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Guardant Health

Fourth Quarter 2021 Earnings Call

February 23, 2022

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PRESENTATION

Operator

Hello and welcome to today's Guardant Health Q4 2021 Earnings Call. My name is Elliott and I'll be coordinating your call today.

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

I would now like to hand over to our host, Carrie Mendivil, Investor Relations. Please go ahead.

Carrie Mendivil

Thank you.

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

Joining me 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 within the meaning of federal securities laws. These statements involve material risks and uncertainties that could cause actual results or events to materially differ from those anticipated. Additional information regarding these risks and uncertainties appears in the section entitled Forward-Looking Statements in the press release Guardant issued today. For a more complete list and description, please see the Risk Factors section of the Company's Annual Report on Form 10-K for the year ended December 31, 2020, and in its other filings with the Securities and Exchange Commission.

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

Except as required by law, Guardant disclaims any intention or obligation to update or revise any financial projections or forward-looking statements, whether because of new information, future events or otherwise.

This conference call contains time-sensitive information and is accurate only as of the live broadcast, February 23, 2022.

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

Helmy Eltoukhy

Thanks, Carrie. Good afternoon, and thank you for joining our Fourth Quarter and Full Year 2021 Earnings call.

I'll start off today's call by highlighting our progress across oncology as we continue to build on our strong position as the liquid biopsy leader. I will then turn the call over to AmirAli for an update on our screening program. And finally, Mike will provide a more detailed look at our financials and our outlook for 2022.

Starting on Slide 3. Twenty twenty one was a significant year for Guardant. We launched a number of new products, surpassed 100 biopharma partners, reached target enrollment for our ECLIPSE study, started enrolling a second registrational grade study in lung cancer screening, continued to advance our technology platform, and significantly scaled our organization as we prepare for future growth.

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Our mission at Guardant is to conquer cancer with data and ultimately transform cancer care. The driving force of our work is our commitment to putting patients first. We are dedicated to bringing the absolute best products to market that will continue providing clinically actionable information to inform patient care.

Before I provide an update on our progress, I would like to start off with a patient story.

In 2017, a 60 year old man was diagnosed with Stage 2 rectal cancer. He quickly underwent surgery. But soon after surgery, his oncologist discovered the cancer had already spread to a lymph node. The patient immediately began chemotherapy. Fortunately, he responded well to treatment, was considered to be cancer-free and transitioned to long-term follow-up care. This past summer he was still feeling great and was due for a periodic check-up. His CT scan was normal, his CEA was within normal limits, so the oncologist scheduled follow-up tests including colonoscopy, CEA and CT scan to be performed six months later.

His oncologist also ordered a Guardant Reveal Test, which came back positive for residual disease. With these results, his oncologist immediately ordered a PET scan that detected a small lung nodule which had not been visible on the CT scan. After a biopsy, the nodule was confirmed as an isolated metastatic rectal cancer. The patient had a second surgery to remove the tumor and is recovering well.

This story highlights how Guardant Reveal can bring critical information to oncologists and patients catching cancer recurrence early in order to treat cancer before it continues to spread.

Now, turning to our performance on Slide 4.

We ended Q4 with another quarter of record revenue of $108 million, up 38% over the prior-year quarter. This brought total revenue for 2021 to $374 million, up 30% over 2020.

Moving on Slide 5.

During the year, we continued to build our commercial organization focused on oncology, now a team of more than 250 individuals that we believe is second to none. They delivered strong clinical test volume for the fourth quarter reaching 25,600 tests, an increase of 48% from the prior-year quarter.

Over the course of the year, despite continuing impacts from COVID, clinical volumes reached 87,600 tests, up 39% year-over-year. The products we have in the market today are in a league of their own in terms of performance, product market fit and customer experience.

Penetrating the large market for oncology tests takes more than just amazing technology. It takes clinical evidence, regulatory approvals, reimbursement and, above all, a very robust commercial channel. I continue to be proud of how well our commercial team is executing in this environment and achieving strong growth.

Notably, we are continuing to make inroads in community accounts where we are growing twice as fast as in academic centers. While we are continuing to grow in academic centers, our volume mix is becoming increasingly weighted towards a community setting where the majority of cancer patients reside. Approximately 70% of our volume in the quarter came from the community setting compared to 63% in the same period last year.

Today, roughly 50% of our team's interactions with oncologists are face-to-face, while the remaining half were virtual. We have equipped our team with the tools needed to continue to drive adoption of our products through both virtual and in person interactions. Across the board, we are seeing excellent traction with existing oncologists ordering more tests and new physician additions. More and more

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oncologists are seeing Guardant as a whole Precision Oncology platform. We have the largest share of voice in the market, nearly double the number of interactions with oncologists compared to our closest CGP competitor.

Looking more closely at recurrence monitoring, on Slide 6.

We are encouraged by the growing interest in the early success of Guardant Reveal and are continuing to invest heavily in the vast opportunity ahead while leveraging our existing channel of oncologists. At the end of January, we presented new data on Guardant Reveal at the ASCO Gastrointestinal Cancer Symposium that demonstrated high performance for recurrence detection in early stage colorectal cancer. An interim analysis from COSMOS, a large prospective observational study, showed that Guardant Reveal when used after curative, intense surgery for Stage 2/3 colorectal cancer can detect MRD prior to disease recurrence with a longitudinal sensitivity of 91% and an average lead time of greater than six months. The test integrates genomic and epigenomic signatures to detect disease without the need for tumor tissue. Tissue biopsies can be difficult to obtain, time consuming and lead to complications, all of which can delay a patient's treatment. Our blood-based tests can overcome these barriers and provide fast and actionable information to help guide treatment decisions across the continuum of care.

Turning to Slide 7. The opportunity for recurrence monitoring has grown from $15 billion to over $20 billion today due to increasing frequency of utilization of such tests in the surveillance setting as well as a more favorable reimbursement landscape. It should be noted that this $20 billion TAM is for blood-only approaches. Tissue dependent or informed approaches would potentially only access less than half of this opportunity given some of the logistical challenges of accessing tissue, especially in the surveillance setting many years out from the date of curative resection.

