REFINITIV STREETEVENTS

EDITED TRANSCRIPT

DMTK.OQ - Q4 2021 DermTech Inc Earnings Call

EVENT DATE/TIME: MARCH 01, 2022 / 9:30PM GMT

REFINITIV

CORPORATE PARTICIPANTS

John D. Dobak *DermTech, Inc. - President, CEO & Director*

Kevin Sun *DermTech, Inc. - CFO, Treasurer & Secretary*

CONFERENCE CALL PARTICIPANTS

Alexander David Nowak *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

Griffin Rex Soriano *William Blair & Company L.L.C., Research Division - Research Analyst*

Kevin Michael DeGeeter *Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst*

Mason Owen Carrico *Stephens Inc., Research Division - Senior Research Associate*

Max Masucci *Cowen and Company, LLC, Research Division - Senior Analyst*

Thomas Flaten *Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst*

Caroline V. Corner *Westwicke Partners, LLC - MD*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the DermTech's Fourth Quarter and Full Year 2021 Earnings Conference Call. (Operator Instructions) As a reminder, this call maybe recorded.

I would now like to hand the conference over to your first speaker for today, that is Caroline Corner, Investor Relations. Please go ahead.

Caroline V. Corner - *Westwicke Partners, LLC - MD*

Thank you, operator. Welcome to DermTech's fourth quarter and full year 2021 earnings call. Joining me on today's call are Dr. John Dobak, President and Chief Executive Officer; and Kevin Sun, Chief Financial Officer.

This call will include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements made on this call that do not relate to matters of historical fact are considered forward-looking statements. Forward-looking statements made during this call, including projections of future performance, are based on management's expectations as of today, March 1, 2022, and are subject to various factors, assumptions, risks and uncertainties, which change over-time. Actual results could differ materially from those described in such statements.

Several factors that may contribute to or cause such differences are described in today's press release and DermTech's most recent filings with the SEC, including DermTech's quarterly report on Form 10-Q for the quarter ended September 30, 2021. In addition, you are encouraged to review the companies to be filed Annual Report on Form 10-K for the year ended December 31, 2021, for any revisions or updates to the information in this release. DermTech undertakes no obligation to update these statements except as required by applicable law. DermTech's press release with fourth quarter and full year 2021 results is available under the Investor Relations section of the DermTech website, www.dermtech.com and includes additional details about DermTech's financial results. Also available on the DermTech website are DermTech's latest SEC filings, which you are encouraged to review.

A recording of today's call will be available on the DermTech website by 5 p.m. Pacific Time today.

Now, I'd like to turn the call over to John.

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Thank you, Caroline, and thank you everyone for taking the time to join us today. In January of this year we had a national sales meeting. This was our first national meeting with the fully scaled and resourced commercial team, an important milestone for DermTech and one that I've been waiting on for almost 2 years now. We have the necessary capacity to drive adoption of our DermTech melanoma test or DMT. With this test, we want to change the status quo of our melanoma detection to our noninvasive genomics platform enabled by our Smart Sticker. The quality of the sales team members is impressive in terms of their commercial experience in dermatology and the numerous accolades they received as sales managers and leaders from their prior companies. But what was most impressive was their motivation and enthusiasm to lead our effort to fundamentally change the practice of dermatology and bring the genomic revolution to dermatologic care. As we will discuss shortly, we believe our investments in the commercial organization are already contributing to the growth and adoption of our melanoma test.

Turning to our 2021 performance. We finished the year with over 44,000 billable samples and $11 million in DMT assay revenue, which represents 86% sample volume growth and 160% assay revenue growth over 2020. For Q4 2021, compared to the same period of the prior year, we increased our unique quarterly ordering physicians from about 1,000 to approximately 1,800 providers. We are quite pleased with our 2021 performance despite experiencing 3 waves of the COVID pandemic. In addition, as I just noted, we implemented a large commercial scale-up that has significantly redrawn our territories and reporting structures, resulting in some near term disruption, but positioning us for the growth we see ahead.

We often field questions from the investment community about the overall speed of our revenue and test volume ramp up. In general, we believe we are making meaningful progress given the overall pandemic environment we have been operating in. However, another way to answer this question is to look at the historical performance of our peers. In about 2.5 years since launching DMT in earnest, we have reached the milestone of approximately 50,000 samples in a single year. And I will emphasize that in our effort to be thoughtful about scaling the organization during a pandemic with reduced physician access, our commercial team growth was slower than we anticipated 2 years ago. On average, it took many of the peers in our space approximately 5 years to achieve a similar level of adoption if they achieved that level of adoption at all, as measured by sample volume.

