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Lucid Diagnostics

Fourth Quarter 2021 Earnings Conference Call

March 28, 2022

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PRESENTATION

Operator

Greetings. Welcome to the Lucid Diagnostics Fourth Quarter 2021 Earnings Conference Call.

Please note, this conference is being recorded.

I will now turn the conference over to your host, Adrian Miller, Vice President of Investor Relations at Lucid Diagnostics. You may begin.

Adrian Miller

Thank you, Operator. Good afternoon, everyone, this is Adrian Miller, Vice President of Investor Relations at Lucid Diagnostics. Thank you for participating in today's business update. Joining me today on the call are Doctor Lishan Aklog, Chairman and Chief Executive Officer of Lucid Diagnostics, and Dennis McGrath, Chief Financial Officer of Lucid Diagnostics.

The press release announcing our business update and financial results will be available shortly on Lucid's website. Please take a moment to read the disclaimer about the forward-looking statements in the press release. The business update press release and the conference call both include forward-looking statements, and these forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially from the statements made. Factors that

cause actual results to differ are described in the disclaimer and our filings with the Securities and Exchange Commission.

For a list and description of these and other important risks and uncertainties that may affect future operations, see part one, item 1A entitled "Risk Factors" in Lucid's most recent annual report on Form 10K, filed with the Securities and Exchange Commission, and any subsequent updates filed on our quarterly reports on Form 10Q and any subsequent Form 8K filings. Except as required by law, Lucid disclaims any intention or obligation to publicly update or revise any forward-looking statements to reflect changes in expectations or events, conditions or circumstances, on which those expectations may be based, or that may affect the likelihood of the actual results, will differ from those contained in the forward-looking statements.

With that said, I would like to turn the call over to Lishan Aklog. Doctor Aklog?

Lishan Aklog, M.D.

Thank you, Adrian. Good afternoon, everyone. Thank you for joining us on our Lucid Diagnostics quarterly update call. If you've noticed, we've decided moving forward to hold a separate quarterly call focused entirely on Lucid. Really looking forward to having the time to tell the full Lucid Diagnostics story each quarter.

Happy to report that Lucid Diagnostics is firing on all cylinders. Our rapidly growing team is making excellent progress on all fronts, and is laying a solid foundation for us to continue driving our long-term growth strategy. Our strong balance sheet provides us with the resources to execute on this strategy.

Before proceeding, I'd like to thank our long-term shareholders for your ongoing support and commitment. Every day, each member of our team is singularly focused on growing Lucid while enhancing long-term shareholder value.

I'll start by providing an overview of our business, and I'll then pass the baton over to Dennis, who will provide our financial update, before opening it up to questions.

First some background on our Company and its mission. Lucid Diagnostics is a commercial-stage cancer prevention diagnostics company, focused on the millions of chronic heartburn patients who are at risk of developing highly lethal esophageal cancer. Unlike other common cancers, the esophageal cancer mortality rates are high even in its early stages. Preventing deaths requires us to detect esophageal precancer, which occurs in approximately 5% to 15% of at risk chronic heartburn patients. The good news is that esophageal precancer can be monitored in its early phase and cured with an endoscopic procedure in its late phase, which reliably halts progression to esophageal cancer.

Although esophageal precancer screening is already recommended in millions of chronic heartburn patients, fewer than 10% undergo traditional invasive endoscopic screening. The profound tragedy of nearly every esophageal cancer diagnosis is that likely death could have been prevented if the patient had been screened.

The missing element for a viable early detection program to prevent these thousands of tragic deaths has been the lack of a widespread screening tool. We believe our EsoGuard next generation sequencing methylated DNA test and our EsoCheck cell collection device together constitute the first and only commercially available diagnostic test capable of serving as such a screening tool. We believe EsoGuard has the potential to become the standard of care to detect esophageal precancer in at risk patients, with a total addressable U.S. market or opportunity greater than $25 billion, based on an effective Medicare

payment of $1938 and a targeted U.S. population of at least 13 million patients already recommended for screening by clinical practice guidelines.

Let's now review how EsoGuard commercialization has been going. The short answer is that it's going very well. We are very encouraged with the progress we are making, as we are starting to see excellent traction with robust growth in EsoGuard testing volume. We processed 303 EsoGuard tests in the fourth quarter of 2021, that represents an approximately 50% increase sequentially from the third quarter and a nearly 200% increase annually from the fourth quarter of 2020. This growth has continued nicely into the new year, both in referrals to our Lucid test centers and tests performed at gastroenterology and foregut practices. We're seeing broad growth across all geographic regions.

Although our strong focus is on these two commercial channels, we are also making encouraging strides across multiple non-GI specialties choosing to perform the procedure themselves, including family medicine and primary care practice, and even ear, nose and throat specialists.

We have also made steady progress engaging with large practices and health systems. For example, we have new EsoGuard programs under way at several academic medical centers in the Southeast, and will soon launch a program at multiple Florida locations of a major integrated health network. We are also getting traction at community-based hospitals, with multiple such hospitals having launched or in the process of launching EsoGuard programs. We've also gained favorable attention from a couple of large private equity-backed gastroenterology groups such as Gastro Health, which has multiple locations which have begun EsoGuard testing.