Turning to Slide 8. Outside of the United States, we are making great progress particularly in Japan. Our lab there is up and running and we expect to see regulatory approval for Guardant360 CDx in the near future. Following approval, we will turn our focus to securing public reimbursement by the end of 2022. Japan represents a very large market opportunity with about 400,000 late stage patients compared to 700,000 in the U.S., and similar reimbursement rates for CGP.

We are also investing in Europe and our partners are currently building two labs, one in Spain with Vall d'Hebron and another at the Royal Marsden in the U.K. We expect their services to become operational over the next 12 months. These labs 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 the U.K. We believe this strategy of building a global network of laboratories by partnering with key academic centers is the most effective way to unlock the international opportunity.

Moving on to biopharma on Slide 9. We saw a healthy rebound in our biopharma business with volume of 6,600 samples, up 36% from the third quarter, and up 36% year-over-year. We're also seeing growing interest with our biopharma partners for using Reveal in the adjuvant setting beyond just CRC indications including lung, bladder and breast. Our partners see 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 reached our 2021 target and ended the year with more than one hundred active biopharma partnerships. We have a healthy pipeline of discussions and the breadth of our product offering, strong customer service and our clinical market leadership makes us an attractive partner.

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We expect the number of customers to continue to grow. We recently signed two new CDx contracts with a number of others in discussion. While we continue to see strong 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 given the timing of project milestones.

We are continuing to demonstrate the clinical utility and real-world evidence of our products, recently presenting real-world clinical outcomes data from the GuardantINFORM platform in both breast and colorectal cancers. In December, at the 2021 San Antonio Breast Cancer Symposium, we presented new data from the PATA 1 (phon) study demonstrating the benefits of using Guardant360 Response for patients with advanced breast cancer to help switch therapy to a more effective option as soon as resistance to treatment emerged.

Excitingly, this approach doubled progression-free survival, demonstrating the clinical utility of therapeutic monitoring via liquid biopsy. Importantly, there was no need for a tissue biopsy, which can be difficult and time consuming, potentially delaying time to treatment.

Additionally, at ASCO GI, we presented new clinical utility data that demonstrated that the Guardant360 test detects microsatellite instability-high status in patients with advanced gastrointestinal cancers and a similar frequency to tissue-based testing. MSI-High is an important biomarker used to predict a response to immunotherapy.

Moving on to Slide 10. At Guardant, we have always moved at a rapid velocity motivated by the North Star of patient care. At the JP Morgan Conference in early January, I shared our vision for a smart liquid biopsy platform, which we believe will be a quantum leap forward for liquid biopsies. Our first product from this new platform will have capability that are profoundly more rich than our current oncology products. Drawing on close to 10 years of research and experience from hundreds of thousands of liquid biopsies, our smart liquid biopsy will allow for a genomic footprint nearly 100 times larger than Guardant360 CDx, provide even greater sensitivity and include comprehensive analysis of genomic, epigenomic and immune signatures, among many other capabilities.

We believe this new platform will advance liquid biopsies in the same way that smartphones upended first generation cellphones, by enabling a rich ecosystem of countless applications ranging from deep analysis of tumor genomics, interrogation of the tumor microenvironment, diverse immuno-oncology applications, much more sensitive therapeutic monitoring, identification of complex prognostic signatures, and many others.

We look forward to sharing more about this next chapter of our smart liquid biopsy platform at an Investor Day planned for the fall of this year.

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

AmirAli Talasaz

Thanks, Helmy.

Turning to Slide 11. We are continuing to make great progress across our screening program. At Guardant, we've always believed that a blood-based screening test during wellness checkups 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. For blood-based screening to stabilize, we must offer a test with high sensitivity in detecting cancers at early stages. In order to save lives at scale, patients need broad access to such tests, ensuring that access requires a reimbursement

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pathway and its strategy for inclusion into screening testing guidelines, alignment with value-based care and the objective of health systems, and finally, FDA approval.

For colorectal cancer, blood-based screening has an established Medicare NCD and FDA approval pathway, the utility of CRC screening is well established and guidelines recommend screening in the vast majority of individuals over the age of 45. The benefit of screening has been limited due to the lack of compliance despite many efforts. The ease of use of blood tests holds great potential for increasing compliance.

Turning to Slide 12. Almost two years ago, we started our pivotal registrational ECLIPSE study that we expect to read out in the middle of this year. Given that this is a registrational grade study, all data will be unblinded at the same time. Although we have experienced some slowdown in our internal productivity as well as clinical site activities during the last few weeks due to a resurgence of COVID. At this time, we do not expect a material impact to our study timeline. We also expect to submit our PMA package to FDA in the latter part of this year and expect to receive approval in 2023, pending successful review by the agency.

We are on track to launch the LDT version of this assay called Guardant Shield in the first half of this year and have already onboarded an approximately hundred member PCP commercial team. We are planning to gradually expand our commercial team to over 700 members by the time our test is included in USPSTF guidelines, which we expect in 2026. Our strategy this year is to engage in commercial development activities that will accelerate adoption of Guardant Shield post FDA approval. We have started to engage key stakeholders and target primary care physicians to increase awareness of blood-based CRC screening. We are pleased with the early feedback we are hearing and the high interest in a blood-based CRC screening.

It is increasingly clear that there's a significant unmet need for a high compliance modality for CRC screening with high sensitivity. We believe that a successful early clinical experience with Guardant Shield and confirmation of its potential impact in improving compliance rates will be instrumental to drive long-term adoption of the test.