Another metric to look at is sales rep productivity. We had on average about 40 fully trained sales managers during 2021. These sales managers produced on average between 1,100 and 1,200 samples for the year. We estimate sales manager productivity for some of our peers during a similar period after product introduction was between 507 samples per year per rep. Now we recognize that we do have a larger market opportunity for our melanoma test and some of our peers have for their respective tests, but if we look at company with a company with an even larger market opportunity than us, for example, one in colon cancer screening, we estimate historical sales representative productivity was approximately 1000 samples per rep per year, at a similar stage of commercialization.

We are clearly seeing significant levels of adoption relative to our peers with the melanoma test, which is bringing transformational change to dermatology, a specialty that has not had much exposure to the genomic revolution, nor products that have dramatically changed their method or practice. Now where we are lower relative to our peers is our top line revenue growth, which is hindered by our lower average selling price or ASP, which was $252 for Q4 2021. As we have consistently discussed, we believe we will monetize this sample volume by growing our ASP and as this price approaches our Medicare reimbursement rate of $760, we will see top line revenue compound meaningfully. The main variables we look at to grow our ASP are increasing the Medicare and covered billable sample proportion; two, increasing our appeal success; and three, attaining additional payer coverage from third-party payers.

Medicare represents half of the total addressable market. So ideally, our proportion of Medicare samples should be 50%. While we have managed to steadily grow this proportion, we still have significant work to do here as our proportion for Q4 was 23%. We will continue to raise awareness of our product in the Medicare community through our digital marketing effort, and continue to educate our customers on the benefits of the product in the Medicare population. Clearly expanding our payer coverage will meaningfully improve our ASP. We currently have approximately 90 million covered lives. Given the fact that we lost approximately 1 year of payer activity due to the pandemic, our growth in covered lives since our Medicare coverage is on par with peer companies that introduced highly novel diagnostic tests.

As we've discussed, we have significant ongoing activity with regional national payers, and our team is hard at work educating them so they better realize the clinical value of our proposition, which should ultimately the coverage. We continue to provide peer reviewed publications that support

coverage of our DMT. In March, we expect the results of the Optum Healthcare economic study to be published. Also, the 2022 edition of the NCCN Guidelines reaffirms the 2A recommendation for the DMT. We also believe the 2022 document strengthens the overall recommendation by delineating our test as a standalone pre-biopsy assessment and removing some ambiguous preamble language that was present in the 2021 guidance document. We remain optimistic that we will achieve coverage in 2022 from at least one nationally recognized payer.

Looking now at recent trends and the patterns we saw in the fourth quarter, we like so many others continue to see pandemic related choppiness, which continued into November. However, December proved to be quite strong and we set new records for samples received and unique ordering clinicians despite a significant drop off in the last week of the year due to the holidays and Omicron surge. Like many companies, January 2022 remained challenging. However, our growth has recently rebounded and February broke the sample record, volume record that we set in December.

Part of our commercial expansion involved developing our peer-to-peer and medical science liaison educational efforts and we are seeing interest in this effort with well attended physician-led educational meetings, suggesting the medical community is learning to live with COVID. In March, we plan to attend the AAD Annual Meeting and will have a significant presence and marketing effort there including a prominently placed booth and marketing banners throughout the venue.

We continue to invest in our direct-to-consumer marketing to facilitate patient education and to raise product awareness and demand. We currently average about 25,000 searches on our Find a Specialist tool each month by people who are potentially interested in the DMT. In addition, we have made progress with Electronic Medical Record or EMR integrations through EMA, the most common EMR used by dermatologists and have onboarded nearly 300 locations. We have efforts to onboard approximately 200 additional locations, which should help with process efficiency. All of this gives us confidence that we expect to approximately double our billable sample volume in 2022 and more than double our DMT assay revenue.

We continue our expansion into primary care. We have built a small team of account managers to engage with primary care network administrators and executives. The Florida IDN rollout continues, but was slow due to Omicron. However, activity has recently picked up and we expect to complete the first phase of this rollout to approximately 300 clinicians in the near future. As discussed previously, our initial efforts in Florida are centered around quantifying certain metrics regarding deployment into primary care including such factors as the number of accounts a primary rep can handle, the number of sales calls needed to secure an order, conversion rates and utilization ramp expectations. The pilot we have ongoing in the Midwest continues, but also had some Omicron delays.