Across the board, these sites are embracing the potential for EsoGuard to increase engagement with GERD patients and create downstream revenue opportunities, including consults, confirmatory and surveillance endoscopy, adjunct diagnostics such as manometry and pH testing, endoscopic interventions and surgical consults.

The pillar of our growth strategy remains our expanding network of Lucid test centers. The Lucid test center program has completed its first stage, having advanced from a pilot program in Phoenix, launched in the third quarter of 2021, to a regional program covering, in addition to Phoenix, Denver, Salt Lake City, Las Vegas, Seattle, Portland, and Boise, Idaho.

The Lucid test centers operate in leased medical office suites, each staffed by a Lucid employee, EsoCheck-trained nurse practitioner and medical assistant. Chronic heartburn patients in these seven metropolitan areas across the Southwest and Pacific Northwest can now undergo a brief non-invasive office-based test to detect esophageal precancer before it progresses to deadly esophageal cancer. A single nurse practitioner can perform up to 20 EsoCheck procedures per day.

The test centers have very modest fixed costs and attractive margins. Each test center operates almost entirely as a marginal variable cost business, covering its personnel and medical office lease costs with only a couple of reimbursed tests per week.

We are now in the process of launching the next stage of our leased test center program, with accelerated expansion into larger states across the nation. We have built a robust compliance program, which allows us to proceed with this expansion, including in states with more complex laboratory regulation. We've also hired a fulltime experienced director of clinical services, who will oversee this expansion.

Our experience with the test centers over the past six months has clearly validated the test center model as a key driver of EsoGuard testing volume. Its greatest impact has been to simplify the engagement of our sales reps with primary care physicians. The reps simply educate the physicians on the relationship

between chronic heartburn and esophageal cancer, and on the availability of a new non-invasive alternative to screen at risk patients. The physicians then simply order the test, directly through the electronic medical record if possible, and the test is then performed at one of our Lucid test centers. We have even encountered gastroenterologists in Lucid test center cities who have opted to send patients to our test centers instead of performing the EsoCheck procedure themselves. The Lucid test center model clearly works.

We also continue to pilot our EsoGuard telemedicine program, operated in partnership with our independent third party telemedicine provider, Upscripts, which we launched in December of last year. Patients who learn about EsoGuard testing can request an online video visit with a telemedicine physician who can send the patient, if appropriate, to the Lucid test center for EsoGuard testing.

Although patients in any Lucid test center city can access the telemedicine program, we're only actively pursuing a direct to consumer advertising program on a limited pilot basis in Phoenix. The program there is operating very smoothly, and a steady flow of self-referring patients have undergone telemedicine evaluation and EsoGuard testing at Phoenix area Lucid test centers.

We've also significantly expanded our sales infrastructure and operations during the fourth quarter and recent months. Our very first employed sales rep started just in September of 2021. Our sales team has grown substantially since then. We've been able to attract high-caliber personnel to feed this growth, despite challenges with COVID-19 and broader economic forces facing all growth companies looking to hire.

The team, led by our national VP of sales, now consists of three area directors covering the East, Central and West respectively, six market development managers, 10 sales reps, and several sales operations staff. The market development managers focus on establishing EsoGuard testing at gastroenterology, foregut surgeons, large primary care and multispecialty practices, as well as large and academic medical centers and integrated health networks. The sales reps, on the other hand, are focused on engaging with primary care physicians, including those within the referral networks of our gastroenterology and foregut surgeon practices. We expect the overall sales team to double in size and the number of sales reps to triple by the end of the year.

During the fourth quarter and recent months, we have also made substantial progress in honing the sales process and sales training to assure that our outstanding team is well positioned for success. The sales reps are now armed with a very detailed, highly structured and field-tested process to efficiently target primary care physicians to generate interest and convert interest into action, namely ordering EsoGuard tests. The process has become entirely data- and analytics-driven, utilizing Salesforce and other sophisticated tools.

The team has also had good success leveraging peer-to-peer educational events to drive adoption.

Our sales program has also become quite robust combining an intense five-day educational course and extensive field training with established reps.

I'd like to now discuss exciting important developments in our laboratory operation.

Last month we were thrilled to announce that LucidDx Labs, a wholly-owned subsidiary of Lucid Diagnostics, had acquired certain licenses and other related assets from our longtime CLIA laboratory partner Research Dx, which allowed us to operate our own new CLIA-certified CAP-accredited clinical laboratory. Our laboratory operates in a freestanding 20,000 square foot building in Lake Forest, California, and the laboratory has acquired, installed and qualified all the necessary technology and equipment to perform the EsoGuard assay, has completed the necessary assay validations to process

clinical samples as a laboratory-developed test, completed a College of American Pathologists or CAP audit, and has begun performing EsoGuard testing at the new facility.

I'm so proud that the team was able to get the lab up and running and secure CAP accreditation in record time, and that the lab is now performing all EsoGuard testing, including DNA extraction and bisulfide-converted next generation sequencing on EsoCheck samples.

