Guardant Health Q3 2021 Earnings Call — Thursday, 04 November 2021

Carrie Mendivil Thank you. Earlier today Guardant Health released financial results for the quarter ended September 30, 2021. If you did not receive this news release or if you would 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, co-CEO, AmirAli Talasaz, co-CEO, and Mike Bell, Chief Financial Officer. Before we begin, I'd like to remind you that Management will make statements during this call that are forward-looking statements without needing a federal security clause. 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 factor section of the Company's Annual Report on Form 10K for the year ended December 31, 2020 and other filings with the Securities Exchange Commission.

This call will also include a discussion of certain financial measures that are not calculated in accordance with generally accepted accounting principles. A 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 advise any financial projection or forward-looking statement, whether it be because of new information, future events or otherwise. This conference call contains highly sensitive information and is accurate only as of the live broadcast on November 4, 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 third quarter 2021 earnings call. I'll start off today's call by highlighting our progress across oncology as we continue to build on our strong foundation as the liquid biopsy leader. I will then turn the call over to AmirAli for an update on our screening programme in colorectal cancer and our plans for expansion into multicancer screening.

And, finally, Mike will provide a more detailed look at our financials and our outlook for the remainder of 2021. Our mission at Guardant is to conquer cancer with data, fuelled by a commitment to putting patients first. To this end, we are dedicated to bringing the absolute best products to market that will provide clinically actionable information to inform patient care.

Before I provide an update on our progress, I would like to start the call off with a patient story. This past summer a 54-year old woman was diagnosed with colorectal cancer. Her oncologists ordered a Guardant360 CDx test which identified her cancer as KRAS negative, indicating that she may respond to anti-EGFR therapy. With this information she was enrolled in a clinical trial.

As her treatment progressed she began to experience worsening symptoms that led to uncertainty about whether or not she was responding to treatment from the clinical trial. Her oncologists ordered a Guardant360 Response test, which is the first commercially available blood-only liquid biopsy test to detect changes in circulating tumour DNA levels to provide an early indication of a patient's response to treatment.

The test confirmed her cell-free tumour DNA levels were decreasing, meaning she was indeed responding to treatment and her symptoms were likely a side effect from the therapy. With this her oncologist had the information he needed to continue treatment through the trial and the patient's symptoms have since improved. This story highlights how Guardant360 can provide powerful information across multiple stages of cancer care, from rapid treatment selection with our Guardant360 CDx to early patient response monitoring with Guardant360 Response.

Today the Guardant360 product portfolio is increasingly providing oncologists with a set of comprehensive tools to unlock the full potential of precision oncology across the continuum of a dense cancer care.

Now, turning to our performance, realised record revenue during the third quarter of approximately $95 million, growing 27% year over year. On our earnings call in early August, we shared that the resurgence of COVID-19 cases was impacting oncology office visits and salesforce access, with our international business particularly impacted. While the environment didn't worsen, these impacts persisted through August and into September.

Despite these continuing impacts from COVID, our team delivered strong clinical volumes of 22,806 tests, up 9% from the second quarter of this year and 35% compared to the prior year. I continue to be proud of how well our commercial team is executing in this environment and achieving healthy volumes and continued growth.

Notably, approximately 50% of our volume in the quarter came from the community setting, which represents over 10% growth over the previous quarter. We have also continued our strong cadence of clinical evidence supporting Guardant360. In September, we shared new data at IASLC World Conference on Lung Cancer that demonstrated the advantages of using the Guardant360 liquid biopsy test for clinical decision-making in advanced lung cancer.

Shortly after we showed data at ESMO highlighting molecular targets for important treatment-resistant patterns and advantages of the Guardant360 liquid biopsy test to help improve the management of advanced colon cancers.

These certainly add to the growing evidence demonstrating that Guardant360 is an easy and quick way of identifying more patients with actionable biomarkers, allowing clinicians to start biomarker-informed treatment sooner as compared to tissue biopsy for comprehensive genomic profiling.

Turning to recurrence monitoring, we are encouraged by the growing interest and early success of Guardant Reveal and are continuing to invest heavily in the vast opportunity ahead while leveraging our existing channels of oncologists. We now have a full commercial channel dedicated to Reveal and have added over 50 employees to the team during the third quarter.

Across our oncology portfolio, we have a commercial organisation of more than 250 employees across sales, marketing and medical affairs. We are making solid progress towards our multi-cancer goal with data on colorectal cancer as well as bladder, lung and breast indications.

Similar to our approach in therapy selection, we are investing in clinical studies across MRD to demonstrate the clinical utility of our tests. To that end, in October we initiated the ORACLE study to evaluate the performance of Guardant Reveal to predict recurrence across many early stage cancers. Specifically, this is a 1,000 patient

prospective observational multi-centre study designed to evaluate the performance of Reveal to predict cancer recurrence after curative intent treatment across 11 solid tumour types.

This study, in combination with our existing studies will establish clinical evidence for Guardant Reveal across nearly 80% of all solid tumour cancers. The first patient was enrolled in early October. If successful, ORACLE will pave the path for reimbursement for Guardant Reveal across multiple cancer types, definitively establishing the blood-only approach for MRD and unlocking the $15 billion total addressable market for MRD across all tumour types.