Looking beyond CRC to our opportunity with multi-cancer screening on Slide 13, our focus is to develop a blood-based test to screen for multiple cancers where lives can be saved. In regard to CRC, lung cancer screening is known to save lives. Lung cancer is the leading cause of cancer related death in the United States. In terms of lung cancer, typically do not appear until the disease is already at an advanced stage. The evidence-based screening guidelines recommend annual lung cancer screening for high risk individuals, however the screening compliance studies demonstrate gross underutilization as only around 14% of people eligible for screening are up-to-date with screening recommendations. We believe this simple blood test has the ability to detect the majority of lung cancer cases in early stages when it can most easily be treated and can also improve compliance to screening.

Moving on to Slide 14. As we shared last year, to validate the performance of our assay in the lung cancer screening cohort, we have designed a new prospective registrational study called Shield Lung. Shield Lung is designed to provide regulatory grade evidence for the accuracy of our next-generation multi-cancer screening Guardant Shield assay in individuals between the ages of 50 to 80 who undergo standard of care screening for lung cancer using low dose CT scanning. All subjects enrolled in Shield Lung will be high risk for lung cancer. We are targeting enrollment of nearly 10,000 individuals.

We announced at the beginning of this year that we had already enrolled our first patient and expect to continue enrollment within 36 months. Through ECLIPSE, our team has developed core competencies running a large registrational screening study and I believe this expertise will prove invaluable for us. We

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are expecting to present the performance of this multi-cancer screening test in several cancer types throughout 2022.

Turning to Slide 15. 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. The successful readout of our ECLIPSE trial will open up a $20 billion screening opportunity in colorectal cancer by bringing high performance life-saving blood-based cancer screening tests to millions of people. Shield Lung, aligned with other future studies, will open up opportunities in lung and additional cancer types paving the path towards a total addressable screening market of more than 50 billion. I'm confident about our strategy in developing blood-based tests for the screening market. I believe we can be the first to have a blood-based cancer screening test with Medicare coverage and FDA approval.

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

Mike Bell

Thanks, AmirAli.

Turning to Slide 16. Starting with the fourth quarter of 2021, total revenue was $108.1 million, up 38% from $78.3 million in the prior-year quarter. Total Precision Oncology Testing revenue for the fourth quarter was $88.7 million, with growth of 37% compared to $64.7 million in the prior-year quarter. This increase was driven by strong growth in both clinical and biopharma sample volumes. Precision Oncology revenue from clinical tests was $64.2 million, up 40% from $45.9 million for the prior-year quarter. Fourth quarter clinical test volume was 25,600, which is an increase of 48% from the same period of the prior year.

The blended clinical ASP for the fourth quarter of 2021 was approximately $2,500, in line with our expectations. Guardant360 ASP was between $2,600 and $2,700, consistent with the last couple of quarters. Importantly, the Medicare ADLT reimbursement rate of $5,000 for Guardant360 CDx, which was initially set in April 2021, is being maintained at the same $5,000 rate for 2022 and 2023. As a result, we expect the ASP for Guardant360 to continue to be in the range of $2,600 to $2,700 during the quarter of 2022.

We are seeing solid traction for our new clinical products - Reveal, TissueNext and Response - and we expect volume from these products to continue to increase throughout the year. However, we don't expect these new products to start to significantly contribute to revenue until we receive Medicare and private payer reimbursement. Therefore, once we expect Guardant360 ASP to be stable in 2022, the blended clinical ASP will be impacted as reimbursement of new products will take time to ramp-up.

Precision Oncology revenue from biopharma tests in the fourth quarter totaled $24.5 million, up 30% from $18.8 million from the prior-year quarter. Biopharma volume was strong with fourth quarter samples totaling 6,600, up 36% from the prior-year quarter.

Biopharma sample ASP in the fourth quarter was approximately $3,700, down 4% from approximately $3,900 in the prior-year period, but in line with the third quarter of 2021 due to a similar product mix.

Development Services and Other revenue in the fourth quarter totalled $19.4 million, up 43% from the prior-year quarter. During the quarter, approximately half of the Development Services and Other revenue came from royalties related to the settlement and licensing agreement with Foundation Medicine that was finalized at the end of 2021. Specifically, this revenue represented royalties starting in May when the legal settlement was reached through to the end of December and was anticipated in the full year guided for

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2021 that we shared last year. For 2022, we expect to start to recognize royalty revenue on a quarterly basis and anticipate full year royalty revenue to be similar to the total we recognized in 2021.

As we communicated last quarter, while we continue to see strong demand for our Development Services, several companion diagnostic projects have recently been successfully completed, and as such, we expect that our Development Services and Other revenue will be lower throughout 2022 as new projects take time to ramp-up.

Gross profit for the fourth quarter of 2021 was $74.7 million compared to a gross profit of $49.9 million in the same period of the prior year. Gross margin in the fourth quarter was 69% which was positively impacted by the royalty revenue we booked in Q4, compared to 67% in the third quarter of 2021, and 64% in the prior-year quarter.

Operating expenses for the fourth quarter of 2021 were $172.9 million, an increase of 23% compared to $141.1 million in the fourth quarter of 2020.

Non-GAAP operating expenses exclude stock-based compensation and related employer payroll tax payments, acquisition-related expenses, amortization of intangible assets, and changes in fair value of contingent consideration. Non-GAAP operating expenses for the fourth quarter of 2021 were $146.2 million, a 73% increase from $84.7 million in the prior-year quarter.

Other net income and expense increased to $25.9 million for the fourth quarter of 2021, up from $1.2 million from the corresponding prior-year period, primarily due to the $25 million settlement from Foundation Medicine.

Net loss attributable to Guardant Health common stockholders was $90.9 million or $0.89 per share for the fourth quarter of 2021, compared to $93.7 million or $0.94 per share in the fourth quarter of 2020. Non-GAAP net loss was $70.4 million or $0.69 per share for the fourth quarter of 2021, compared to $36.7 million or $0.37 per share for the fourth quarter of 2020.

Adjusted EBITDA was a loss of $64.6 million in the fourth quarter of 2021, compared to a $29.7 million loss in the fourth quarter of 2020. We define Adjusted EBITDA as non-GAAP net loss attributable to Guardant Health adjusted for interest, income tax, depreciation, amortization and other income and expense.