I really can't overstate how critical a milestone securing our own CLIA laboratory has been. It markedly streamlines and simplifies numerous important EsoGuard testing processes. More fundamentally, it provides us with a strong long-term scalable infrastructure to accommodate accelerating growth in test volume from expanding EsoGuard commercialization activity. Perhaps most importantly in the short term, it simplifies our billing and collection process, eliminating some of the complexities we have had to previously accommodate, as Dennis will describe in more detail later.

Speaking of reimbursement, now, a brief update on where we stand with—in conjunction with us taking over the laboratory and fully controlling the EsoGuard billing and collection process, we have been able to upgrade all of our processes including our revenue cycle management providers. With these boxes checked, we are now in a position to start submitting Medicare claims using the effective $1938 Medicare payment rate.

On the Medicare coverage side, we continue in a holding pattern. We're approaching now the two-year anniversary of our submission of the covered technical file to the MolDx program of Medicare administrative contractor Palmetto GBA, the same group which issued our effective Medicare payment for EsoGuard in 2021. The processing of molecular diagnostic local coverage determinations really ground to a snail's pace during the peak of the pandemic and has not yet fully recovered. We remain encouraged, however, by the October 2021 MolDx contractor advisory committee or CAC meeting on the topic of molecular testing for certain gastrointestinal cancers, including EsoGuard. The expert gastroenterologist panel voiced strong support for esophageal precancer testing in high-risk chronic heartburn patients. We believe that the CAC meeting was a strong indication that MolDx has actually started technical review of our file, and that a draft LTB should be forthcoming, we just can't say when.

Unlike Medicare payment and coverage, which is binary, private payer payment and coverage is a marathon, where one negotiates contracts with local, regional and national private payer programs to steadily increase the number of covered lives for a test. The laboratory has been submitting claims to private payers, and we have been encouraged that it has been receiving approximately $1150 per test, representing approximately 60% out of network coverage. This percentage is consistent with the patient's policies and suggests that, at least for now, the payers are basing their out of network payment on the full price we are submitting.

We're just reaching the critical threshold of submitted and processed claims in certain locales, which will allow us to begin having meaningful conversations with select private payers in these locales, in network payment and coverage. We're beefing up our market access team to allow us to fully engage in these negotiations.

We're also collecting the critical clinical utility data demonstrating that EsoGuard positively impacts cares that the payers are seeking as part of these negotiations. We believe, based on extensive outreach, that our Lucid test centers will actually facilitate these discussions, including the potential to participate in more tightly controlled innovation projects, which payers are increasingly pursuing in advance of broader coverage.

Now let's move on to our clinical studies. As I have said on many occasions, expanding the clinical evidence for EsoGuard testing is a pillar of our growth strategy, and was a key impetus for us raising growth capital in the fall.

We are significantly expanding our clinical trials infrastructure and the number of Company- and investigator-initiated clinical studies. For the sake of time, I'll only be able to provide some highlights.

We continue to actively enroll patients in the two international multicenter clinical trials, EsoGuard BE1 and BE2, to support eventual FDA PMA approval of EsoGuard used with EsoCheck as an *in vitro* diagnostic or IVD indicated to detect esophageal precancer. The study has 68 sites in the U.S. and Europe. Enrolment has been steady, despite the winter Omicron surge, and we are still targeting completion of enrolment by the end of 2022, and PMA submission in 2023.

We recently announced that investigators at the Cleveland VA have enrolled their first patient in a Department of Defense-funded EsoGuard study. I'm very excited to see this investigator-initiated study launch, as it'll add important clinical evidence on the impact of EsoGuard in enhancing early detection of esophageal precancer by reserving endoscopy for those with a positive EsoGuard test. The study will enroll up to 100 Cleveland VA patients who fulfill American College of Gastroenterology criteria for esophageal precancer screen.

As I mentioned, we've also launched multiple clinical utility studies at busy clinical sites to demonstrate that EsoGuard positively impacts the care of (inaudible) GERD patients. These clinical utility studies and an EsoGuard registry that we are launching will provide important data to support our private payer discussions, as well as ongoing improvements and modernization of the EsoGuard assay.

Finally, we continue to provide support for other investigator-initiated studies, including NIH-funded ones, which are generating positive data to be presented at upcoming meetings, and we believe will expand the peer-reviewed literature supporting EsoGuard testing.

Let me close my portion of these remarks with a few business development updates. PAVmed's EsoCare device, to endoscopically treat esophageal precancer, continues to progress well. PAVmed completed another successful animal study, including head-to-head comparisons with Medtronic's Barrx device. Feedback from key opinion leaders who are busy esophageal ablators have been universally positive, and very encouraging. Given this progress, Lucid and PAVmed decided to enter into a formal intercompany license agreement whereby Lucid will have the exclusive worldwide rights to commercialize EsoCare, which is tightly synergistic with the EsoGuard and EsoCheck products.