We have expanded our telehealth offering DermTech Connect, which is now available in Florida, New York, Illinois, Pennsylvania, Connecticut, Colorado, Missouri and West Virginia. There are also another 15 to 17 states in which DermTech Connect will be available in the coming months. As a reminder, the telemedicine platform is designed to match an interested patient with a participating independent dermatologist who can assess a suspicious lesion using the DermTech Connect Store and Forward telemedicine option. The dermatologist may have wanted also order our DMT as tests for the patient. We plan to gain synergies with our marketing efforts and Find a Specialist tool by providing the DermTech Connect option to people who visit our website that are interested in connecting with doctors who use the DMT.

We are pleased to report that Luminate development is now complete and the assay is currently being transferred into our commercial lab. The supply chain constraints related to sequencing flow cells we mentioned on the last call did spill into this Q1 a little bit and affected Luminate development slightly. We expect to begin introducing this product in the second quarter, and recently hired a Vice President of Consumer Products, Adelle Walker, with commercial experience from companies such as Allergan and SkinMedica to spearhead our efforts in the consumer based genomic health and wellness testing market. Given Adelle's background, we plan to commence the introduction of this product directly to the consumer with physician oversight, however, sometime in the future, we may look to deploy this test into physician office that have consumer product offerings as part of their practice. We are also exploring the development of additional consumer oriented health and wellness tests to offer through our consumer channel.

We continue to make progress on our Carcinome test. Though we have more work to do there, the performance of the assay continues to improve, but we have not yet achieved our desired performance metrics. We are still targeting validation of the assay by mid-year and will work to generate utility data in the second half of 2021 to support a Medicare submission.

We recently launched DermTech Stratum, to expand our presence in product offerings with the pharma and academic research community. DermTech Stratum includes additional services such as biomarker identification, new target identification, patient segmentation and stratification, and bioinformatics support. In the last couple of quarters, we are pleased to have seen an increase in engagement with pharma collaborators and have multiple contracts in various stages of negotiation and several new contracts completed. Current indicators suggest that clinical trial activity is resuming after the pandemic it was low and we expect this increased activity to drive more research business through Stratum.

In summary, we believe the table is set for a robust 2022 as it will be the first year of commercializing the DermTech melanoma test at an appropriate commercial scale. While the vast majority of our effort will be spent securing adoption in the professional dermatology channel, which should drive nearly all the performance for the year, we will continue our expansion into primary care, professional channel, the DermTech Luminate consumer channel, the DermTech Connect telehealth channel and our DermTech Stratum research channel. I look forward to answering your questions during the Q&A.

With that, I'm going to turn it over to Kevin to go over the financial results.

Kevin Sun - *DermTech, Inc. - CFO, Treasurer & Secretary*

Thanks, John. Assay revenue for Q4 2021 increased 90% to $3.0 million compared to $1.6 million for Q4 2020. Assay revenue for full year 2021 increased 160% to $11.0 million compared to $4.2 million for 2020. Total revenues for Q4 2021 increased 49% to $3.2 million compared to $2.1 million for Q4 2020. Total revenues for full year 2021 increased 101% to $11.8 million compared to $5.9 million for 2020. Q4 2021 ASP was $252 per sample, a 34% increase compared to $188 per sample in Q4 2020, and was flat sequentially. Our potential assay revenue that could be recognized from having broader payer coverage is still meaningfully higher than the actual reported revenue.

Billable samples for Q4 2021 were approximately 11,780 compared to approximately 8,300 for Q4 2020, or a 42% increase and was up slightly sequentially compared to Q3 2021. Billable samples for full year 2021 increased 86% to approximately 44,620 compared to approximately 24,000 for 2020. Medicare samples represented about 23% of our billable samples in Q4 2021, compared to approximately 19% in Q4 2020, and 22% in Q3 2021. With approximately 2,800 unique ordering clinicians during the last 12 months, we penetrated 56% of our initial target market of approximately 5,000 dermatology clinicians who account for a high concentration of the total annual surgical procedures to diagnose melanoma. This translates into a 29% penetration of our expanded initial target market of 9,000 to 10,000 dermatology clinicians and penetration of about 22% of the 13,000 total practicing dermatology clinicians.

We had approximately 1,800 unique ordering clinicians in Q4 2021 compared to approximately 1,040 in Q4 2020 or 73% increase when compared to approximately 1,590 in Q3 2021 or 13% sequential increase. Our average quarterly utilization or average number of tests ordered per unique ordering clinician was 6.5 billable samples in Q4 2021 compared to 7.4 in Q3, 2021, and 8.0 in Q4 2020. We continue to see new users typically ordering less per month when they first start using our melanoma test. Overall utilization did decline slightly as expected since we added more new accounts during the quarter. We still expect a higher number of overall ordering clinicians to contribute to higher billable sample volumes and offset the potentially lower utilization rate.

