven't seen that to be the case and we're very confident about the performance of the assay. We're seeing really good performance, both in sensitivity and specificity, and the beauty of it is it is just such a simpler (inaudible), a tube of blood and not needing the logistical balancing act of trying to find tissue samples.

David Westenberg

Perfect. Thank you. That's very helpful.

I'm not sure if this has been asked; I've been jumping around three calls today. In terms of any of the incoming competitors, particularly private, I mean I think there's one that's spent a lot of money marketing and has a fairly compelling proposition in the CGP space, and they just entered liquid biopsy I believe a couple of weeks ago. Are you seeing any different competitive threats that you haven't seen in the past? Or is it continuing to be kind of the same environment, just given the fact that we really have an underpenetration of liquid biopsy, and really, frankly, an underpenetration of CGP generally. And I'll stop there, of course.

Helmy Eltoukhy

We haven't really seen anything. Some of these competitors, this has been almost a normal in this space of everyone and their brother trying to come in. It's a lot more difficult, I would say, than just putting a test out there. There's performance, there's brand, there's data. Frankly, a lot of these competitors we haven't even seen a publication or a poster from assays. I think we're now over 300 publications with the Guardant technology, the Guardant (inaudible) hasn't really changed from (inaudible).

David Westenberg

Thank you.

Operator

Thank you. The next question today comes from the line of Derik De Bruin of Bank of America. Please go ahead. Your line is now open.

Derik De Bruin

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Hello, good afternoon. Thanks for taking my question. I've got two.

The first one is how do we see the ASP rolling out into next year? I mean I realize you're talking about a $2.400 blended ASP for 2022, but as you get—as you ramp up Reveal and Tissue, but you also have Shield coming in with it. Is that $2,400 a good number to sort of look at as a base for next year? Also, and appreciate you've going to have to build out your commercial infrastructure for Shield, but could you give us a little bit more clarity on some of the ramp, particularly as we sort of look into '23 in terms of how you're going to do it. Particularly, you have to hire salespeople; are you going to meter this ahead of guideline inclusion? Just a little bit more clarity on how to sort of think about the Opex ramp. Thank you.

Mike Bell

Yes, Derik. It's Mike here. I'll take that.

From an ASP point of view, one thing that is very clear is with respect to Guardant360, we've had this ASP of $2,600 to $2,700 now pretty consistently for the last few quarters. The potential for—it could go up if we get some of the larger private payers to start covering Guardant360 or CGP in terms of, but as a base case we would probably say for next year it's going to remain the same.

Then overall, from the blended perspective, yes, we've got good news now on reimbursement from Medicare. We've got good news for Reveal reimbursement from Medicare, so that's a positive for us. I think it's going to depend on volume and on the mix between Guardant360, Tissue, Reveal response and then Medicare and non-Medicare. So, $2,400 is probably a good starting point but there are potential movements in that.

Then from the Opex ramp, you know, I think from a sales and marketing perspective, last year we invested heavily on the oncology commercial side and really built out the commercial field team there. Then later last year we built out the screening sales force (inaudible) which is going very well.

Going forward, for the screening we'll really build that out on a milestone basis, and so we need (inaudible) but I think when we're on track for (inaudible) reimbursement then we'll look to (inaudible) commercial launch.

We're taking it (inaudible) and it's going to depend on those milestones.

Derik De Bruin

Thank you.

Operator

Thank you. The next question today comes from the line of Julia Quinn from JP Morgan. Please go ahead. Your line is now open.

Amy

This is Amy on for Julia. Thank you for taking my question. I have two specifics on the Reveal pricing. The first one is could you expand a little bit on the potential cost for Reveal and when can we have some clarity on that? The second one is I'm curious to see when can we expect to see any updates on coverage for additional indications outside of CRC. Thank you.

Helmy Eltoukhy

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(Inaudible) if that was the question, something that is just like every other product we have we typically are targeting high gross margins in the 60-plus percent range and we're very confident we can get that. Then as we get private payer reimbursement, really get to operational scale.