Last year a PAVmed subsidiary acquired CapNostics LLC, which manufactures EsophaCap, a non-endoscopic sponge-based esophageal cell collection device, which has been used in precommercial clinical research with esophageal precancer markers at major academic medical centers. The company has entered into discussions with these centers and has agreed to continue to support this research. It has closed a clinical trial agreement with Mayo Clinic, and is close to doing the same with Johns Hopkins. Since this technology is firmly within Lucid's business, PAVmed and Lucid entered into an agreement for Lucid to acquire the CapNostic asset under the same terms as PAVmed did in the fall.

Finally, we continue to receive a steady inflow of business development opportunities, and carefully assess each in terms of synergy with our current portfolio and the potential to be accretive in the near and medium terms.

With that, I will hand the reins over to Dennis to provide an update on our financials, before proceeding with questions.

Dennis McGrath

Thanks, Lishan, and good afternoon, everyone.

Our preliminary and summary financial results for the fourth quarter and for the full year ended December 31, 2021, were reported in our press release that was published just earlier today. We plan to file our annual report for Lucid Diagnostics in Form 10K with the SEC in the coming days, and at that time it will be available at sec.gov and on the Lucid website.

As you already know from our previous quarterly corporate update calls that, as a rule, EsoGuard tests performed are recognized as GAAP revenue when cash is collected by the Company. Also as previously mentioned, this more than likely will be true during this transition period of negotiating third party private payer reimbursement contracts and related coverage policies.

As I reported to you last quarter, for compliance purposes during this reimbursement transition period, we negotiated a short-term month-to-month fixed payment arrangement with the contract laboratory that was processing the EsoGuard assay and was performing the insurance company billing and collections function. This commercial agreement became effective on August 1, 2021, and terminated concurrently with the opening of our own laboratory at the end of February 2022. We recognized $0.5 million of revenue as part of the EsoGuard commercial agreement with Research Dx for the year ended December 31, 2021.

Now that we are operating our own laboratory following the February 2022 agreement where LucidDx Labs purchased certain assets from Research Dx, Lucid will have the ability to directly invoice the CMS and private payers.

Future revenues will be recognized based upon actual collections, until such time as the coverage policies are in place with CMS and payment contracts with the private payers. This obviously can result in the timing of revenues recognized, versus the timing they are submitted for third party reimbursement, until these future conditions are all met.

Consequently, it is our expectation that we will begin to recognize GAAP revenue related to our LucidDx Lab in the second quarter of this year, and will be adjusted based upon actual collections received for tests submitted for reimbursement by the laboratory.

The number of EsoGuard tests performed and submitted for payment are provided in the press release and was discussed earlier by Lishan. Obviously we're in the early stages of our commercial launch, particularly with our test centers. We'll continue to evolve our reporting metrics as various sales and marketing efforts further influence adoption, particularly with the ramp-up of our Lucid test centers and our EsoGuard telemedicine program in cooperation with Upscript.

Presently there are now five banking analysts who have issued coverage on Lucid, and others doing their diligence. The 2022 revenue estimates provided by the analysts are achievable. The quantity and collections are highly dependent upon the evolving reimbursement landscape.

As you are likely aware from our last corporate update, the local coverage decision, as Lishan mentioned, has still not been published. But we are optimistic that it is being worked on and should be forthcoming.

With regard to revenue, Lucid recognized $0.5 million of revenues related to EsoGuard for the year ended December 31, 2021. Despite the negative gross profit for last year, which reflects the initial test centers startup-related costs at moderate volumes, incremental gross margins can be around 90%, and

contribution margins was 60% to 65%. These lower volume amounts have a minimum level of fixed costs associated with just being operational.

Now a few comments about operating expenses, sales and marketing to start.

For the year ended December 2021, sales and marketing expenses were approximately $5.3 million for the year, compared to $1.3 million for the corresponding prior year period, with a $4 million increase principally related to the following items: approximately $1.7 million was an increase in compensation-related costs, largely related to an increase in head count; approximately $1.1 million increase for outside profession services related to EsoCheck, EsoGuard, and consulting and other professional service fees; and $0.9 million increase in the management services agreement, the fee allocation from PAVmed related to the growth and expansion of Lucid's business and the services incurred through PAVmed.

On the G&A front. G&A expenses were $12.8 million for the year ended December 31, compared with $1.5 million for 2020, with the approximate $11.3 million increase related to a couple items: about $9.1 million of that increase was non-cash stock-based compensation from restricted stock award grants to Lucid and PAVmed employees and non-employees; and approximately $2.1 million in consulting services related to patents, regulatory compliance, legal processes for contract review, the transition of our public relations and investor relations firms, and public company expenses.

On the R&D front. The R&D expenses for the year 2021 were approximately $9.3 million as compared to $5.4 million for the prior year, with the increase of $4 million related to the following items: about $3.2 million were an increase in development costs; about $0.2 million in compensation-related costs; and approximately $0.4 million an increase in the management services agreement to fee allocation with PAVmed.

There's a table we provide in the press release, it was published earlier, that adjusts each of these three components of operating expenses for the embedded non-cash stock-based compensation expense. Without the stock-based compensation expense, total operating expenses for Lucid stand-alone were $17.7 million and $8.2 million for the years 2021 and 2020 respectively.