Moving on to biopharma, we saw a healthy rebound in our biopharma business with a volume of 4,839 samples, up 32% from the second quarter and up 58% year over year. We are seeing growing interest with our biopharma partners for using Reveal in the adjuvant setting with non-PRC indications such as lung, bladder and breast. Our partners have seen significant benefit with our blood-only tissue-agnostic approach and we look forward to growing usage of Reveal in the biopharma setting.

In addition to increasing sample volumes, the number of customers we serve continues to grow. We now have more than 90 active biopharma partnerships with a healthy pipeline and we expect to have more than 100 partners by the end of the year. The breadth of our product offering, strong customer service and a clinical market leadership makes us an attractive partner.

Outside of the United States, we continue to expand our presence in Europe through established partnerships with premier cancer organisations. We have partnered with the Royal Marsden, a leading specialist treatment hospital in London. This is similar to the previously announced Vall d'Hebron partnership in Spain, which establishes in-house liquid biopsy testing services running Guardant360 tests and sequencing on site.

This service is expected to become operational in 2022 and will be available for clinical research and clinical care, providing industry-leading, next generation sequencing to private and self-paying patients with a plan for future expansion for National Health Service patients. In addition, we continue to make important progress with our JV in Asia, the Middle East and Africa.

Specifically in Japan, we are on track for PMD approval of Guardant360 and launching our clinical laboratory outside of Tokyo by early next year. We are also making excellent progress in other countries in the region as well as growing clinical volumes with both biopharma customers and oncology clinics. Accordingly, we have decided to exercise our call right to purchase the remaining 50% of our joint venture from SoftBank.

We are working towards a future where all patients with cancer around the world have access to the latest innovations to inform treatment decisions and then also care for the best possible outcomes. This additional partnership in Europe and our redoubled commitment to our efforts in Asia, Africa and the Middle East are important steps towards realising that vision.

Finally, before I turn the call over to AmirAli, I want to take a moment to welcome Myrtle Potter to our Board of Directors. Myrtle currently serves as Chief Executive Officer and Board Member of Sumitovant Biopharma. Prior to Sumitovant, Myrtle served as the President of Commercial Operations at Genentech.

Myrtle has previously served on the Boards of Amazon, Express Scripts, Medco Health Solutions, Everyday Health, among others. Her extensive knowledge and experience bringing the world-class healthcare products to market will be invaluable as we scale our organisation.

As Guardant grows, I continue to be amazed by the incredible talent we are bringing onboard, joining our efforts to bring the best products to market as we strive to provide patients across all stages of cancer with access to the latest advancements and precision oncology.

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

AmirAli Talasaz Thanks, Helmy. At Guardant we've always believed that a blood-based screening test during wellness check-ups has the potential to guard us against cancer. Blood-based screening is simple, reduces the need for patient follow-through, is much easier to integrate into health system workflows, expand accessibility to underserved communities and would likely improve the compliance to screening tests.

That said, the complexities of malignant disease, the imperfect nature of screening tests and the morbidity associated with follow-on diagnostics means that early detection does not intrinsically construe positive net health benefits. The net health benefit of early detection versus potential harm from unnecessary screening and follow-on diagnostic procedures varies for different cancer types.

While such a large study showed that while it was possible to find ovarian cancer early, the long-term outcomes sadly were no different for cancers detected early versus later, at least based on the current interventions. In some haematologic malignancies, such as chronic lymphocytic leukaemia, early chemotherapy confers no survival benefit to patients diagnosed in the early stages and may introduce significant psychological and even financial distress for a condition in which no treatment is required.

Some investigators have applied blood-based screening even in those sensitivity tests in a one size fits all approach, regardless of cancer type with the presumption that early detection is always positive. In contrast, at Guardant Health our focus is to develop a highly accurate blood test to screen for cancer types where early detection can offer a clear net population health benefit.

We started our screening programme with CRC where the patient compliance rate for screening remains stubbornly at 66% in a disease where screening reduces the risk of death by 62%. In addition, we believe that developing a highly sensitive blood test was visible and the regulatory approval and endorsement pathway is very clear.

We launched ECLIPSE, our prospective registrational study in November of 2019 and made excellent progress over the past 24 months amidst the backdrop of a global pandemic has an impact on overall colonoscopy screening procedures. I'm so proud of our team who have worked arduously to continue patient enrolment and have kept us on track to hit our original timeline set back in 2019. We expect to hit our target patient enrolment in the coming weeks.

Shortly after target enrolment is achieved, we are planning to start running the collected samples in our lab while we continue to collect colonoscopy reports and centralised pathology reports of these cases in parallel. We expect to

have the trial readout in mid-2022. Through ECLIPSE, our team has developed core competencies running a large registrational study and I believe this expertise will prove invaluable as we move on to additional cancer types.

We are also making great progress building our commercial infrastructure to launch our screening product and are on track to launch the LDT version of our CRC screening assay in the first half of 2022. We expect to launch the IVD version of the assay in 2023, pending a successful FDA review and approval. Recently our collaborators at Samsung Medical Centre presented our beta data at the American College of Gastroenterology Annual Scientific Meeting.