Turning to the full year on Slide 17. Total revenue was $373.7 million, up 30% from $286.7 million in the prior year. Precision Oncology revenue increased 29% to $304.3 million, and was comprised of clinical testing revenue of $236.4 million, which grew 38% year-over-year and biopharma testing revenue of $67.9 million, which increased 5% year-over-year. Clinical test volumes for the year grew to 87,600, up 39% year-over-year from 63,200 tests.

Overall blended clinical ASP, including the impacts of cash true-ups for test performed in prior periods, was approximately $2,700 for 2021, which was consistent with the blended clinical ASP in 2020.

Biopharma testing volume increased 16% year-over-year to 18,600 tests. Biopharma sample ASP in the full year was approximately $3,650, down 9% from approximately $4,000 in the prior year, due to changes in product mix.

Development Services and Other revenue grew 38% to $69.3 million in 2021, reflecting the successful completion of two of our companion diagnostic partnership programs during the year, as well as royalty revenue from the licensing agreement we signed with Foundation Medicine.

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Gross margin for the full year 2021 was 67% compared to 68% in 2020.

Operating expenses for the full year 2021 were $661.7 million, an increase of 47%, compared to $449.1 million in 2020.

Non-GAAP operating expenses for the full year 2021 were $506.8 million, a 72% increase from $295.2 million in the prior-year quarter.

Twenty twenty one was a year of significant investment as we expanded our oncology commercial team and launched several new products during the year, and as we started to build out the infrastructure to support our future screening business. In 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 commercial launch of Guardant SHIELD LDT, completing the data readout from ECLIPSE, the PMA submission for our CRC device and the continued development of our multi-cancer screening test.

Net loss attributable to Guardant Health common stockholders was $405.7 million in 2021 compared to $253.8 million in 2020. Net loss per share attributable to Guardant Health common stockholders was $4 in 2021 as compared to $2.60 in 2020. Non-GAAP net loss was $251.7 million for 2021 as compared to $91.0 million for the corresponding prior-year period. Non-GAAP net loss per share was $2.48 for 2021 as compared to $0.93 for the corresponding prior-year period.

Adjusted EBITDA was a loss of $231.5 million in 2021 compared to an $84.4 million loss in 2020.

As a reminder, we previously shared our decision to exercise our call right to purchase the 50% of the Guardant Health EMEA joint venture shares that we do not currently own. We still expect to complete this transaction before the end of the second quarter of 2022.

We ended 2021 with $1.6 billion in cash, cash equivalents and marketable securities. We feel we have a strong cash balance that can support our ongoing operations for the foreseeable future and which gives us flexibility to continue to invest in our business to drive robust future growth.

Now turning to our revenue outlook for the full year 2022 on Slide 18. We expect revenue to be between $460 million and $470 million, representing growth of approximately 24% over 2021 at the midpoint. Included in this range are a few key assumptions. Firstly, we expect clinical oncology sample volume for 2022 to grow by more than 50% compared to 2021, and biopharma volume to grow by at least 30%. As a result, we expect Precision Oncology testing revenue to grow more than 35% over the prior year.

Secondly, as mentioned earlier, although we have a strong Development Services pipeline, these partnership projects will take time to ramp up. As such, we expect Development Services and Other revenue to be approximately $50 million for 2022.

Finally, while we are excited about the upcoming launch of Guardant SHIELD LDT, we are not expecting significant revenue contributions from it this year.

Moving on to Slide 19, we made great strides in 2021 as we continue to broaden our oncology product portfolio and expand our reach into the cancer screening market. We are aggressively pursuing the vast 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 the call up to questions.

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Operator

Thank you.

Our first question comes from Tycho Peterson from JPMorgan. Please go ahead.

Tycho Peterson

Thanks, guys. And maybe just first to clarify on the numbers, the ASP decline in the quarter was that just all a function of Reveal and Response kind of weighing down the average or was there something else there that you would point to?

Helmy Eltoukhy

Do you want to take that, Mike?

Mike Bell

Yes, I can take that, Eltoukhy. Yes, that's right. And it came down as we expected that G360 ASP was similar to previous quarters in this $2,600, $2,700 range. Yes, it's new products with lower reimbursement, just bringing down that overall blended. So that was expected. We probably expect that to continue through 2022.

Tycho Peterson

And the guidance at the high end, you're coming in a tad below the Street despite the Foundation royalties. Is that really just reflecting lingering COVID uncertainties? And anything you can say about clinical volume trends in the first quarter? And then also, is the U.K. lab contribution embedded in guidance?

Helmy Eltoukhy

Yes, no, I'll start, and maybe Mike can patch in. Yes, we feel very bullish about clinical volumes for 2022. We're projecting 50% growth year-over-year, which is, I think, very strong and excellent to see. That being said, we did see some impact from Omicron in the first part of first quarter, physician access was certainly limited. We're seeing that begin to resolve very nicely. And so we're hopeful that throughout the year that we will start seeing more positive trends in terms of really moving away from some of the negative impact of COVID. In terms of the U.K. lab, I think that's still in its early days.

So it's not a significant contributor to this year. I would say that we're projecting very strong growth in the Precision Oncology business, both in pharma volume samples and clinical samples. One of the challenges has been just the development services revenue. We're just in a low—really, we have large projects ramping down and new large projects ramping up and we're sort of in a trough in terms of—between those two stages.

I don't know if, Mike, there is anything else you want to add?

Tycho Peterson

Okay.

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Mike Bell

No, I don't think there is anything else for me, and I think you covered it all.

Helmy Eltoukhy

Okay.

Tycho Peterson

Okay. And then, Helmy, lastly, just on pipeline, on smart liquid biopsy, are you able to kind of fine-tune timelines there and talk about what needs to happen ahead of the launch? And then similarly, on Reveal, can you just talk about reimbursement updates there?