I would say in terms of indications, we announced that we're going to launch lung and breast this second half of the year in terms of Reveal, and we are working on data in terms of publications. We've released some of it but we'll (inaudible) more data, collecting more data in terms of studies that hopefully we can publish in the coming quarters. That would be the basis for further validation data for reimbursement.

Amy

Thank you. Just a quick follow-up. Can you give us a little bit of update on the reimbursement for the G360 Response?

Helmy Eltoukhy

There's no update there. We're still in discussions.

Amy

All right, thank you.

Operator

Thank you. The next question today comes from the line of Max Masucci from Cowen & Co. Please go ahead. Your line is now open.

Stephanie

Hi. This is Stephanie on for Max. Thanks for taking my questions. A quick one from me. Could you touch on some early feedback that you've been seeing from your early access launch of the Smart Liquid Biopsy platform, along with your plan for a broader commercial launch of the platform?

Helmy Eltoukhy

Sure. (Inaudible) I think it's really piquing kind of the imagination of a lot of our partners in terms of what they could potentially do with it. We're seeing it generating a lot of interest in terms of new studies (inaudible). We think it's had the right product market fit for the (inaudible) where it is (inaudible) in terms of scaling our throughput to be able to handle what we is good demand for that product (inaudible). We'll keep you posted as we make more progress with that platform, but we're really I think right no target and right on schedule in terms of the development of that. It's going to be really the future of a lot of our products here at Guardant on the oncology side.

Stephanie

Got it. That's helpful. A quick follow-up on the strategic partnership agreement you've done with Adicon in China. How should we think about the impact and ramp to biopharma testing volumes going forward? Thanks.

Helmy Eltoukhy

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It should be helpful. A lot of our partners are global companies. They do a lot of work in China, which is quickly becoming the second largest opportunity from the biopharma side, and so it's going to give us the ability to really unify testing across one platform with our new platform for a lot of our partners there. So, we're very excited about the opportunity. We have a large pipeline already building ahead of the launch of that laboratory. We know it's going to be very positive for us.

Stephanie

Got it. Thanks for taking the questions.

Operator:

Thank you. The final question today comes from the line of Patrick Donnelly from Citi. Please go ahead; your line is now open.

Patrick Donnelly

Hey guys. Thanks for taking the questions. AmirAli, maybe two quick ones on ECLIPSE. Can you just talk about, you mentioned the USPSTF in '26. Do you view that as kind of the big potential inflection point of volumes, or do you think we could have material contributions before that? Then secondarily, just in terms of confidence level that the study size is correct and you guys have enough cancers. Any update? I know you can kind of see the amount of cancers that you have so far. Can you talk about where we are, and again, confidence level that the enrollment is the right number still? Thank you.

AmirAli Talasaz

Yes. In terms of material revenue contribution, we believe after we get CMS coverage we are going to really have a material contribution to Guardant's top line. Actually, I'm just getting more and more (inaudible) even the volume projection based on what we are seeing today. But material contribution would be post CMS coverage. We expect to have approval sometime next year; maybe by end of next year, and CMS coverage right after that based on the MCD. So, (inaudible) definitely way before USPSTF, but USPSTF is a major milestone that will take us to a different kind of a league and it's definitely a catalyst, a big catalyst for our volume growth.

Regarding the number of CRCs, as I mentioned earlier, I think that our (inaudible) in terms of when to unblind the study. We are just one CRC away from that 60 to 70, and we are going to monitor this study, what's happening. It's not just (inaudible) already powered; we are going to definitely consider also setting a precedent for other tests in terms of their approvability and their review. So we are going to consider that in terms of when we are going to basically press the button and unblind the database and get the results readout. But we have full control over it and we believe actually—we have a very good confidence it's going to be the fourth quarter.

Patrick Donnelly

Understood. Thank you.

Operator

Thank you. There are currently no more questions registered, so that concludes today's conference call. Thank you all for your participation. You may now disconnect your lines.

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