This was a retrospective study that used biobank samples from individuals with known CRC where 37% of individuals were symptomatic. In the study, researchers evaluate the performance of our test in an expanded cohort of 699 patients with known CRC and found a test achievement and overall sensitivity of 96% with 94% specificity. In patients with Stage I and II CRC, the test offered 93% overall sensitivity. Additionally, our test identified 90% of patients with a symptomatic Stage I or II CRC.

Now, looking beyond CRC to our opportunity with multicancer screening. Our focus is to develop blood-based screening for cancers where lives can be saved. Our differentiated core technology platform which leverages combined analysis of genomic methylation and fragmental mixed signatures within cell-free DNA has the potential to detect many cancers at their earliest stages.

We have developed a new generation of our high-sensitivity sequencing assay for evaluation of cell-free DNA across multiple tumour types. This new assay uses a custom targeted 16 megabase panel to increase cell-free DNA across a set of highly informative regions in order to detect the presence of tumour-derived signals while maintaining a low sequencing cost per sample.

In addition, we also utilised epigenetic signatures to evaluate tissue of origin or TOO of cancer. We evaluated the performance of the assay in a pilot study using the biodine [?] cohort of 191 treatment-naïve lung cancer patients and 1,576 cancer-free individuals. The assay demonstrated high sensitivity for detecting lung cancer cases for both early- and late-stage disease, while maintaining 95% specificity.

Our sensitivity of detecting Stage 1 and 2 cancers was 78% and further increased to 93% in late-stage patients, Stage 3 and 4. Importantly, we observed even higher performance, with a sensitivity of 95%, for Stage 1/2 in squamous cell carcinoma cases, which is a more aggressive form of lung cancer frequently found in smokers.

To evaluate the accuracy of tissue of origin prediction, we have developed a classification model distinguishing lung cancer patients from patients with colorectal and breast cancers. Overall, the model correctly identified TOO for 90% of detected lung cancer patients. We are thrilled by our progress in lung cancer screening. Lung cancer is the leading cause of cancer-related death in the United States.

The evidence-based screening guidelines recommend annual lung cancer screening for high-risk individual, however the Screening Compliance Study demonstrates gross underutilisation as only around 14% of people eligible for screening are up-to-date with screening recommendations. We believe lung cancer is a great clinical indication candidate for our screening tests.

To validate the performance of our assay in a lung cancer screening cohort, we have designed a new prospective registrational study called SHIELD. SHIELD is a single-arm clinical validation study designed to provide regulatory-grade evidence for the accuracy of our blood-based assay in individuals between the ages of 52 and 80 who undergo standard of care screening for lung cancer using low-dose CT scanning.

As per USGS DF recommendations, all subjects enrolled in SHIELD will be high-risk for lung cancer and either current or former smokers. We are targeting enrolment of nearly 10,000 individuals. We expect to begin enrolment in December of 2021 and to complete enrolment within 36 months.

We believe the promise of blood-based cancer screening is quickly becoming a reality and we see a brighter future for humanity by improving population health. A successful readout of our ECLIPSE trial will open up a $20 billion screening opportunity in colorectal cancer and SHIELD, along with other future studies, will open up opportunities in lung and additional cancer types, paving the way towards a total addressable screening market of more than $50 billion.

I am confident about our strategy in developing blood-based tests for a screening market, not just in CRC but also in multi-cancer screening. With that I will now hand the call over to Mike for more details of our financials and outlook for the remainder of 2021.

Michael Bell Thanks, AmirAli. Total revenue for the third quarter of 2021 was $94.8 million, up 27% from $74.6 million in the prior year quarter. This increase is primarily driven by strong growth in both clinical and biopharma sample volumes. Total precision oncology testing revenue for the third quarter was a record high of $79.3 million with a growth of 31% from $36.4 million in the prior year quarter.

Precision oncology revenue from clinical testing in the third quarter was $61.3 million, up 27% from $48.3 million for the prior year quarter. Third quarter clinical test volume was 32,806, which is an increase of 35% from the prior year quarter. Blended clinical ASP for the third quarter of 2021 was $2,689, which was above our estimate due to improvement in ASP for Guardant360 CDx where the team has done an excellent job, ensuring payers were well prepared for the new ADLT code and efficiently processed claims.

We are seeing solid traction for our new clinical products, Reveal, TissueNext and Response and we expect those volumes to continue to increase with time. However, we don't expect these new products to significantly contribute to revenue until we've received Medicare and private payer reimbursement. Therefore, whilst we expect Guardant360 LDT and CDx ASPs to continue at similar levels, we expect the blended clinical ASP will be impacted as we await reimbursement of the new product.

Precision oncology revenue from biopharma samples in the third quarter totalled $17.9 million, up 49% from $12.0 million for the prior year quarter. Biopharma volume was strong with third quarter samples totalling 4,839, up 58% from the prior year quarter. We are very pleased with the healthy rebound and we are still on track for low double-digit volume growth for 2021.