Helmy Eltoukhy

Yes. So smart liquid biopsy, as is typical, we will launch that to biopharma initially. And that will be later in the year, we hope to present a lot more details about how that platform at our Investor Day in the fall. And then shortly thereafter, we will launch it to the clinical markets. But we're very excited about that new platform, and we think that—and we're very excited to share details around that. With Reveal, there has been some back and forth and we have submitted more information and we are still waiting for final feedback from OBIA (phon).

Tycho Peterson

Okay, thank you.

Helmy Eltoukhy

Yes. Thank you, Tycho.

Operator

Our next question comes from Brian Weinstein from William Blair. Please go ahead.

Brian Weinstein

Hi, guys. Thanks for taking my questions. I guess starting out, you've talked about utilizing different types of technologies as you kind of build out your capabilities, especially around smart liquid biopsy, but I'm just curious about kind of more of a multimodal approach here. Can you talk about the importance of that and how you're positioning yourself to move kind of beyond genomics? You made that AI imaging, you were an investor in Lunit earlier. I'm just curious kind of you're thinking longer term about bringing in other kinds of technologies.

Helmy Eltoukhy

AmirAli, you want to take that?

AmirAli Talasaz

Yes, sure. So Brian, actually, we are very excited with the bunch of tech stack that we have at Guardant and some that we are working on that we haven’t talked about obviously yet. Yes, at Guardant, in

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general, we have this mentality that based on unmet clinical names figure out what are the technologies that you can use to really open up that unmet need in a very meaningful way and impactful way. That's why like, for instance, on our epigenomic front and on ventilation, we have a novel assay like many other players in the field who are just using off-the-shelf reagents and hoping for the best. We never had that mentality, and we built a novel ventilation assay. On fragmentation side, again, on epigenomic front, I think we are second to none in terms of our performance there and contributions there that hopefully, over time, we would talk about the detail of how that technology stack works.

Regarding radiology AI, definitely, that's something that we are working mainly with our partners. One of them is Lunit that we talked about it before. And hopefully, like in near future, maybe in the fall Analyst Day that we are going to have, we can go over into some of these details more.

Brian Weinstein

Great. And then on CRC, as that product gets launched. I'm just curious how you see that product over time playing out in terms of where volume comes from? Obviously, there is unscreened folks. There is colonoscopy, there's stool DNA and then there is FIT FOBT. I think you're kind of leaning on the on-screen side, but I'm just curious kind of what the plan is there to really target those patients, especially seeing that most of those don't really interact very much with the healthcare system potentially anyway. So how do you really go after the unscreened people? And where do you think your volumes will come from?

AmirAli Talasaz

I think initially that unscreened patient population and new to screening patient population, which what we mean by that the age of 45 to 49, to our total of about 40 million, 50 million of them that are in play, really the unmet need is really big. In fact, a good fraction of them are actually in touch with the health system when you just look at the people who say, yes, they want to get tested by stool-based kind of colorectal cancer screening devices and they never submit their samples or basically, it's really a lousy (phon) workflow just based on how much patients follow through is needed and really the patient preference of doing those kind of tests or not.

So a bunch of them are, in fact, really are connected with the health system, and we feel very good about it. And I think really as PCPs get experienced with our test and a close readout comp and they see really our superior performance that hopefully—we expect and hopefully ECLIPSE is going to have confirmation for it, I think based on patient preference, which is toward blood, a bunch of those testing has a potential to get covered as blood-based CRC screening. But we have to see, they have to see what the ECLIPSE readout would be and the initial experience of the doctors with our blood test how that would be.

Brian Weinstein

Okay, thank you so much.

Operator

We now turn to Tejas Savant from Morgan Stanley. Your line is open.

Tejas Savant

Hi, guys. Good evening. I'll start talk with one on MRD and then switch to biopharma. So help me, can you share any sort of quantitative color on adoption so far? And what exactly is embedded into your guide

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for Reveal and Response? Is it fair to assume it's contributing to volumes, but you're not expecting much in terms of contribution to your clinical revenue this year?

Helmy Eltoukhy

Yes. So we continue to be very pleased with the progress around Reveal. We see very robust adoption of that product, I think the patient story that we mentioned, I think, shows some of the really exciting applications of that technology and how it's having impact today. In terms of—I mean we're not—for competitive reasons, we're not necessarily breaking things out in terms of—into the individual products, we may in the future, but we're keeping that volume kind of aggregated at this point.

I would say that in terms of revenue contribution, certainly the core products. Guardant360 are contributing the bulk of our clinical volume. We do have a risk-based approach in terms of our guidance in terms of the likely kind of puts and takes in terms of reimbursement. Obviously, private payer reimbursement on the Reveal side will take much longer with Medicare being a near-term. Opportunity. We think with tissue, we think that's also a near-term opportunity. And Response, once again, I think, will be more similar to Reveal.

Tejas Savant

Got it. That's helpful. And one follow-up on pharma, are you seeing any impact from cancellations here in terms of your backlog? Or should we be expecting a more back-end loaded year in '22? And then on the Smart LB launch that you spoke about as being positioned for pharma customers, is it fair to expect that to essentially be a replacement for Omni on a go-forward basis at a similar price point or too early to tell?

Helmy Eltoukhy

Yes. So maybe I'll start with a smart liquid biopsy and maybe, Mike, you can speak to the first question. With smart liquid biopsy, we typically launch to biopharma initially, especially in the REVO (phon) setting. It allows us to fine-tune that test and really start, I think, important clinical collaborations around collecting data. So it's really no different than other products that we've launched in the past. We do see it as segmenting our customer base between smart liquid biopsy on the Guardant360 CDx.

And so we see it as another opportunity to really, I think, segment and provide a full gamut of tests for the entire spectrum of applications that biopharma will have. But certainly, smart liquid biopsy will be the future of Guardant360 at some point.

Mike Bell

Maybe to add on the biopharma volume. We had a very strong closeout of the year, and we've seen that sort of healthy rebound in the second half of 2021. And we see that definitely flowing into 2022. We've not really been impacted by any cancellations or any real impact on the business. It's always back-end loaded on the biopharma side. Q4 is always by far the strongest quarter. So although we are forecasting biopharma volume growth of greater than 30%, it will be back ended.