Contract revenue decreased 65% to $0.2 million for Q4 2021 compared to $0.6 million for Q4 2020. As of December 31, 2021, we had a maximum of $4.2 million in potential remaining contract revenue related to our current agreements. Gross margin for Q4 2021 was 4% compared to 19% for Q4 2020. The decrease in gross margin was largely driven by lower contract revenue during Q4 2021 compared to Q4 2020. Assay gross margin for Q4 2021 was negative 1% compared to negative 9% for Q4, 2020 and 3% for Q3 2021.

Sales and marketing expense increased 161% to $13.3 million for Q4 2021, compared to $5.1 million for Q4 2020, primarily due to additional headcount for the commercial teams and additional marketing investment, including digital media, direct-to-consumer advertising and professional promotion. We expect sales and marketing expense to continue to increase as we recognize the fully burdened cost of our expanded sales force for the full reporting periods and due to increases in our marketing initiatives to raise awareness of our technology.

Research and development expense increased 213% to $6.0 million for Q4 2021, compared to $1.9 million for Q4 2020. The increase was primarily due to higher compensation related costs, increased clinical trial costs, and additional lab supplies. We expect R&D expense to continue to increase as we ramp-up our pipeline development efforts.

General and administrative expense increased 152% to $7.2 million for Q4 2021 compared to $2.8 million for Q4 2020. The increase was primarily due to higher payroll related costs and higher stock-based compensation and higher audit and legal costs. We expect our general and administrative expense to continue to increase as we implement systems and infrastructure to support our direct-to-consumer efforts for our growth.

Net loss for the fourth quarter of 2021 was $26.1 million, which included $3.8 million of non-cash stock based compensation, offset by $0.3 million of benefits related to a non-cash change in fair value of the warrant liability, compared to a net loss of $10.7 million for the same period of 2020, which included $1.4 million of non-cash stock based compensation and $1.3 million of expense related to a non-cash change in fair value of the warrant liability.

At December 31, 2020, our cash, cash equivalents, restricted cash and marketable securities totaled $228.5 million. We are issuing full year 2020 assay revenue guidance to be between 22 and $26 million, which represents growth of 100% to 136% over 2021. In addition, given the softness in January due to Omicron with a nice recovery in February, we estimate Q1 2022 assay revenue to be between 3.4 and $3.8 million, which represents growth of 55% to 74% over Q1 2021. We are very happy with the strong growth of all our key metrics during 2021, especially given the challenging pandemic environment. We are keenly focused on executing on our growth drivers during 2022.

Now I'll turn the call back to the operator for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Brian Weinstein from William Blair.

Griffin Rex Soriano - *William Blair & Company L.L.C., Research Division - Research Analyst*

This is Griffin on for Brian, thanks for the questions. I'll just start on the full year guide. Can you just talk a little bit more about the assumptions there in terms of where you think ramp access is for the full year utilization and in particular ASPs?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

So we're comfortable with that guidance we gave. Again, when you look at periods when the virus has settled down, we see the growth that we expect. Some of this came from some numbers we saw back in actually the June-July time period where reps were doing 6 samples per day per rep. And if you amortize those numbers out over a larger sales team that we just put in place the 72 reps, you can see how we're comfortable with the guidance that we can double our sample volume revenue.

What we saw in February is very encouraging and it suggests that that is achievable and so we're comfortable with that. ASP is very hard to model out. I'll let Kevin comment on that. And rep access I think is improving and I think again, just points given what we saw in January when Omicron was raging, and what we see now in February, I think that just shows that when the environment normalizes, and the frequency of visits that we can attain to with physicians goes up, we see the kind of demand and adoption of the product and sample growth that we want.

Kevin Sun - *DermTech, Inc. - CFO, Treasurer & Secretary*

Yes. As we mentioned on the call, so increasing our ASP, we've got 3 main variables; increasing the Medicare and covered billable sample proportion. So being that Medicare was 23% in Q4, we've got opportunity to improve our ASP by getting more Medicare patients as we raised the awareness in that population. And then also the covered contracts we have in California, Texas, Illinois, and others. We also plan to increase our appeal success, and then additional coverage.

So we model moderate growth over the year, because we can't predict when a payer will come on-board. But as we can pull these levers with proportion and appeal success that we can drive activity in, we model some steady growth throughout the year. And then that's how we say that the revenue guide is essentially at least doubling from 2021 with the upside based on our top-end of the range of our guidance.