Biopharma sample ASP was approximately $3,700, down 5% from approximately $3,900 in the prior year period but improved from the second quarter of 2021 due to the OMNI and Guardant360 mix.

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Development services and other revenue in the third quarter totalled $15.5 million, up 9% from the prior year quarter. While we are continuing to see stronger overall demand for development services, several projects have recently been completed or are soon to be completed and we expect some near-term lumpiness in this revenue line, related to the timing of Project Mars Dance and other contractual arrangements.

As a result, we expect that our development services and other revenue may be sequentially lower in the fourth quarter and as new projects take time to ramp up, this is likely to persist into next year.

Gross profit for the third quarter of 2021 was $64.0 million compared to a gross profit of $53.4 million in the same period of the prior year. Gross margin was in line with our expectations and in the third quarter was 67% compared to 68% in the second quarter of 2021 and 72% in the prior year quarter. Operating expenses for the third quarter of 2021 were $171.3 million, an increase of 34% compared to $127.6 million in the third quarter of 2020.

Non-GAAP operating expenses exclude stock-based compensation and related employer payroll tax payments, acquisition-related expenses, amortisation of intangible assets and changes in fair value of contingent considerations. Non-GAAP operating expenses for the third quarter of 2021 were $135.1 million, an 88% increase from $71.8 million in the prior year quarter.

2021 has been a year of significant investments and we expect operating expenses to continue to accelerate for the remainder of the year as we invest in our LUNAR programme, ECLIPSE study and other development activities, 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 $107.5 million or $1.06 per share for the third quarter 2021 compared to $77.7 million or $0.78 per share in the third quarter of 2020. Non-GAAP net loss was $70.5 million or $0.70 per share for the third quarter of 2021, compared to $15.4 million or $0.15 per share for the third quarter of 2020.

Adjusted EBITDA was a loss of $65.2 million in the third quarter of 2021 compared to a $14.1 million loss in the third quarter of 2020. We define adjusted EBITDA as non-GAAP net loss adjusted for interest, income tax, depreciation, amortisation and other income and expense. We ended the third quarter of 2021 with $1.7 billion in cash, cash equivalents and marketable securities.

As Helmy mentioned, on November 1, 2021 we elected to exercise our call right to purchase 50% of the Guardant Health AMEA joint venture shares that we do not currently own. As a result, we have initiated the process stipulated in the joint venture agreement to determine the purchase price, which at a minimum will be an amount that yields a 20% internal rate of return on the $41 million capital invested by SoftBank in May 2018.

We currently fully consolidate the joint venture business in our financial statements and as such the impact of exercising the call right will be to adjust the fair value of the redeemable non-controlling interest liability on our balance sheet to be equal to the purchase price of 50% of the joint venture and to reflect that adjustment on the income statement.

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As we exercised the call right on November 1, there was no impact to the fair value of $59.4 million as of September 30, 2021. We expect to complete the purchase before the end of the second quarter of 2022.

Now, turning to our revenue outlook for the full year 2021, we continue to expect revenue to be between $360 million and $370 million, representing a growth of approximately 27% over 2020 at midpoint. We experienced some COVID-related impact to clinical volumes during the third quarter with respect to field service access to oncologists and tightened restrictions internationally.

We saw a recovery in September and in October as compared to a relatively weaker August but continue to see an impact on oncology [unclear] taxes in the US and across our global business. While we expect clinical volumes to grow compared to this quarter, we continue to be cautious, given the uncertainty around the impact of COVID-19. Despite this, we are expecting quarterly clinical volumes to finish the year strongly and grow approximately 40% year over year in the fourth quarter of this year.

We've made great strides this year as we continue to broaden our oncology product portfolio and expand 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 open up the call for questions.

Operator Thank you. We will now proceed with the Q&A. If you would like to ask a question, you can press star one on your telephone keypad. If you would like to withdraw your question, you can press star two. Please note we will only be taking one question and one follow-up from each person. Thank you. Our question today comes from Puneet Souda from SVB Leerink. Puneet, your line is now open.

Puneet Souda Hi, Helmy and AmirAli. Thanks for taking the question. So, first one on ECLIPSE, I just wanted to clarify in terms of enrolment versus completion or collection of the samples and also the completion of colonoscopies there. You said you'll finish enrolment here in the next few weeks. Is there any reason you would need to increase the enrolment of the trial at this stage. I'm really asking that because there are now two CRC screening trials in this space, where they have to increase enrolment to over 20,000 patients and extend their trial timing.

So, I just want to clarify in terms of completion of samples and collection of samples and colonoscopies, I just want to make sure that there is reason to expand from what you're seeing currently and also your enrolment is going to stay intact at 13,000, given the event rates that you're seeing so far.

Helmy Eltoukhy Yes, thank you, Puneet, for your question. So, yes, you may know actually these studies are powered based on the number of CRC that basically we need to identify in these prospective registrational studies and, as we elaborated in our last earnings call, when we increased the target enrolment from 10,000 to about 13,000, that was based on the intermediate readout of the CRC incidents that we've seen so far for patients that had finished the colonoscopy and we had the colonoscopy reports and their CRC were confirmed.

