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Lucid Diagnostics

First Quarter 2022 Earnings Conference Call

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PRESENTATION

Operator

Greetings. Welcome to the Lucid Diagnostics Business Update Conference Call.

Please note that this conference is being recorded.

I will now turn the conference over to Adrian Miller, Vice President of Investor Relations. Thank you sir, you may begin.

Adrian Miller

Thanks, 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 call. Joining me today on the call are Doctor Lishan Aklog, Chairman and CEO of Lucid Diagnostics, along with Dennis McGrath, Chief Financial Officer of Lucid Diagnostics.

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

are described in the disclaimer and in 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 1 item 1a entitled Risk Factors in Lucid's most recent annual report on Form 10-K filed with the SEC, and the subsequent update filed quarterly reports at Form 10-Q, and any subsequent Form 8-K filings. Except as required by law, Lucid disclaims any intentions or obligations to publicly update or revise any forward-looking statement to reflect changes in expectations, or any events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements.

With that, I'd like to turn the call over to Lishan Aklog, Doctor Aklog?

Lishan Aklog, M.D.

Thank you, Adrian, and good afternoon, everyone. I'm happy to report that Lucid Diagnostics is making excellent progress on all fronts, and that we're laying a solid foundation for driving our long-term growth strategy. We continue to drive EsoGuard commercialization, expand our sales infrastructure, execute the second stage of our Lucid Test Center roll-out, transition to our own fully staffed laboratory, and update our clinical trial strategy to best serve our growth strategy. Our balance sheet remains strong, providing us with the resources to execute this growth strategy.

Before proceeding, I'd like to thank our long-term shareholders for your ongoing support and commitment; we are singularly focused on growing Lucid while enhancing long-term shareholder value.

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

Let me first provide 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, mortality rates are high even in their earlier stages, so preventing deaths requires us to detect esophageal precancer, which occurs in approximately 5% to 15% of at risk chronic heartburn patients. Esophageal precancer can be monitored in its early phase, and cured with an endoscopic ablation procedure in its late phase. Ablation 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 NGS methylated DNA test, performed on sample collected in a brief non-invasive office procedure using our EsoCheck collection device, is the first and only commercially available diagnostic test capable of serving as such a widespread screening tool. We believe EsoGuard has the potential to become the standard of care to detect esophageal precancer in at risk chronic heartburn patients, with a total addressable market greater than $25 billion.

As we previously announced, the American College of Gastroenterology recently updated its clinical guideline on the diagnosis and management of esophageal precancer, the first such update since 2016. The guideline reiterates the longstanding recommendation that chronic heartburn patients should undergo esophageal precancer screening if they have at least three of six defined risk factors, which include male sex, age over 50, obesity, smoking, and a family history of it.

I would like to highlight two key updates that greatly enhance the commercial potential of Lucid products contained in this guideline. First, the guideline no longer hedges on recommending screening for women. This more than doubles the target population for EsoGuard testing to an estimated 30 million Americans. Second, and most importantly, for the first time, the guideline endorses non-endoscopic biomarker screening as an acceptable alternative to costly and invasive endoscopy. EsoGuard and EsoCheck, which are described in the guideline, are currently the only such non-endoscopic biomarker screening tests. This is an exciting development for Lucid, and I can't overemphasize its importance in supporting our efforts to eradicate esophageal cancer. We look forward for other professional society guidelines to follow suit.

Let's now review how EsoGuard commercialization has been going.

We continue to see excellent traction with robust growth in EsoGuard testing volume. We processed 533 commercial EsoGuard tests in the first quarter of 2022. That represents a 76% sequential increase from the fourth quarter of 2021, and a nearly 500% increase annually from the first quarter of 2021.

Testing volume growth was strong in both sales channels, primary care physician referrals to our Lucid Test Centers as well as tests performed by gastroenterology and foregut surgeon specialty practices and institutions.

Now that our sales process and sales training is well honed and increasingly predictable, our near term growth strategy is clearly defined. We are investing in sales infrastructure, training and supporting resources sufficient to drive steady testing volume growth, to demonstrate clinical utility and generate claims history to support our reimbursement efforts. Once reimbursement is more fully established, we will transition to full-throttle efforts to drive testing volume and revenue growth.

Our sales team consists of market development managers, who focus on establishing EsoGuard testing at gastroenterology, foregut surgeon, large primary care, and multi-specialty practices as well as large academic medical centers and integrated health networks. Our sales reps are focused on engaging with primary care physicians, including those within the referral networks of our gastroenterology and foregut surgical practices. 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, 17 sales reps, and several sales operation staff. We are hitting our hiring targets, and are actually a bit ahead of schedule to hit our end-of-year goals.

Our sales training process is continuing to be developed, and is well honed and quite intense. Our goal is to have new reps operating effectively within about four months of hire.