Griffin Rex Soriano - *William Blair & Company L.L.C., Research Division - Research Analyst*

Okay. And then just can you give us your updated thoughts on primary care and telemedicine, the sort of market expansive initiatives you're working on? Do you feel more or less confident about those with some of the pilots that have been going on?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Sure. So right now we see the best opportunity in primary care with these primary care networks or integrated delivery networks. They kind of exist to avoid referrals outside the network to specialists because it cost them money to do that basically, and so they want to retain the patients within their networks. Our melanoma test allows them to avoid referrals to dermatologists for melanoma, suspicious lesions, most of them which are likely to be negative and so the referral never needed to occur in the first place. It's a top-down sell. So we started out at the executive level. And then we have to sort of get a license to hunt, if you will, to offer the test to the physicians within that network. We have just built up that team. We have a nice pipeline of opportunities that we're exploring there and they are moving forward.

In terms of how we want to approach it, we want to understand how we need to deploy sales reps against a primary care network, so that we can get the right pull through of the product and that's what we're trying to learn through the effort we have going on in Florida and we just haven't gotten complete the rollout completed there because of the various pandemic waves that have occurred. But again, as Omicron has waned, we're back now training those doctors up and then we'll understand those metrics and that will inform us as we bring new ideas on how we need to deploy against those types of accounts.

Kevin Sun - *DermTech, Inc. - CFO, Treasurer & Secretary*

Yes. Regarding telemedicine, we plan to have close to half the country available with DermTech Connect here in the coming months, as we just mentioned. And so again, we've always viewed that telemedicine is a great kind of alternative for certain people, which obviously was highlighted during the heights of the pandemic, but telemedicine for diagnostic, especially for melanoma, it's a new market, and it will take some effort to kind of fully build that out.

But we see that still as a good opportunity in the future and which is why we're investing into it in current day. But like John also mentioned on the call, we expect that probably 90% or so or more of our effort -- our actual commercial effort for 2022 will come from the professional dermatology channel.

Griffin Rex Soriano - *William Blair & Company L.L.C., Research Division - Research Analyst*

Okay, and if I can get just one more on the contract. There's a maximum of $4.2 million there exiting the year. Any sense of how we should be thinking about that, the case of that rolling off and maybe what you're expecting in 2022 there?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Yes, it's hard to predict because a lot of that it's really back-loaded in the trial. So the biggest portion of the contract revenue we receive is the extraction work once the trials have been fully enrolled and samples have been taken. So because of the pandemic delays, again this is where a lot of the pharma trials were just delayed for a while. We are seeing that activity pick up now, but it is hard to predict of when they will fulfill their enrollments and when we will actually get those samples in. We hope to have some better insight here in the coming months as it looks like this pandemic wave is waning and seeing what activity these pharma companies can do. But as of right now, it's very hard to predict what it looks like throughout the rest of this year.

Operator

Our next question comes from the line of Max Masucci from Cowen & Co.

Max Masucci - *Cowen and Company, LLC, Research Division - Senior Analyst*

I just want to start, just curious if you're seeing any gross margin pressure due to rising input costs, inflation, supply chain disruptions. I'd love to get your latest view on supply chain. And if there's anything you can offer on the cadence of gross margins during the year, that'd be great?

Kevin Sun - *DermTech, Inc. - CFO, Treasurer & Secretary*

Yes. We haven't seen a lot of supply chain issues or cost issues yet. So as the waves of the pandemic go down, the requirements on PCR supplies also go down and so we haven't had challenges running our melanoma test. We have seen just I'd say from inflation in general, is wages where San Diego is a competitive market and we have adjusted wages in certain laboratory areas that are in COGS to be competitive with the market.

And then equipment, I'd say longer term equipment around additional capacity or some of the new technologies and things like that, that's where we haven't seen issues yet, but we have to be very good at planning on when we need to place those orders so that we can get there appropriately timed. So quick answer is, we haven't seen a lot of impact yet other than maybe some wages here just locally, given how hot the laboratory and scientific markets are here in San Diego, but we are monitoring it very closely.

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

It's also fair to say in anticipation of what was potential disruptions, particularly when the pandemic was at its peak, we've always kind of built-up supplies and even headcount to make sure if people -- if we had an outbreak of the of the pandemic. So we've run a little bit rich in general into COGS, because we just didn't want to get caught short when everything was turbulent during the pandemic, so that's another factor that we're trying to get that more in line with the growth we're seeing.