So I think we will see sequentially lower volumes in Q1, and then that starts to ramp up throughout 2022, again, to get to that 30% plus growth on volume.

Tejas Savant

Very helpful. Thanks for the time guys. I appreciate that.

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Helmy Eltoukhy

Thanks.

Operator

Our next question comes from Puneet Souda from SVB Leerink. Please go ahead.

Puneet Souda

Yes. Hi, thanks for taking the question. So first one on screening if I could ask? ECLIPSE, you mentioned is nearing enrollment completion of 13,000 with 12,750 enrolled already. Could you maybe just elaborate where colonoscopies stand? And do you feel still good about reaching the desired event rate for CRC that you want to have in this trial? Anything you can provide there, that would be helpful. And then a question that we get from investors is around advanced adenomas. How important are they in your view? And should we expect to see any data before the pivotal ECLIPSE readout?

AmirAli Talasaz

Sure. Thanks, Puneet, for asking the question. So in terms of the 12,750 actual enrollment, we reached that at the middle of December now. So ECLIPSE is active. The patients are going through their colonoscopy. Additional patients are getting in through the whole workflow of the journey in terms of biopsies and diagnostic tests where patients who have colonoscopy find something and then staging, which typically involves some additional imaging to really figure out the stage of the disease.

So, different patient population is in different phases of that journey. So far, we have over 10,000 colonoscopy reports. But even for the ones that we have colonoscopy reports, a bunch of them are going into the next phases of the diagnostic journey until we really get into the CRC identification and confirmation by the central pathology that we have.

So, that's why this thing takes a few more months and all-in, without going into a lot of details in terms of the timeline, still we are expecting that, hopefully, (inaudible) ECLIPSE read out sometime around middle of this year, and we are excited to see what's going to happen.

Regarding advanced adenoma, we talked about it earlier, too, and it's kind of interesting. When we look at the PCP market as of that, at least based on our findings so far and mainly coming from a 300 physician survey that we have done, the differentiation of advanced adenoma performance across different available tests out there are not there. Still PCPs cannot really distinguish different tests based on their performance and lot of focus has been around CRC sensitivity.

Having said that, in mid-term to long-term, I believe the advanced adenoma performance would get a lot of—we are going to see a lot of detailing and messaging and education in the field that over mid to long-term, this could be a competitive kind of a factor still. It's why we worked on the advanced adenoma development and data generation.

In terms of timeline to put the data out there, the data that we have with our partners and collaborators, they are going to get published and presented in conferences. Obviously. ECLIPSE readouts, which is basically, we have full control of disclosure of that data, the top line data whenever we have it, it's going to get disclosed very quickly without any bundling to conferences, obviously.

So, in terms of timeline, we have to see, which one is going to be ahead. But I think that main data is going to be presented as part of ECLIPSE readout.

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Puneet Souda

Got it. Super helpful. And then just a quick follow-up on MRD and Reveal and recurrence monitoring, help me, what sort of data readouts we should be looking out for in terms of maybe larger patient size or other prospective trials or more actionability around the Reveal? And when can we get an early glimpse of the smart liquid biopsy performance? Thank you.

Helmy Eltoukhy

Yes. No, great questions. Obviously, we presented some updated data, some new data at ASCO GI recently, and we are very excited by that. We presented some data on breast at JPMorgan, and we are hopeful that we can present kind of a fuller analysis of that in the interim. So, I would say that those two trials, I think will continue to have data readouts throughout the year and the interim. There are other studies we are working on besides ORACLE and COBRA and some of the larger studies that will likely read out over the next few quarters.

So, it's something where the engine is working, and we are hopeful that there will be a steady stream of data, not just across CRC, but other indications. I would imagine the smart liquid biopsy platform, probably the deepest and kind of most expensive maybe preview we would give of that, would probably be at our Investor Day in this fall.

Puneet Souda

Okay. All right. Fabulous guys. Thanks.

Helmy Eltoukhy

Yes. Thank you.

Operator

We now turn to Derik De Bruin from Bank of America. Your line is open.

Derik De Bruin

Hello. Good afternoon and thank you for taking my call. A couple of questions. I think the first one is on biopharma. Getting asked by investors about the competitive dynamic in that space, just because there is clearly a lot of companies that are going on there, trying to go into that market. Can you talk a little bit about how your partners are choosing Guardant? And are they running head-to-head trials with 360 and with Reveal and some of the other things like this? Just some of this like what—give us a flavor of some of the studies that are going on in the competitive dynamic in there would be really helpful.

Helmy Eltoukhy

Yes. No, that's a good question. I would say that for therapy selection market around 360 and OMNI, we are past that head-to-head phase. I mean that was a few years ago. And that's an area that we do extremely well. I think if we don't win, it's largely because maybe someone's broken the bank on their end in terms of cost or so on.

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So, we obviously want to keep our margins in line. We want to make sure that our costs and prices kind of remain stable. And so it's not something we typically compromise on. And so yes, we feel like we have had excellent win rates there. We are working with over 100 biopharma companies now and growing.

So, all the metrics we track are very positive. We don't see much churn on the biopharma side.

In terms of new products, we are often in that phase where pharma companies are doing head-to-head analyses. And we have also been very pleased with results of all the head-to-head studies that we have been a part of.

And so we very much see it as the early days of Guardant360 and OMNI. And we are seeing interest from some of the newer areas we are working on, smart liquid biopsy and other products. And so we see that not only are—not only is the demand for existing products continuing to grow, even something like Guardant360 CDx is growing very nicely, and we are seeing more demand as that's now an approved platform that sort of de-risked some of the analysis that can be done with that. But we are seeing really strong demand from new products that we are launching as well.

So, we are very pleased with the breadth of the portfolio and as it's getting broader, we are seeing—we are able to create a stronger engagement and frankly, stronger moat around our relationships with biopharma clients.