And based on all the data that we've seen, we felt comfortable that actually we need to increase enrolment target from 10,000 to 13,000 and since then still our prevalence and CRC incidence remains the same. So, we believe,

based on all the information we have right now, we feel very comfortable that 13,000 is the right target enrolment for us.

I cannot, obviously, comment about other companies' trials but probably, actually, maybe what's giving experience is, maybe how well the sites have been selected for the trials, what's the expected prevalence of CRC in different locations, different geo, I think there are a bunch of factors there that potentially help Guardant.

As you may remember, during the early days of COVID, in fact, we doubled down on our screening study instead of slowing it down and during those days, in fact, we [unclear] towards additional high throughput, high prevalence kind of sites since our study but I know well the data that we are seeing at Guardant and unfortunately I cannot comment about other trials out there.

Puneet Souda That's great and very helpful. And for my follow-up, I know it's early to talk about the reimbursement for the SHIELD trial or the SHIELD assay when it emerges out of the trial but could you maybe just talk about potentially how are you thinking about the pricing of this assay and what is the regulatory pathway there, the guidelines inclusion pathway that you need in order to get the screening tests onto the market? Thank you.

Helmy Eltoukhy Yes. Screenings like that has been something that we very well studied during the last couple of years, always the criteria that we use for selecting our next indication as multifactored in our really biologic technology but also reimbursement pathway and regulatory pathway. As such we believe lung impact is a great second candidate for us. Obviously not the only candidate but a great one.

As we make more progress towards this programme and initiative, and we will keep you posted, but based on conversations that we have and research that we have done, we believe we know actually what we have to do to really take such a device through, hopefully a successful FDA review and also for the Medicare review. But as we make more progress, definitely we will keep you guys posted.

Puneet Souda Great, thank you.

Operator Thank you, Puneet. Our next question comes from Brian Weinstein from William Blair. Brian, your line is now open.

Brian Weinstein Thank you so much and thanks for taking the questions, guys. Good afternoon. AmirAli, we've talked about this in the past but given the recent data a couple of weeks ago from ESG, I just wanted to go back into the concept of the representation of sensitivity in that trial versus what we should be thinking about relative to your bar for ECLIPSE, not the bar for the FDA but where you think things are going to come in relative to thinking about degradation in the pivotal versus the case control.

So, how representative do you think that case control study really was when thinking about what we should be thinking about relative to ECLIPSE? Hopefully that makes sense.

AmirAli Talasaz Yes, absolutely. So, let me start with saying ECLIPSE is one kind of a study and other analyses and biobank studies could really completely show the performance that we are now seeing in ECLIPSE. We don't need to do this prospective two-year study of sample collection of ECLIPSE and run it. Having said that, throughout

the years, actually, since 2019 we tried to risk the technology on our assay in the cohorts that can mimic, as closely to the screening population that we're going to get in ECLIPSE.

I think the closest, although it's not exactly the same, symptomatic patients with early-stage CRC that we are seeing the performance of our assay. We talked about the limitation of those data. That said, we're very excited and, actually, thrilled with the performance of our assay and we're very optimistic of what we're going to see in ECLIPSE. But according to the comments, I always mention, ECLIPSE is ECLIPSE, so we have to just wait. And we are just a few months away from really getting this data from ECLIPSE.

All the signs that we are seeing so far in general gives us a lot of confidence, but we have to see what ECLIPSE is going to have for us at the end when we run that cohort.

Brian Weinstein Okay, great. And then, as a follow-up, we've been monitoring the job posting sites and you guys are clearly building an organisation in advance of the launch of that product as an LVT next year. Can you just give us any idea about the type of salesforce that you're looking to have here, be it size, be it qualifications, where you're going to be getting people from? Any kind of information on that, I think, would be helpful. Thank you.

AmirAli Talasaz Yes, absolutely. We're very excited about 2022. It's going to be a year for us where we're going to go after a bunch of market-shaping activities. Really our goal is to do the right investment. That once we have FDA approval in 2023, we can maximise the market adoption at that time. We are building a sales channel accordingly to meet the objectives that we have in this market shaping phase of our commercialised phase.

It ranges from engagement to a bunch of high-value stakeholders that can help set the right framework for blood-based screening to be used in a proper way in health systems. And also, a bunch of early adopters on the PCP side. Also, we are going to engage heavily with a bunch of health systems and try to get a bunch of engagements when we are on the post-LVT validation of our test, to really integrate the blood-based screening aspect into procedures, workflows and systems that these healthcare systems have.

That would be our activity in 2022 and we are currently appropriating investments as high-level commercial channel to really go after those opportunities for us.

Operator Thank you, Brian. Our next question is from Derik De Bruin from Bank of America. Derik, your line is now open.

Derik De Bruin Hi, good afternoon. The first question is on the OUS expansion, you're making some big pushes into Spain and the UK, and obviously there's the JV purchase. How should we think about, particularly in the Spain and UK situations, what were the volumes? What liquid biopsy [unclear] how do you think this changes the utilisation going forward? And when do you see the OUS revenues becoming material?