Pillar of our growth strategy remains our expanding network of Lucid Test Centers. The Test Centers operate in leased medical office suites, each staffed by a Lucid-employed EsoCheck-trained nurse practitioner or medical assistant. The Centers support our primary care physician sales channel by providing a facility where a patient referred for EsoGuard testing can undergo the EsoCheck cell collection procedure. The reps work to educate the primary care physicians on the relationship between chronic heartburn and esophageal cancer, and on EsoGuard's availability as a new non-invasive alternative to screening at risk patients. The physician then just orders a test, which is performed in one of our Test Centers. Single nurse practitioner can reasonably perform 20 EsoCheck procedures in a normal work day. Each Test Center covers its personal and medical office lease costs with only a couple of reimbursed tests per week.

The Lucid Test Center program completed its first stage during the first quarter of 2022, having advanced from a pilot program in Phoenix, launched in the third quarter of 2021. The program has developed into a regional program covering seven metropolitan areas in western states.

We recently launched stage two of our Lucid Test Center program. We plan to open test centers in nine additional states this year. Last month we hired a Director of Clinical Services, with extensive experience operating dialysis facilities for Fresenius and DaVita, to oversee this expansion.

We continue to pilot our EsoGuard telemedicine program, which we launched in December. Patients who learn about EsoGuard testing can request an online visit with a telemedicine physician who can send the patient, if appropriate, to a Lucid Test Center for EsoGuard testing. Although patients in any Lucid Test Center city can access the telemedicine program, we continue to only actively pursue direct to consumer advertising on a limited pilot basis in Phoenix, consistent with the near term strategy I previously described. We're just over four months into the program, and will soon have sufficient numbers to assess the efficacy of various modes of direct to consumer engagement.

Like to now discuss our laboratory operations.

The first quarter and recent months have been full of important developments in our laboratory operations, which are critical to the future success of the Company.

At the end of February, LucidDx Labs, a wholly-owned subsidiary of Lucid Diagnostics, acquired the assets necessary to operate our own CLIA-certified CAP-accredited clinical laboratory. The laboratory operates in a free-standing 20,000 square foot building in Orange County, California, and last month we hired a new VP of Laboratory Operations with nearly two decades of clinical laboratory experience, including at Labcor, Abbott, and Rosetta Genomics. Under his and our Chief Scientific Officer's leadership, we plan to accelerate the transition from the current management services agreement to the lab being fully staffed by Lucid employees.

In parallel with the acquisition, we upgraded our revenue cycle management provider to Synergene Solutions. Synergene will be up and running this month, and will begin billing and processing claims on behalf of LucidDx Labs. This will be the first time a Lucid entity will be billing directly for EsoGuard testing. Claims held since the lab transition in February will be submitted once Synergene is active later this month. The transition from fixed monthly payments from our former laboratory partner to direct billing will result in a temporary pause of out-of-network receipts and recognized revenue, as Dennis will describe in more detail.

Now a brief update on where we stand with reimbursement.

On the private payer side, we were pleased to announce earlier this week that we executed our first commercial payer agreement. LucidDx labs entered into a participating provider agreement with MediNcrease Health Plans LLC, a national directly-contracted multi-specialty PPO provider network with over 8 million lives covered through its clients and payers. Persons covered by MediNcrease, clients and payers, will have in-network access to the EsoGuard testing. The agreement provides rates of reimbursement as a percent of charges for services rendered, including performance of the EsoGuard test. We are pleased that the effective payment for EsoGuard under this agreement, which is based on a list price of approximately $2,500, is consistent with our goal of protecting the effective Medicare payment of just over $1,900. We will continue to work tirelessly to secure many more such participating provider agreements, covering millions more lives, in the coming quarters.

In parallel, we continue to collect critical clinical utility data demonstrating that EsoGuard positively impacts patient care. Such data will be necessary for us to secure direct in-network coverage from major regional and national health plans.

We've also seen progress on the Medicare reimbursement front. Last month, Medicare contractor Palmetto GBA's MolDX program published a proposed local coverage determination, or LCD, for tests designed to detect upper gastrointestinal pre-cancer and cancer. Consistent with its practice over the past couple of years, the proposed LCD is a foundational LCD. That means it provides criteria for a category of testing, not a specific test. Proposed LCDs are by definition works in progress for public review. We have been patiently awaiting this important next step in the process, since we completed CMS's clinical laboratory fee schedule or CLFS process culminating in the important first step, namely final Medicare payment determination, which became effective on January 1, 2021.

The proposed LCD outlines criteria that MolDX expects upper gastrointestinal pre-cancer and cancer molecular diagnostic tests to meet. These criteria include active GERD with at least two risk factors, as well as evidence of analytic validity, clinical validity, and clinical utility. Although it found that no currently existing test has fulfilled these criteria, it indicated that it will monitor the evidence and will provide coverage based on the pertinent literature and society recommendations.