With regard to the loss and per share amounts, Lucid Diagnostics reported a fourth quarter '21 and a full year 2021 net loss attributable to common stockholders of $11.3 million and $28.1 million, or a loss of $0.32 or $1.51 per common share, respectively, versus the same period in in the prior year, the fourth quarter of '20 and the full year, of $2.7 million loss or $0.19 a share and $8.3 million or $0.59 a share in 2020.

The press release also provides a table entitled "Non-GAAP", which highlights these amounts along with interest expense and other non-cash charges, namely depreciation, stock-based compensation, financing-related costs, so that there's a—it enables a better understanding of the Company's financial performance. You'll notice from the table that, after adjusting the fourth quarter and the full year GAAP loss by approximately $3.6 million and $10.3 million for non-cash and interest costs for those two periods, the Company reported a non-GAAP adjusted loss for the fourth quarter and for the full year, $7.7 million and $17.8 million or $0.22 and $0.96 for the quarter and for the full year, per common share.

Lucid had cash of $53.6 million as of December 31; that compares to $0.1 million in the year end 2020.

Today, Lucid entered into a committed equity facility with an affiliate of Cantor Fitzgerald, where Cantor committed to purchase up to $50 million in the Company's common stock from time to time at the request of the Company. Any future funding from this facility is completely at the discretion of the Company and, if utilized, likely would extend the Company's runway well into 2024.

Unlike PAVmed, Lucid is not eligible to put a shelf registration into action until after November 2022, or more than 12 months after the IPO. Like we described about the PAVmed shelf, the Board considers having available financing options part of their governance duties, even if utilization would finance us well into 2024. So they consider it part of their duties to understand what the long-term opportunities to the Company are, and this gives us that vehicle, short of being able to put a shelf in place.

With that, Operator, let's open it up to questions.

Operator

Our first question is from Kyle Mikson with Canaccord Genuity. Please proceed with your question.

Kyle Mikson

Hey thanks. Hey guys, congrats on the quarter. Thanks for the questions.

Great updates obviously. I hate to be myopic here, but I just wanted to talk about the COVID impact in early first quarter. Clearly there were headwinds that affected the diagnostics industry during January and February, due to Omicron. Just was wondering what the impact on Lucid was, early in the first quarter, and could there be any systemic impact that lasted throughout the quarter, rather than just the transient impact early on? Thanks.

Lishan Aklog, M.D.

As I said before, our team has done a good job of insulating ourselves, or inoculating ourselves, no pun intended, from some of these COVID-related effects. That's primarily because our engagement with physicians is entirely outpatient-based. Our test centers are entirely under our control, and we control how we handle precautious at our test centers. Generally we have not seen, with this or even with the previous, the summer surge for example, the Delta surge, any meaningful impact, certainly compared to companies that call on hospitals, where elective procedures and other things could be cancelled. We do get a bit here and there of centers that, at the absolute peak, which slowed down the ability of our reps to get into offices, but that's a relatively modest. As I've said before, the main issue frankly was around travel, cancellation of flights and so forth, and that was a very very narrow window during this last Omicron spike.

Bottom line is that it hasn't had a major impact, at least so far, and that we expect moving forward.

Kyle Mikson

All right, great. Maybe just one on the CLIA lab. When do the benefits from that in-house lab, internally owned lab, really fully take shape, or maybe have they already? Why did it make sense to acquire that capability relatively early into the launch, before Medicare reimbursement was secured?

Lishan Aklog, M.D.

The benefits are accruing immediately. We had planned, and if you recall during the S1 we talked quite a bit about the need to have this infrastructure in place moving forward. But the thing that really dominated our thinking to move more quickly, as we described previously, has been the complexities around using a third-party laboratory for the billing and collection and invoicing of tests submitted to payers, when you marry that to our test centers. There are a lot of hurdles that come with that, that relate to federal and other regulations. It was getting quite onerous and complex to do so.

By having our own laboratory, it provides us with the ability, as Dennis mentioned, to invoice payers directly, to really enter into direct negotiations with private payers and so forth, and they really are somewhat linked. There's a bit of a chicken and egg process with regard to secure private payer payment and coverage.

The impact beyond the initial price to get these licenses in place, on the marginal aspects, and Dennis could elaborate on this, are really not significant, since we do continue to use Research Dx to help us run the assay, through a management services agreement. The big difference has been that it's allowed us to be the official laboratory of record, not have to go through all the various convoluted mechanisms to allow us to do so under a third-party arrangement.

Dennis, would you like to add anything more to that?

Dennis McGrath

Yes. If we were to—eventually, we would have our own lab anyway, in the thrust of your question. The timing of it certainly made sense. If we were to start our own lab from scratch, the delay could be upwards of a year to get the appropriate licensing. By buying certain assets and funding that, we get it in place now. We said we would do it in the registration agreement. As we're in this process of putting and negotiating payer contracts, it made sense to have those contracts in the name of our own laboratory, rather than have them in Research Dx and then have to go through the administrative process of transferring over. Given this year is a transition year, given it was part of the funding and used proceeds, the opportunity presented itself. It shortened the game to get it in place. It's in advance of the negotiations we're having with private payer side, and where the coverage policy we'll put in place. For all those factors that made sense to pull the trigger now.