Max Masucci - *Cowen and Company, LLC, Research Division - Senior Analyst*

Yes, it makes sense. And then just curious if you've made any more incremental adds to the sales force or the numbers have held steady since the Q3 call. And then in terms of the COVID impact that you're seeing today, is that more in your customer bay terms of access or within your sales force?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

We're at about 70 reps. I mean, I think we've had very minimal turnover and we plan to kind of maintain our sales force at that 72 number throughout the year right now. We may add some reps in the primary care setting as we learn to understand what those metrics are, but we're still in the process of planning there.

And I'm sorry, the other question was in terms of…

Max Masucci - *Cowen and Company, LLC, Research Division - Senior Analyst*

(inaudible)

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

I mean look the funny thing about Omicron is the doctors were getting sick. That's what we noticed, which was kind of different than the other waves. And not only access would go down, but we had some challenges with doctors going out for a week or 2 because they were picking up the virus. It's hard to say all those things. All I know is that as the numbers came down on Omicron and the people started to kind of relaxing, and going back to their daily lives, our volume picked up substantially.

I think we saw in terms of our average daily sample numbers, about 20% to 25% increase over what we saw from our prior peak in that December time-frame. So we saw a robust rebound. We're optimistic it will continue. We're just hoping that the virus is in the endemic phase, so we don't go through any of these things or we hope that just people are learning to live with it. But whatever the issues are, it's clear the correlations between our success with adoption and the rise in the ebb and flow of the pandemic, just it's a one to one correlation, you just see it. And with smooth sailing, I think we can see the kind of adoption we want to see with the product.

Max Masucci - *Cowen and Company, LLC, Research Division - Senior Analyst*

Got it. Just one final one for Kevin. Just in terms of the guidance, I understand that the timing of new reimbursement wins is very challenging to predict, but if you look at the size and types of payers that you are engaged with right now, do you see ASPs trending more gradually throughout 2022 or should we expect more of a call it a step function in the back half?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Yes. We model a more gradual kind of increase throughout the year, just because it is really so hard to predict. So we take it that if we get any of these payer wins it's really upside to us, but yes, that's how we model is more of a gradual ASP ramp.

Operator

Your next question comes from the line of Kevin DeGeeter from Oppenheimer.

Kevin Michael DeGeeter - *Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst*

I guess ours -- first on reimbursement, I appreciate you calling out the expectation for signing up one national payer. Are there any particular milestones that you think were sort of potentially drive some of those discussions potentially to fruition? Specifically, you called out publication in March and some other features, but I'm just trying to better sort of appreciate that confidence?

And maybe can you even talk about kind of how you're thinking about potential reimbursement wins kind of beyond national payers, where that's a total covered lives metric or some other feature? But I think we're just trying to better understand sort of what you're understanding of the payer landscape is that's baked into your guidance.

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Well, we just we -- in the past you heard well we want to see the trust study, we want to see the Optum economic study and those are now out in the public domain and so the payers that ask for that data and that information, we're obviously going to circle back with them. And now that we have those, I mean that gives us some confidence that they're going to take the look at the test the way they promised us to, based on that data that was set to be published and needed to be published. There was also some discussion about the NCCN wasn't totally clear. There was this preamble language and we went to the NCCN, we ask them to clean it up and they did. So obviously circle back with them.

So we're trying to address the things that the payers have sort of spoken to us about, about what they want to see. We believe we have addressed them and that's why we believe we're making progress with the payers. As we talked about in the past it's hard to predict. We know that we've gotten some medical directors on board with the test. They've recommended the test to their policy panel, but the policy panel that we have no input into, that has come back with an additional question or 2. So we think we're doing what we need to do to educate the payers. We're providing the information they're asking for and that's the best we can do in terms of trying to drive a potential coverage policy and that's why we think it's a question of when not if to get these payers on board.

In terms of regional payers, we've built out a team. We've got regional activity in all quadrants of the US now and it's the same thing there. It's a new product. Payers aren't good with new technology. It totally changes, transforms particularly a pathway in medicine and have to get their head around it and we're in that same stages with a lot of regional payers where they're trying to understand that value proposition. Again, we think, we'll have some success there just like we talked about last call when we brought on a regional payer within 2 million lives in the Midwest. So lot of activity. We believe that activity is going to bear fruit. We can't predict exactly when, but we like what we're seeing and we think it's positive activity.