Derik De Bruin

Thanks for that. And just one other one. So just digging up some ancient history when we were doing the IPO in 2018, there was a lot of focus on lung during our discussions and then that shifted more to CRC for obvious reasons. I guess what's evolved and what's changed in the lung assay? (Inaudible) you have got a next-generation assay. But how has it sort of been enhanced? Is it with the new smart vertical? And also, there is another company out there that's looking in the liquid biopsy space on lung cancer. I mean at first glance, they look like they are using perhaps some similar technologies, but any sort of like compare and contrast on what's going on in the market and how that's evolved over time would be really helpful? Thank you.

Helmy Eltoukhy

AmirAli, (audio interference)

AmirAli Talasaz

Yes, so in terms of the lung versus CRC question, it's really around the screening. So, the exciting thing is I think since 2016 that we started publicly talking about our Lunit program, which is around our screening and MRD, we talked about multi-cancer kind of initiatives. And during those days, there were four cancers that I believe we started at the same time: colon cancer, lung cancer, breast cancer and ovarian cancer and a few other cancer types over the years got added in terms of understanding the biology and generating visibility data.

Now, why CRC became our lead anchor (phon) indication is really because of other factors, including regulatory pathway, now, in fact, reimbursement pathway. And looking at it this way that once we have this FDA-approved CMS and Medicare covered test really our test is indicated for a vast majority of people at the age of 45 years or above. And that's a very good actually anchor indication for us to really add other cancer types on top of that. So, that's why I think CRC has become our anchor indication. But as you have seen, like we are adding lung.

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And throughout 2022, you are going to see the data from a few other cancer types. So, I think already in some conferences, we have shown data in pancreatic, bladder, maybe a couple of other cancer types, but you are going to see more of those. So, it's been really a multi-cancer screening journey for us with CRC as our anchor lead indication.

Operator

We now turn to Max Masucci from Cowen and Company. Please go ahead.

Max Masucci

Thanks for taking the question. First on MRD, do you have a rough idea or expectation of what the split will be between MRD monitoring clinical volumes coming from the adjuvant setting versus test used for cancer recurrence monitoring in 2022? And then how quickly do you expect that volume mix to shift in favor of cancer recurrence? Is that a 2023 event?

Helmy Eltoukhy

You mean just to kind of break it out like first kind of test after in the adjuvant setting versus test for monitoring that are subsequent to that first test?

Max Masucci

Yes. Yes, exactly. So, just in 2022, what percentage of MRD monitoring volumes across all vendors will come from tests that are used on patients maybe in that six month adjuvant window versus those that are in remission and are using the test for cancer recurrence?

Helmy Eltoukhy

Yes. We are still in the early days. And obviously, our call points is mostly to the oncologist. And so given that we are still ramping up very strongly, we are getting a lot of those initial time points. And so we think that throughout '22 and certainly into '23, majority of the tests will continue to be that initial time point. But we are seeing the strong growth in that sort of recurring testing stream as well. So, we are monitoring both sides, seeing that mix, and it's something that I think we are very pleased with the progress.

I think over time, to your point, one of the advantages of a blood-only test is really being able to access that prevalent population. If you think about the 15 million cancer survivors there are, the majority of them, 90% are more than a year out from their curative resection with an adjuvant kind of period. And so we see that as we continue to build our position that there is an enormous opportunity we have before us even as we build out our primary care franchise, for instance, on the screening side, there is really a lot of synergistic interplay we can have in terms of accessing that prevalent population, even in the primary care setting.

So, we are very excited by kind of what the future holds for us.

Max Masucci

Makes sense. And you have built a 100-plus person primary care sales team. It would be great to hear what sort of initiatives and responsibilities the PCP sales reps have on their plate today? How much time and effort they are dedicating to the Guardant SHIELD LDT launch versus preparing for a broader rollout in 2023 after potential FDA approval?

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AmirAli Talasaz

Yes, sure. Actually, the team is now well on-boarded, well trained, a bunch of them got deployed to the field, setting the scheduling and (inaudible), maybe, in fact, started to happen, as I mentioned in the prepared remarks in terms of bringing awareness to blood-based cancer screening and getting the feedback from our targeted (inaudible), in terms of the way we are looking at the market. And I can tell you that we are very pleased with a bunch of these early feedback that we are getting from the market. In fact, many of them are waiting for Guardant SHIELD LDT to come live. Many of them already have patients in mind that if we were live, they want to start using the test.

So, very encouraging for us and it really confirms a bunch of assumptions that we had. The team is busy with tracking and getting this LDT launch as a very successful launch for us. And then they are going to actually expand their activities to support the IVD launch. But all the focus for us at this time would be a successful LDT launch in 2022—in the first half of 2022.

Operator

We now turn to Jack Meehan from Nephron Research. Please go ahead.

Jack Meehan

Thanks. I had a question for Mike. You talked about the investments going into the business. I was just hoping you could walk us maybe down the income statement, gross margin, R&D, sales and marketing, G&A, maybe just give some color on cost guidance for 2022.

Mike Bell

Yes, sure, Jack. On gross margins, we always talk about this 60% to 70% sort of target. Target that we have for 2021, we were very successful though we had gross margins for the full year at about 67%. I think we will expect to see some pressures on gross margins in 2022, mainly coming from the fact that we have got new products, the volume's starting to ramp up, but it's going to take time to get reimbursement. So, we probably expect the gross margins to be in the sort of the low-60s.

And then on the opex side, again, yes, we talked about the investments on the prepared remarks earlier. We increased our opex about 70%, and this is non-GAAP opex, about 70% in 2021. And most of that growth was coming from R&D and in sales and marketing we made heavy investments there. I think when we look at 2022, that growth level is going to be lower. It's probably going to be a growth of about 40%, and probably most of that growth will be on the commercial side. We hired roughly 100 people on the screening side of the business towards the end of last year.