It's important to emphasize that the provisional LCD was published prior to the publication of the updated ACG guideline, and as such does not take into consideration the recommendation supporting non-endoscopic biomarker testing, such as EsoGuard, as an acceptable alternative to endoscopy for esophageal precancer screening.

The publication of the proposed LCD triggered a written comment period that extends until this Saturday. We, along with multiple other stakeholders, will be submitting comments suggesting important modifications to the proposed LCD. MolDx also held a substantive open meeting yesterday, during which we, along with other stakeholders and interested parties, had the opportunity to address the proposed LCD. We previewed our suggested modifications to the proposed LCD. Subsequently, Doctor David Poppers of NYU, who has performed hundreds of EsoGuard tests, discussed the clinical utility of EsoGuard testing in his practice. Finally, Mindy Mordecai, founder of the Esophageal Cancer Action Network and a widow of an esophageal cancer victim, offered a moving and passionate statement on how critical non-endoscopic biomarker testing is to prevent esophageal cancer deaths.

In addition, we recently learned that Meridian Healthcare Solutions, the Medicare contractor which covers LucidDx Labs in California and participates in the MolDx program, has scheduled its own open meeting on May 26 and a written comment period that extends through June 11. We look forward to the opportunity to address the proposed LCD directly with Meridian as well. A final LCD will not be issued until the Medicare administrative contractors have had the opportunity to assess and consider the comments written and comments during the public meetings.

Let's now wrap up with 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 capital in the fall. Over the past couple of months, our management team, along with our Board, have been reviewing our clinical trial strategy to make sure that the substantial capital we are investing in clinical trials is being deployed in an optimal fashion consistent with our short- and long-term strategic goals and situation on the ground.

There are numerous factors we're considering in addition to optimal capital utilization. These include our current understanding from the trenches on what drives clinical adoption, the rapidly evolving reimbursement landscape I just described, promising research data on a next-generation version of the

EsoGuard assay, and the opportunity to conform the clinical trial processes to current clinical practice. We expect this updated clinical strategy to be finalized in the coming months.

One key aspect of our updated strategy is already under way. We are doubling down on our efforts to generate clinical utility data to support commercial and Medicare reimbursement. Clinical utility trials are designed to demonstrate that EsoGuard impacts medical decision making. We have multiple such studies which we expect to launch in the coming weeks, including a retrospective review of Doctor Popper's NYU experience, focused on the impact of EsoGuard on medical decision making; additionally multiple prospective clinical utility studies, including a Lucid-sponsored registry at existing commercial sites, a prospective Lucid-sponsored clinical utility study named Clue, C L U E, and prospective clinical utility studies that are institutionally sponsored at Northwell Health and at Saint Joseph's Health, New Jersey.

With that, I'll pass the baton on to Dennis to provide an update on our financials before opening it up for questions.

Dennis M. McGrath

Thanks, Lishan, and good afternoon, everyone.

Our preliminary and summary financial results for the first quarter ended March 31, 2022, were reported in our press release that was published earlier today. We plan to file our quarterly report for Lucid Diagnostics on Form 10-Q with the SEC on May 16, the due date. At that time, it'll 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 in previous quarters, 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 lab on February 25, just a couple weeks back. We recognized $189,000 of revenue as part of the EsoGuard commercial agreement with ResearchDx for the partial period from January 1, 2022, through the end of the agreement on February 25.

Now that we are operating our own laboratory following the February asset purchase agreement, we will be able to directly bill payers. As Lishan described, direct billing will occur in the second quarter once our new revenue cycle provider comes on line. 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 timing of revenues recognized versus timing they are submitted for third-party reimbursement, until these future conditions are met. The gap in claims submission from this transition will impact near-term GAAP revenue recognized, until the system catches up with claims for tests performed during the transition.

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 five banking analysts who have issued coverage on Lucid, and others doing their diligence. The quantity of EsoGuard tests payable at the CMS payment rate required to meet the 2022 revenue estimates provided by the analysts are achievable. The quantity of collections are highly dependent upon the evolving reimbursement landscape.

With regard to revenue, Lucid recognized approximately $0.2 million of revenues related to EsoGuard for the quarter ended March 31. Despite the negative gross profit for this period, which reflects the initial Test Center startup-related costs at modest volumes, incremental gross margins continue to be around 90% and contribution margins can be north of 60%. These lower test 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 quarter ended March 2022, sales and marketing expenses were approximately $3.3 million for the quarter, compared to $0.7 million for the corresponding prior year, and also reflects an increase of about 12% sequentially, not including stock-based compensation charges. This largely reflects head count increases and related costs.