Lishan Aklog, M.D.

If I could just add one thing, Kyle, in terms of immediate benefits, we actually are able to secure our own revenue cycle manager. That's been challenge, because prior to this we've been at the mercy of the one that the laboratory used. We hold all the cards now, with regard to really efficient submission of claims, proper submission of claims, efficient processes for appeals and processing claims across the board. It's super critical, and we're really happy we have this all teed up and ready to go for our future expansion.

Kyle Mikson

Yes. That was great. The benefits are clear; I just was wondering about the timing. But I think that all was great color, it all makes a lot of sense now.

Just moving to denials, cash collections: could you help us think about the denial rate during the quarter and where that stands today? I heard the number, I think it was 1,150, from private payers, that's great. Obviously, a large portion of the target patient population is Medicare patients, and so it's obviously really not getting reimbursed right now, so, could you help us think about maybe denial rate right now, as well as—is the flow of patients, the 300 or so tests during the quarter, is that mostly private payer patients, or Medicare as well?

Lishan Aklog, M.D.

The balance between—let me answer your last question first, that the payer mix is a bit more skewed towards private payers than we would expect from the overall epidemiology of this, which should be about 60% Medicare. But that's just various factors, related to geography and locale and so forth.

In terms of—they don't really—the cycle between submissions and claims is so long. It can be three months or longer. We don't really have good numbers with regard to denial rates, because the vast majority of claims are still just being adjudicated. We've submitted them and we haven't gotten a response. We haven't gotten a payment or a denial. We have had some denials, and those are actually fairly important, to get denials, so that you can go through the appeals process and engage with the payers on that front. But we're not yet able to give you a percentage with regard to denials, just that we're getting, some amount of network payments are coming through, but the vast majority of the claims are still sort of in the hopper waiting to get processed.

Kyle Mikson

All right, great. That makes sense. It's fair.

For a final question, just want to lump two thought processes come together here, and it's around basically the announcements that you made towards the end of the call, regarding EsoCure and EsophaCap. Those are very positive, obviously.

First on EsoCure, I believe that PAVmed planned to conduct additional development work and animal testing of EsoCure to support a planned 510(k) submission in early '22? Just wondering if that still stands.

Then on EsophaCap, what does that mean for Lucid's competitive positioning? Does the Company basically think that it could essentially control certain players from entering the market that use that EsophaCap as a cell collection device? Thanks.

Lishan Aklog, M.D.

The answer to the first one is, no, early '22 is not the completion of these studies, completion of the verification and validation testing will get us further into this year. We don't expect that to happen early. But the progress has been really solid and great, and we look forward to just getting to design freeze and getting the verification and validation testing to allow us to submit to the FDA, and we think we have a very good regulatory strategy to do so and to get it cleared and to be able to offer that commercially. The time just seemed right, right now, to formalize the engagement with Lucid as it relates to licensing of the technology when it's ready for commercialization.

With regard to (inaudible), I'll just be somewhat brief about that response. There are two 510(k)-cleared sponge-based devices in the U.S., three noninvasive collection devices you include EsoCheck. The other sponge-based device is the Medtronic Cytosponge device, which has been off the market for a couple of years.

The indirect answer to your question is, right now, we do control the only 510(k)-cleared sponge device for use in screening GERD patients with biomarkers. I'll just leave it at that.

Kyle Mikson

Okay. Perfect. Thanks again, guys. Appreciate it. Congrats on the quarter.

Lishan Aklog, M.D.

Thanks, Kyle.

Operator

Our next question is from Mike Matson with Needham & Co. Please proceed with your question.

Lishan Aklog, M.D.

Hey Mike. Good afternoon.

Michael Matson

Hey, good afternoon. For the 300-roughly tests that were performed in the fourth quarter, can you just remind us how many test centers those were going through? I can't remember where you were at as of the end of the year. Then, were they pretty evenly spread out, or were they concentrated in one versus another?

Lishan Aklog, M.D.

I'll give you some color on that without—the numbers are too small to really give you a lot of granular numerical data on that. But if you remember, the first test center was launched in—really didn't get rolling until September. For most of the fourth quarter we had just Phoenix test centers, the three, but just in the Phoenix area, and we didn't launch the Salt Lake, Vegas and Denver centers until the mid-portion of that year.

The majority of those cases were actually not test center cases, because the test centers were just getting up and running, and were actually cases performed by physician practices. As I said, the geography is really spreading out nicely across the country. The busiest geography has actually been in the East, which doesn't actually have any test centers.

We expect, as we continue to grow, that an increasing portion of the volume won't be cases that pass through our test centers, but to be honest we've been quite encouraged, as I mentioned in my prepared remarks, in the expansion of non-Lucid test center activity at community hospitals, at integrated health networks, at academic medical centers and GI practices, including very large private equity-backed GI gastroenterology networks.

We expect that volume to continue to grow, but I would say, over time, particularly as we get into this next stage and enter into larger states across the country, that an increasing portion of the volume will be represented by Lucid customer cases that get referred by primary care physicians or eventually self-referrals.