Kevin Michael DeGeeter - *Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst*

Great. Now that's super helpful. And then maybe just like others sort of passing part, the guide here if we back out Q1 revenue guide on assay that kind of implies $21 million or so for the last 3 quarters of 2022, if my math is more or less correct. Either should we think of this as more similar to kind of a step-up with 3 quarters, give or take around kind of that $7 million, kind of figure or a kind of pretty steady build for the year, exiting $8 million, $9 million kind of range (inaudible) for quarterly guidance because all the annual guidance implies pretty significant step-up after Q1, so I just want to appreciate cadence.

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Yes. We estimate that it will be kind of each quarter will be better than the next, right? Because with the sales force that we hired, I mean Q1 is really the first quarter that they were fully trained into the field and contributing, and so that's how we build the model of that as more time goes on and as those new reps can get fully up to speed, they'll contribute more over-time. So that's how we model out, is that every quarter is better than the last.

Operator

Our next question comes from the line of Alex Nowak from Craig-Hallum Capital.

Alexander David Nowak - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

Great, good afternoon, everyone. Staying on that last point there, I was hoping you could expand on how that bigger sales force is helping out there in the field so far, is productivity ramping similar to how you expected or the team is finding that now that the territories are a bit smaller that they have a bit more capability take on more? And then any initial jostling of the territories that's being included in that Q1 guide?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Well, I think it's early for us to know exactly what the appropriate ramp up is. As we've talked about many a times, we're trying to map that out, but we've always had sort of slowdowns when the virus occurs. We don't have a good number, but, again we saw a very robust February. I would say areas where we had a footprint already maybe a territory that was too large because of the smaller size sales team before that we now split and added a new rep and now the frequency of calls has gone up to where they should be, that's where we're seeing that impact currently of the new sales reps and places where there's virgin territory that's where we're trying to map out, what should that growth rate like look like when it's completely new territory.

But hopefully in the next couple of quarters assuming we don't have another setback with the macro environment and the virus, we'll be able to understand what is the typical ramp-up for rep both in a virgin territory and someone who's now in a more right-sized territory with the adequate frequency of calls. But again, February is telling us the things we're doing, the things we put in place, the training, the peer-to-peer education, all those things are working and we just need to keep executing according to that plan and keep our fingers crossed that the environment stays normal, more normalized than it's been in the past.

Alexander David Nowak - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

It's a bit hard to look at utilization, just given you're adding a lot more physicians in the mix. But if you look at those physicians that have used the test for I would say year, year and a half or so or longer, are you seeing that the same store sales is already starting on the increase from here?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

We definitely know that time and consistency of sales calls leads to higher utilization with our customers, in general. As we've talked about before there's often a catalyst where the test finds something that a physician didn't expect, and that often has another catalyst to drive more utilization and we see our consistent users have had the consistency of sales calls, their utilization grows fairly steadily over-time with some step changes when we have one of those moments. So that's really what we're looking for.

The game is about frequency of calls, that's why we wanted to scale the sales team so that we can get the right sized territories, we can get the right frequency of calls. The early data from territories that were split where we had some presence and now we see a higher frequency, we're seeing that frequency of call and regularity of visits improve the pull through. So those are the things we're looking at and I think it's pretty clear that it's all about regular customer engagement to drive that utilization.

Alexander David Nowak - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

Okay understood. And then per person, can you expand on what you're doing there to improve the assays performance? Is this, you're starting to look at additional genetic targets or is this just basically refinement of the current test?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

It's a little bit of both, refinement of the tests. A lot of the performance we have now has been done with sequencing and sequencing doesn't quite have the fidelity and the dynamic range of like PCRs, so we're migrating some of these targets into the PCR platform to get better differentiation so that's process going on. It's a complicated disease as we've talked about, it's a complicated test because we're talking about 2 cancers that we need to differentiate from a whole host of other things, a list of 9 or 10 others that are confused with those cancers and so it's a challenging assay to develop.

But we are making steady progress, and we're confident we're going to solve the problem and the challenge is there. It's a matter of adding more genes in and improving the algorithms through additional samples and training those algorithms with additional numbers of samples that go in to make it better and more effective at the discrimination.

Operator

(Operator Instructions) Your next question comes from the line of Thomas Flaten from Lake Street Capital.

Thomas Flaten - *Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst*

Hey guys. I appreciate you taking the questions. First one, Kevin for you on gross margin. Could you give us some sense of the level of volume that we need to see to see some real positive movement in gross margins, where you can kind of get to closer to that ideal diagnostic margin? Are we talking 100,000, 300,000, I'm just trying to wrap my head around what that looks like?