So, all of those expenses are going to flow into 2022. So, I think most of that growth will be coming on the sales and marketing side. And then on the research and development side, we are still pushing on the product portfolio and generating data and for oncology products and on the screening side of the business, continuing to develop the multi-cancer screening device. So again, we expect the opex to grow about 40% in 2022.

Operator

We now turn to Matt Sykes from Goldman Sachs. Please go ahead.

Matt Sykes

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Hi. Thanks for squeezing me. I will just leave it to one question given the time. Just on the community oncology market, just given the importance to your clinical volumes, I think you mentioned that the commercial team is around 250. Just what are your plans in terms of growing that? Do you feel like you have got a good size right now to drive that volume growth? And then just on the 50% of interactions with oncologists that are in person, are there expectations that that increases, or have some of the digital engagements that your reps have been doing could offset that if that sort of 50% level stays the same throughout the course of the year?

Helmy Eltoukhy

Yes. Good questions. I think we are hopeful that essentially that the 250 reps we have, I think there is still some room to grow in terms of really getting up to speed in terms of some of the new hirings we have made. Obviously, the access hasn't been the best in terms of when those reps have come on. So, we see a lot of room to potentially grow as restrictions are lifted and access has opened up. We are hopeful that the—I know many of the pharma companies have sort of downsized some of their teams and are going to much more digital engagement, because this test—there is a lot more information behind it. There is a lot that we do to actually help support physicians, especially on the decision support side.

So, we really see that as an opportunity for very close engagement with physicians. That being said, we are increasing our investments on the digital side. I think there is a lot of opportunities there that have opened up, not just where the technology has gone, but I think—physicians, I think are much more adept and more open to some of those engagement channels now. So, that's definitely an area of opportunity for us and growth.

The second part of the question?

Matt Sykes

Yes. Thank you.

Helmy Eltoukhy

Welcome. Bye-bye.

Operator

We now turn to Dan Leonard from Wells Fargo. Please go ahead.

Dan Leonard

Hi. Thank you. I was just hoping you could elaborate on the SHIELD LDT launch. How are you framing success if you are not planning for material revenue in 2022? And could there be more of a revenue opportunity than you framed? Another blood screening test is on the market with some healthy sales expectations for 2022. So, perhaps you could compare and contrast your opportunity. Thank you.

AmirAli Talasaz

Yes, sure. So, our strategy for commercialization of SHIELD in general, LDT or down the road IVD, is to go through classical routes of engagement with payers and securing reimbursement pathways in order to make sure we can go for the long-term win here, which is unlocking this $20 billion TAM and tens of millions of people need to really get access through our screening tests. So as a result, like in the early

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days, obviously, since we don't have any coverage policies, any payments by payers, we expect very minimal kind of ASP, very, very low. And as a result, cannot contribute materially in a meaningful way to the top line of Guardant's revenue.

The first major reimbursement that we are expecting and planning now is hopefully post FDA approval, would be Medicare coverage and after that hopefully followed up by Medicare Advantage and a bunch of early payers would come on board following the Medicare decision. But that would be in the post FDA approval, which, at this time, we are expecting in 2023 if that review goes well.

So, that's the main reason that in 2022 at this time, we are not projecting any material revenue contribution because of very low ASP.

Operator

We now turn to Patrick Donnelly from Citi. Please go ahead.

Patrick Donnelly

Hi guys. Thanks for squeezing me on here. Helmy, maybe one for you, just on the international side, I know you guys have laid a lot of groundwork there in Europe, you have the Japan JV. How should we think about that kind of building in '22, whether it's a catalyst set or maybe even some volume build? What should we be keeping an eye on in the international side as you guys continue to expand there?

Helmy Eltoukhy

Yes. No, great question. We are very excited about the progress we have made over the last couple of years. In Japan, I think we are nearing an important catalyst, which is regulatory approval of Guardant360. We are hopeful that will come in the coming months. And as we mentioned, it's a very large market opportunity with 400,000 late-stage patients, reimbursement rates that are similar to reimbursement rates in the U.S. around comprehensive genomic profiling.

So, we are building up that team and we are gearing up for, I think, a very nice launch of that product. Given ramp times, it's unlikely to be significant in '22, but I think it could be something very nice in '23 in terms of its contribution.

In terms of Europe, we are also laying the groundwork there with two labs that should be up and running in the next 12 months or so in the U.K. and Spain. And we are very hopeful that in those partnerships, we can work together with those KOLs and academic centers to really secure public reimbursement once those labs are up and running. That will be a longer term event horizon, but it's something that I think is a very nice setup for us to really do international the right way and hopefully in a way that really unlocks a significant revenue opportunity.

Operator

For our final question, we turn to Kyle Mikson from Canaccord Genuity. Please go ahead.

Kyle Mikson

Hi. Thanks. So, I want to go back to SHIELD for lung though. So, let's say you launched SHIELD for lung like a few years, presumably after the CRC launch, maybe you have reimbursement approval for CRC at that point. How do you envision like the two cancer assays faring in the market where you already have

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maybe 10 cancer, 50 cancer tests already kind of relatively established? And I just wanted to ask, do you think there is disadvantages to being one of the first to market, and that can actually help your case?

AmirAli Talasaz

Yes. So, we have an LDT route and an IVD route, so Guardant SHIELD LDT and Guardant SHIELD IVD after FDA approval. And you can expect that LDT device would have faster cycle of upgrades innovation behind it. And the Guardant SHIELD IVD is going to have basically a longer time horizon for approval. For instance, in the case of lung, I expect we should be able to upgrade Guardant SHIELD LDT to include lung indication much, much faster than at the time that we have SHIELD LUNG readout for FDA submission and going through FDA review cycle to really upgrade that device that's going to take a few years for us. So, similar story can get applied to other cancer types. A panel of cancer attacks (phon) can get added to the LDT device much faster than getting IVD claim for those cancer types. I hope that answered your question.

Operator

We have come to the end of our Q&A. We would like to thank you for joining today's call and you may now disconnect your lines.

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