Michael Matson

Okay. Just wondering if you could give us an update on the DTC campaign? I know you made some comments on it, but I think I got to say it was really still limited only to the Phoenix area, is that right, and …

Lishan Aklog, M.D.

Yes. Our philosophy, I think I've articulated this before, with the direct-to-consumer aspect of this, is we're really doing it in a very controlled fashion. We don't think it makes sense to really blow it out until two things happen: one, we have a clear understanding of which modalities work and what the yield on each advertising dollar will be, but also until we get more traction with regard to reimbursement. We're taking a

careful approach with regard to deploying dollars into advertising, and have limited it to the Phoenix area, where we do have billboards and TV and radio advertising, and we're continuing to do that.

We don't really have enough data to understand—we were definitely getting responses, and as I said we are having patients who are passing through the telemedicine program and we've gotten tested and have completed the process, and that appears to be growing. We believe we're getting good traction with that.

Typically, with direct-to-consumer work, you really need three to six months of data to really understand which modalities are giving you the best bang for your buck, and so we'll continue to collect that data. We'll likely continue the DTC work, to keep it limited to Phoenix or perhaps one or two other states, for the foreseeable future.

Dennis, do you have anything you want to add to that?

Dennis McGrath

No, I think that summarizes it well. The two gating factors are optimization and reimbursement. As both of those start to evolve, we'll have more of the DTC expansion and investment, so that every dollar spent has a direct relationship to the yield of adoption and revenue.

Michael Matson

Okay. Got it. Then, just as far as MolDx goes, you're confident that this is going to happen, it's just a matter of time, and just a backlog at CMS.

Lishan Aklog, M.D.

Yes. It's a little bit—I wish I could have more details. The fact that they held a CAC meeting, which covered our assay, our test along with others, is a strong indication that they're working on it, as opposed to prior to that, where we had no real evidence that they had actually dusted off our file. We clearly feel they're working on it. Our team does engage with them, we have discussions with them, we check in regularly; and so all of that together, these LCDs, I think we've talked about this, Mike, have increasingly come in batches, centered around certain disease processes or other organizing factors, and so we just expect that that's in fact what's going on, is there's a group of tests that fall under similar umbrella that are all being evaluated, and that we would expect to get a batch of draft LCDs sometime soon, we hope.

Michael Matson

Okay, got it. Thank you.

Lishan Aklog, M.D.

Thanks, Mike.

Operator

Our next question is from Ross Osborn with Cantor Fitzgerald. Please proceed with your question.

Lishan Aklog, M.D.

Hey Ross, good afternoon.

Ross Osborn

Hi everyone, hi. Congrats on the progress. Thanks for taking my questions.

Maybe starting off with test centers, can you walk through the time line on the next set of locations? Then, as a follow-up, has the Company developed any solutions in addressing states with stricter regulations you've previously discussed?

Lishan Aklog, M.D.

The time lines are—we're definitely accelerating things. The first group, we did one city, Phoenix, then we did three and three, and now we're moving towards doing them in larger batches and in larger cities. We've identified nine states where we're going to target, including most of the large states across the country, and we're going to—we're identifying our first target location in each of those, and we're looking to do a bigger launch across multiple states, as opposed to doing them in smaller bite sizes as we've done to date.

In terms of the solutions, we actually have—yes, we're all set with regard to the compliance infrastructure around replicating the test centers in states that have more complex laboratory regulations. There are a variety of factors there, really that fall into two buckets. One bucket is on nurse practitioner, practice regulations and need for supervising physicians. We've been able to establish a straightforward mechanism for dealing with that. There are some states where we have to deal with corporate practice of medicine statutes, which we've been able to establish a program on how to deal with that as well. Then there are some where the relationship between the laboratory and the test centers are important.

Yes. We're good to go. We've got a really outstanding compliance council, and all of those ducks are in a row, and just about ready to go.

Ross Osborn

Okay. Great to hear.

Then, maybe just in terms of education, I think we've previously discussed some pushback with nurses, just given a new offering, which is the basic workflow? Have you guys made any progress in maybe some more efficient education programs, or is it really just knocking on doors? I'm just curious to hear all that.

Lishan Aklog, M.D.

What you're referring to, of course, are not primary care targets, right, where there is no workflow issue, it's just purely educating them on the disease and the risk factors for cancer and the availability of the test. Right? That doesn't require any change in workflow, that's just standard engagement with primary care physicians.

On the gastroenterology front, as well as larger primary practices, it's actually gone pretty well. We're not really getting that pushback, we're getting centers. What's changed over the past couple of quarters is that we've been able to really have these centers, whether they be large practices, community hospitals, academic medical centers or integrated health care networks or these large PE-backed gastroenterology practices, to really see this as a program, as I mentioned in my prepared remarks, as a comprehensive program, either part of a broader program for gastroesophageal reflux disease in a chronic heartburn clinic, or just specifically around EsoGuard, around screening for esophageal precancer.