Kevin Sun - *DermTech, Inc. - CFO, Treasurer & Secretary*

Yes, it's more complicated than just volume because ASP has such a tremendous impact on it. Even if you look at our current results for Q4, if our ASP was in the 500 to 600 range, I mean, we would already be close to like a 50% margin or better. So it really is a combination of both of those, which again, because of the challenges with predicting when payers come onboard, it's hard to model out the ASP. But that's how we think about it is that our COGS for Q4 and for the full year for that matter for 2021, about I think 42% or so of the COGS were fixed for the full year and that represents capacity of about 125,000 to 150,000 tests, given kind of the current footprint and the current equipment and so, where our year was at 44,620 samples. We're not even utilizing a half, or even a third of the capacity.

So that's where the fixed cost can be leveraged up pretty well with just adding some management staff versus more space and more equipment. Where things again, get a little bit more complicated is as we're building the new laboratory which will look to enter into by probably Q3, Q4 of this year, we will greatly expand our capacity, not just for the improvements within the expected volume increases for the melanoma test, but for these other tests that are coming to market. So we're going through that work right now to see how can we minimize any potential overcapacity in the new laboratory, but that's why it's a little challenging to say at what volume is it because it's really a combination both volume and ASP.

Thomas Flaten - *Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst*

And then just one other question on the guide. The volume that you're expecting this year, is that virtually entirely from traditional dermatology or are you anticipating any contribution from primary care market, telemedicine, et cetera. Just, I'm trying to get a sense of how much they might be contributing this year?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Yes. I mean, we've focused a big part of our efforts as we mentioned, right on the professional dermatology channel for the melanoma test. So that's why we say, all of these efforts that we're doing within primary care, within telemedicine, within these new products, we think that they provide either a backstop or upside to it. So the newer products, Luminate, Carcinome again, those are ones where we don't have a whole lot baked in, even if it's upside, because again, they are new and we've got to either get some data for a Medicare submission in respect to Carcinome or with Luminate, it's a different type of test than consumers are used to seeing.

It's not a family lineage or hereditary disposition test, but it's a test that can provide actionable information to help reduce risk of potential skin cancer in the future. So it's a great idea. We have great market research on it, but we've got to price test it, do some beta testing. See what kind of cost it takes to get the right number of leads into the top of the funnel and see what conversion looks like. So that's why we keep saying that, a lot of 90% or more of our effort related to the guide even as really the professional dermatology channel for the melanoma test.

Operator

Our next question comes from the line of Mason Carrico from Stephens.

Mason Owen Carrico - *Stephens Inc., Research Division - Senior Research Associate*

Hey guys, just a quick question from me on Luminate. Given this is a consumer-based product, and you'll be paid by consumers versus having to establish reimbursement, is it fair to assume this product could be accretive to gross margins in 2022 or maybe potentially 2023? And maybe similar to an earlier question, if not, is there a certain level where it could become accretive to gross margins that you could point to?

John D. Dobak - *DermTech, Inc. - President, CEO & Director*

Well, we've become experts at digital marketing over the last few years, particularly as it pertains to the melanoma product. And we learned how you, the steps you have to go through to sort of introduce a product and get consumers interested, and then drive them through the funnel. And we always called it launch and learn and it's a process that takes 6 to 12 months, to kind of optimize the messaging, optimize the algorithms and get that funnel and your customer acquisition cost to where they should be.

So we wouldn't say anticipate much in this year and we would be looking to next year for it to be, to provide some contribution because it's really the launch and learn. We've got to start to understand how the digitally market and how to drive those funnel metrics. We do think that the way we developed the product, that it can be a meaningful product and that, it can have a meaningful gross margin associated. So once it becomes materialable, we will be able to communicate more effectively what we think the contribution will be.

Kevin Sun - *DermTech, Inc. - CFO, Treasurer & Secretary*

Yes. And in terms of the setup within the laboratory, so there are shared technologies with our melanoma test that we can leverage and then just, use some more current capacity, but it looks like that there will be some new technologies around the sequencing side of things. And so that's why -- and when we're at a low volume in the launch and learn type of environment, we don't really utilize that equipment as to the full-scale. So it's possible it could be accretive.

And again it depends on the price testing that we have to perform during the launch and learn to see. Because the market research is good, when the rubber hits the road is one people are willing to put their credit card on the line and what is that price point? And so that's the key testing, one of the key testing areas that we have to do to earn this one launch and learn to see if it they will be accretive right away or not.

Operator

I'm not showing further question at this time. Ladies and gentlemen, thank you for participating in today's conference. This concludes today's program. You may now all disconnect. Everyone have a great day.