Helmy Eltoukhy Derik, thanks for the question. I think a lot of what you're saying is we're laying the groundwork for what we believe is part of the critical inflection point for OUS volume, which is specifically public reimbursement in each respective country. We believe that the approach that we're taking, where we partner with some of the leading institutions and part leaders is an approach that can accelerate that progress towards that goal.

And so, we are seeing a fantastic traction in the study that we're doing, with the [unclear] that we're doing in key academic centres in the EU5 and a lot of Latin America and certainly with our joint venture in Japan and many other countries in the region. But I think you're going to see more of that as we really turn our focus from being a largely US clinical volume driven company to one that really has a local leadership in this space.

Derik De Bruin Speaking of clinical volumes, can you discuss what the contribution was from Reveal this quarter?

Michael Bell Hi, it's Mike here. We're not breaking out the volumes between the different products now and as we get more products, there's going to be more impact from those newly launched products. We've been really pleased with Reveal from the start of the launch back in February, so it's going better than we expected. So, we're really pleased with that, but we're not breaking out those volumes at the moment.

Derik De Bruin Thank you.

Operator Thank you, Derik. Our next question is from Jack Meehan from Nephron. Jack, your line is now open.

Jack Meehan Thank you. Good afternoon. I wanted to dig in a little bit more on the recent data at ACG, just comparing that versus the dataset that was presented at ASCO, I think it was a similar group. The sensitivity improved from 91 to 95%. If you could just elaborate on what drove the performance improvement, was it just related to the incremental samples that were included? Have you made any performance improvements to the test? Again, just trying to think about how this translates to the perspective data?

AmirAli Talasaz That's actually the cohort that got presented, ACG, by our partners in Samsung Medical Centre. They expanded the cohort that some of the earlier data was submitted earlier in the year and was presented in ASCO. It's the single biggest cohort data, basically data held so far by one of our partners.

In terms of what are the factors that went into the performance improvements, I look at all these numbers, are basically in the same ballpark, from my perspective. Definitely the cohort size was expanded. One thing we have in our assay, although our assay's the same on the algorithm side, everything's based on training and learning. So, definitely over time when we generate more and more data, historical data, just the performance is going to improve over time. That's the nature of learning-based systems.

But all those kind of improvements would be really just marginal. So, I don't expect, given from now until at the time we run ECLIPSE you're going to see a significant jump in the performance. But over time, as more data gets generated and just sticking to our algorithms, might be the training is based on more samples' representation of all kinds of smaller cell population. In theory you can expect maybe performance gets slightly better, but very marginally, from my perspective.

Jack Meehan Got it. And as a follow-up, there were some headlines in the quarter around M&A. I was curious, if you could just weight in on your thoughts around continuing to forge ahead with the organic strategy versus maybe the benefits of doing something in terms of more of a big deal.

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Helmy Eltoukhy Thanks for the question. We have an extensive team we've built around the corporate development. We obviously have lot of cash in the bank and I think we'd like to use it for something that makes sense, potentially. As you mentioned, our bar is very high, we're very excited about the organic opportunities we have, about our pipeline, about the progress we're making.

We've launched a whole host of products over the last 12 months into the market and have obviously some pretty great products planned for the coming quarters and years. And so, the bar is understandably very high, but at the same time we're open to anything that can enhance our technology, our platform, enhance our commercial channel, enhance our data offering. And we're always going to be focused on those things that make sense for the long term, that continue to really bolster and enhance our growth process, and so not really going to compromise on that.

Operator Thank you, Jack. Our next question comes from Matt Sykes from Goldman Sachs. Matt, your line is now open.

Matt Sykes Thanks for taking my question to everybody. I just one question and follow-up, I'll do it all in one go. On opex, maybe for you, Mike, obviously a step up every year sequentially. And you guys talked about where some of that is going in terms of the commercial capabilities. I'm just wondering in terms of trends that you can call out, in terms of what we should expect as an elevated level of capex. I know, Mike, you said it will likely continue through this year, but as we entered into this year, was anything pulled forward or accelerated in that aspect?

And then, secondarily on that, can you talk about labour cost component as a portion of that opex increase, if that's material, if at all? Thanks.

Michael Bell I would say, first of all, Matt, nothing has really been brought forward. I think everything that we've done in our opex through the year has been well planned out. For the year we planned to increase the size of the commercial team on the oncology and we mentioned that that's now 250 people, so that's more than doubled in the last 12 months. And as we're coming towards the backend of the year and into next year, we start to build up our commercial team on the screening side, getting ready for the LVT launch.

So, commercially, that's been really the driver of our opex increase this year and it will be going into next year. On the research and development side, because that's also been a big driver of the increase on opex. Obviously we've got ongoing studies with ECLIPSE. We announced the ORACLE and SHIELD study that are commencing. That'll come in to factor next year. And then we continue to innovate and develop new products. Again, we've launched three new products this year, so we're continuing on that spend, so we expect research and development spend also just to continue to drive those initiatives next year.

On the personnel piece, without breaking it out specifically on the percentage, yes, we've obviously seen that increase. Again, I mentioned that the additional people on the commercial, on both oncology and on screening. That's becoming a grower for us and we're investing in people and growing the studies with the organisation, we're also building out the infrastructure of the business as well. So yes, that's also a driving force for our opex increase.