There's now a better understanding, and I think perhaps we've learned how to articulate the downstream benefits to these larger entities around referrals, consults, endoscopy, surgical referrals, ablations and so forth. Really going quite well. As I tried to give a variety of diverse examples of the types of venues where we're starting to get traction, and now it's completely about expanding the team and getting them out there and having these conversations.

The time it takes to convert, let's say, a small GI practice compared to a large academic medical center, as you might imagine, it's quite different, right? You have a large center, there's technology committees and other hurdles that you have to go through, and that time to get traction there can be many many months, six months or longer, at times. But the payoff obviously is greater once you're in, and you have access to the entire facility and program.

Ross Osborn

Understood. Thanks for taking my questions.

Lishan Aklog, M.D.

Thanks, Ross.

Operator

Our next question is from Mark Massaro with BTIG. Please proceed with your question.

Lishan Aklog, M.D.

Hey, Mark. Good afternoon.

Janine for Mark Massaro

Hey guys. This is Janine (phon) on for Mark. Hey.

On the initiation of the Cleveland VA study, could you maybe give a sense of timing for the initial readout? Just any major milestones to look out for there that could potentially help drive a draft LCD or guideline inclusion in the VA. Thanks.

Lishan Aklog, M.D.

We don't have—it's a little too early to know yet what the enrollment pace is going to be, but we expect it to be pretty quick. Just even since our announcement, the investigators have enrolled several patients, so we don't expect this to—we expect it to complete enrollment fairly quickly. There are lots of these patients out there; as you might imagine, the VA has a lot of these patients. It's pretty fertile ground for the typical GERD patient who needs screening.

Yes. Not too long. I can't give you precise timelines yet, but I think I would say certainly this year we would hope to have it completed.

Unlike other studies, there's really no follow-up, right? These are immediate reads upon enrolling the patients, they get their EsoCheck procedure, they get their EsoGuard test, they get their endoscopy; so there isn't a long follow-up period to get the readout. I'm pretty confident we can get it done this year.

Janine for Mark Massaro

Okay, perfect, thanks.

Maybe just one quick follow-up. Could you speak to your mix of prescribing physicians between PCPs and GI specialists? You did mention uptick in non-GI specialties. Just how you view that trending looking to '23 here. Thanks.

Lishan Aklog, M.D.

The non-GI specialties are mixed amongst large primary care centers who have decided to do their own testing, non-internal medicine family practice groups, as well as, of course, primary care physicians who are referring to our test setting. But I don't have a hard breakdown of that, and that's rapidly changing, so the fourth quarter numbers don't necessarily reflect where we are today. If I was to give you a rough guess right now, I would say that if you take primary care referrals, or orders, to our Lucid test centers, along with primary care practitioners, like our busiest practitioner is a family medicine nurse practitioner who does a large number of procedures herself in her practice. If you take all of those together, are we sort of 50:50 GI versus primary care? Maybe not quite, but probably heading towards that.

Janine for Mark Massaro

Okay, perfect. Thanks for taking the questions.

Lishan Aklog, M.D.

Thank you.

Operator

Our next question is from Ed Woo with Ascendiant Capital. Please proceed with your question.

Lishan Aklog, M.D.

Good afternoon, Ed.

Edward M. Woo

Congratulations on the rollout.

It looks like you guys been adding about one city a month. Am I correct that you guys are going to be at a much faster pace over the next 12 months?

Lishan Aklog, M.D.

Yes, I think so, and it's going to be less steady, that we're going to do them in larger chunks. Right? Instead of doing three at a time, which we did in the last couple, and we're going to tackle nine cities in nine states, hit them all at once and try to get those wrapped up as soon as we can.

I think we've said this before, Ed, the rate-limiting factor is not the process of finding a site and identifying the best city within a state to start with, and getting the physical location up and running, or even hiring the nurse practitioner or the medical assistant; it's actually getting the sales infrastructure, the sales reps in place, to be able to drive cases to the test centers. Although in many of the states that we're talking

about, now we already actually have a presence, with market development managers and even sales reps who are already working with non-Lucid test center channel, and so we will be able to place some of these test centers in places where we already have a commercial presence.

Edward M. Woo

Great, well, thanks for answering my question, and good luck. Thank you.

Lishan Aklog, M.D.

All right. Thanks, Ed.

Operator

We have reached the end of the question-and-answer session, and I will now turn the call over to Doctor Lishan Aklog for closing remarks.

Lishan Aklog, M.D.

Again, thank you, all, for joining us today and, as always, for the great questions. As always, we look forward to keeping you abreast with our progress, via news releases and periodic calls such as this one. Again, I'm real excited that we've been moving forward, we're going to be able to provide dedicated calls for Lucid, and this has been, I think, a great first crack at that. The best way to keep up with Lucid news updates and events is for you to sign up for our e-mail alerts on the Lucid investor relations website and to follow us on social media, Twitter, LinkedIn, YouTube, and our website, or you can contact us directly through Adrian, our VP of Investor Relations, at akm@pavmed.com.

Again, everybody, thanks a lot and have a great day.

Operator

This concludes today's conference, and you may disconnect your lines at this time. Thank you for your participation.