Matt Sykes Great, thanks very much. I'll go back in the queue.

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Operator Thank you, Matt. Our next question comes from Patrick Donnelly from Citi. Patrick, your line is now open.

Patrick Donnelly Thank you. Helmi, maybe one for you, just on the volume side. It sounds like September and October recovered pretty nicely from August, I think you talk about 40% volume increase and 4Q. Can you just talk about the cadence as we went through the quarter, your confidence level. Things are stable to pointing up here as we enter into 22. Just trying to get comfortable with the volume piece, it sounds like you guys are a little more confident relative to last quarter, certainly.

Helmy Eltoukhy Thanks for the question. I think the good news was some of the early learning signs of the last call dissipated or destabilised. And it seems like there's been a sort of new normal out there, with Delta obviously still a concern, but not really causing any increased closures or increases of restricted access. It's still restricted, still not like it was pre COVID. But the good news, it's not getting worse and we just have seen great traction with our sales teams, with our products and so on. We are hopeful this means momentum going into 2022.

Patrick Donnelly Okay, that's helpful. And then on SHIELD, might be one for Mike, I apologise if I missed it. But you guys break out into what you think the study will cost. I know you talked about 10,000 patients, maybe three years' enrolment. But if you could just talk about the cost side, it would be helpful. Thank you.

Michael Bell No, we don't break out the cost of individual studies. But obviously this is a multi-year study, large number patients. And so, it'll be a sizeable amount spread over the next few years and a similar level to ECLIPSE. But we're not breaking out each individual study and giving those costs.

Patrick Donnelly Understood. Thanks, guys.

Operator Thank you, Patrick. Our next question is from Julia Qin from JP Morgan. Julia, your line is now open.

Julia Qin Hi, good afternoon. Just a follow-up on Reveal. I know you're not ready to quantify the volume contribution in a quarter, but just qualitatively, is Reveal uptake so far mainly within biopharma users or are you seeing equal traction for clinical customers? And are you still expecting LCD coverage by yearend?

Helmy Eltoukhy Yes, on the last piece, that's still our expectation pertaining to reimbursement. I would say for volume, we're seeing good traction on both sides. We're seeing clinical volumes really grow nicely and the same on the biopharma side. We're seeing really the platform and the tests resonate with a lot of our pharma customers. And obviously as we continue to grow our user base and customer base on the biopharma side, we see ample opportunity to head for good traction for all of our products, including Reveal.

Julia Qin Got it. And then, on an M&A front, just up towing on a previous question, you didn't really rule out the potential to grow your sales channel inorganically. But just thinking about your priorities, how important is it for you guys to acquire a channel in the community oncology setting at this point in time versus building it out organically during this time period, where you're waiting for guidelines and reimbursement to fall in place?

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Helmy Eltoukhy We broke out our growth in the community setting in the [unclear] and we're growing faster in the community than we are in academic, that's really the area of most success for us. It's something we're very, very confident about. You can see the great performance we had in Q3 and heading into Q4 we believe on the clinical side. We're very confident about that.

I think in the previous question, when we think about different M&A opportunities, potentially, it's not about a short term or what's happening in the business now, but what it means for the business three to five years from now. But right now we're very confident with both the mix of products we have, our offering, and the success we're having in our commercial channel.

Operator Thank you, Julia. Our next question comes from Tejas Savant from Morgan Stanley. Tejas, your line is now open.

Tejas Savant Hey guys, this is Edmund on for Tejas, thank you for taking my questions. A couple on biopharma volumes from me. Volume trends appear to be looking very strong, but I was wondering if you guys could benchmark what you're seeing in terms of sample volumes, relative to the pre-pandemic levels. And what is your backlog of work looking like heading into 2022?

Michael Bell It's Mike here. I think we're recovering now from the depths of the pandemic impact. And I think we're back to levels where we were before that. As we forecast going out towards the end of the year, I think we see that rebound getting stronger and stronger. That's very positive for us and I think we're back at the pre-pandemic levels.

Tejas Savant And in terms of backlog of work heading into next year, can you give some colour on what that looks like?

Michael Bell Backlog of work, we don't generally break out a dollar value of backlog of work, but I think on the biopharma side we definitely have backlog. And look at the pipeline and we look at going into 2022, so we look at that as being a continued strong volume coming out of Q4 into Q1. But specifically breaking out that and giving a number, we don't generally do that.

Tejas Savant That's helpful. And then a follow-up for you, Mike. On the mixed skew you saw in terms of volume, shifting away from the skew. I'm not sure if you explained this, but what drove that? It seems to be normalising, but just trying to understand what happened here and if it's going to be something we should be looking out for in the future?

Michael Bell Could you repeat the question from the start? I missed the first piece.

Tejas Savant Sorry about that. On the volume mix skewing away from OMNI in second quarter, that seemed to have normalised a bit this quarter, but I was just wondering what was the underlying driver for that?

Michael Bell That changes every quarter. If you look at our ASP on the biopharma side, it fluctuates quarter to quarter and just depends on what's been processed and what samples we receive for that quarter. We

had a shift this quarter versus last, more towards OMNI, but there's no definitive driver that's changed there. There's no real trend to look at. I think it just fluctuates on a quarterly basis.

Tejas Savant Got it. Thank you very much.

Operator Thank you, Tejas. Our next question comes from David Westenberg from Guggenheim Securities. David, your line is now open.

David Westenberg Hi, thank you for taking the question. I wanted to focus on the community oncologists, you highlighted the growth there. Are there any initiatives there that you want to highlight? And then, as we look to the next three to five years, what do you think the magnitude of growth is going to be in the community oncologists versus the academic setting? And that's all the questions I have.

Helmy Eltoukhy When you think about how the market is segmented, it's often thought to be about 80% in the community. Our mix is well over 60% community now, so there's more growth to be had there. So, it's certainly an area of focus for us. I think there are a number of reasons why we're doing well there. You just need a critical mass to be able to address the nature of the community setting.

We really expanded the commercial team over the last year and especially with the launch of Reveal. It's not just the commercial team, but it's also the medical affairs team that is very critical. And really having the [unclear] specialists and medical partners to be able to help with interpretation of results and feedback on test reports. And so that's something that we invested in very early on in the community [?] to invest in as well.

And then, finally, it's the service offering, really being able to provide customer service experience, a white glove service. That really makes our portfolio and our company an extension of offices that are out there, and that's something we're very committed to. And, as you can see, by the types of products we offer, the nature of the products we have, if they all start working together we believe we'll be more and more sticky in the community setting.

Especially where blood is really much, much simpler to be able to offer the best possible precision medicine and care without needing the logistical hassles that tissue represent in terms of working with a whole host of other medical professionals that may not be on site. And so, blood really does empower the community oncologists and help keep patients close to home, as they desire to do.

David Westenberg Thank you.

Operator Thank you, David. Our next question comes from Lu Li from Wells Fargo. Lu, your line is now open.

Lu Li Thank you for taking my questions. And I think just one question, can you please, if possible, frame the early impact of the Guardant response on volumes or sales. And then, what's your expectation for 2022?

Michael Bell Again, I think like for Reveal and TissueNext, all of the products that we've launched this year we're really pleased with how they've been received and how they've utilised. And so, again, the volume that we're

seeing we're very pleased with and it's in line with our expectations. We have this multi-product from a clinical side and we're not breaking out the volumes, but obviously the main growth driver for us continues to be the Guardant360 LDT and CDx. And from a revenue perspective, the vast majority of our revenue is coming from those two, so it will probably be those products.

Lu Li Got it. And maybe just a final question on how do you think about the market share at this point, any impact on competition from other players? Just wanted to get a sense about how you're thinking about the market dynamic. Thank you.

Helmy Eltoukhy That's a great question. In terms of all the markets we track, we believe we've never really been in a better position than we have now. We continue to make great progress, we think we have great performance from a shared voice perspective. And we continue to invest, not just in our products, but our commercial offering and commercial channel as well. We feel very good in all of the areas that we compete today and we're going to continue to invest more as we continue to have success.

Lu Li Thank you.

Operator Thank you, Lu. Our final question comes from Dan Arias from Stifel. Dan, your line is now open.

Dan Arias Hi, guys, this is Damian on for Dan Arias. First, just a clarification for AmirAli, I think I heard the ECLIPSE readout is expected in the first half of the year, I just wanted to make sure I heard that right. And then if so, I'm just curious if there's a possibility they'll bring it out sooner? And then for Mike, on ASPs, the blended average is lower with new products, but is your expectation that the issue with the private payers and that new ADLT code is largely worked through? I know you mentioned, you said that your team's been working on that, so I'm just trying to get a feel for it. Maybe that's something that is less of an issue going forward. Thanks.

AmirAli Talasaz I'll start with the first question. We expect actually to reach our target enrolment for ECLIPSE in the very next few weeks. We're almost done, so very shortly we will make it to our target enrolment. In terms of the data readout, we expect it to be mid-2022, so middle of next year. And I give it to Mike.

Michael Bell On the ASPs, firstly, with LDT and CDx, we have very strong ASPs this quarter. I think it was guided to 2,600 and it was getting closer to 2,700. Basically made up the blended ASP was 26/89. And so, really strong. And to the ADLT issues, I would say they're pretty much pushed through now on the team, they've done a great job getting payers prepared for that code. There's been a lot less friction in the system than we thought that we would see.

I think as we go into the end of the year, and we fed that in the remarks earlier, as newer products start to gain traction, we'll see some impact on that overall blended ASP. What we see LDT and CDx rate above the 2,600 level, probably on a blended level we'll start to see that overall come down a little bit each quarter. And it'll take time to get the full reimbursement from MEDICA and private payers before we can start seeing the [unclear]. But I think the message is for CDx and LDT that those issues are pushed through and very strong ASPs.

Dan Arias Okay, appreciate it, guys. Thanks.

Operator Thank you, Dan. That concludes the Q&A session for today. Thank you for all joining today's call. You may now disconnect.