On the G&A front. G&A expenses were $5.7 million for the quarter ended March 31, compared with $1.2 million for the corresponding period last year, and approximately a 13% increase sequentially. The increases are largely related to compensation and other outside consulting services related to patents, regulatory compliance, legal costs and public company expenses.

R&D expenses for the quarter just ended were approximately $2.9 million as compared to $1.8 million for the corresponding period last year, and are slightly lower sequentially, with the changes between the periods largely tied to clinical trial expenses. There's a table we provide in the press release published earlier that adjusts each of these components of operating expenses for the embedded non-cash stock-based compensation expense. Without the stock-based compensation expense, total operating expenses for Lucid were $8.1 million compared to $2.9 million for the three months ended March 31 in 2021 respectively.

With respect to the loss per share amounts, Lucid Diagnostics reported a first quarter 2022 net loss attributable to common stockholders of $12.3 million or a loss of $0.35 per common share, versus the same period in the prior year of a loss of $3.7 million or $0.26 per share.

The press release also provides a table entitled "Non-GAAP", which highlights these amounts along with non-cash charges, namely depreciation, stock-based compensation, acquisition-related costs, all to enable better understanding of the Company's financial performance. You'll notice from the table, after adjusting the first quarter GAAP loss by approximately $4 million for non-cash charges, the Company reported a non-GAAP adjusted loss for the first quarter of $8.2 million or $0.23 per common share.

Lucid had cash of $47.9 million as of March 31 that compares to $53.7 million at December 31.

As you are aware from our last call, 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 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 as well into 2024. So they consider it part of their duties to understand what the long-term opportunities of the

Company are, and this gives us that vehicle, short of being able to put a shelf in place. There were no issuances of stock under this vehicle so far.

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

Operator

Thank you, sir.

Our first question comes from the line of Ross Osborn with Cantor Fitzgerald. Please proceed with your question.

Lishan Aklog, M.D.

Ross, good afternoon.

Ross Osborn

Hi, congrats on the progress. Thanks for taking our questions.

Dennis M. McGrath

Hi Ross, how are you.

Ross Osborn

Well. How are you all?

Starting off, maybe just would love to hear what you're seeing in the operating environment. Are you seeing any lingering headwinds that are still limiting growth at this point?

Lishan Aklog, M.D.

I assume you're referring to macro issues like COVID and such?

Ross Osborn

Yes.

Lishan Aklog, M.D.

No. I think we're—yes, look, I think with the lifting of various restrictions and so forth, it's really no longer a significant issue. As I've emphasized in the past, because we're entirely outpatient-based, the challenges associated with inpatient access are just something we don't deal with. We're in good shape there.

Ross Osborn

Okay, great. Then, could you provide a bit more detail of where you stand in the commercialization process with regards to the Phase 2 of your plan?

Lishan Aklog, M.D.

Oh, you mean with regard to the Test Centers.

Ross Osborn

Yes.

Lishan Aklog, M.D.

Yes. Right. We are, as we said, we announced the launch of the second stage. We've identified nine locations in nine metropolitan areas across the country, and these include larger states such as California, Texas, Florida, New York, and Ohio and Illinois. We are in the process of doing what we do to open these centers: identifying geography, looking at various factors that impact that, proximity to health facilities and primary care practices, other demographic criteria. We are in the process of hiring and have hired sales reps in these areas. I think I noted during our last call that actually in several of these states, for example in Ohio and in Southern California, we actually already have a presence with market development managers and supporting reps who've been calling on gastroenterologists. It's a little bit different, a little bit of a lower hurdle than in some of the states where we were coming in fresh during the first stage.

Making solid progress at identifying locations and hiring nurse practitioners and sales reps, and we look forward to starting to bring these cities on line very soon.

Ross Osborn

Okay, great. Then a last one for me, regarding the ACG update, I realize it's only been a month, but have you seen any acceleration in testing volumes since that went out, or at least interest?

Lishan Aklog, M.D.

I think I've said this before, so I'll reemphasize that our interactions with clinicians in the field has been relatively straightforward in terms of making the case based on the existing data and the actually existing ACG guidelines, so it's not like there was this big gap that we were trying to fill with these updated guidelines. That's not to, in any way, understate the importance of EsoGuard and EsoCheck being explicitly mentioned, and literally a photograph of the EsoCheck device in the guideline, and the fact that the guideline really addresses us as the only existing test that serves as a non-endoscopic biomarker screening test.

But the greatest impact from the guideline is certainly going to be around reimbursement, as I mentioned in my comments, the proposed LCD specifically references the importance of guidelines in making final coverage determinations, and preceded the publication of this guideline. Also in our private payer engagements, the updated and more specific guidelines are extremely important.

Will it have some effect? Is it a tool in our armamentarium as we talk to GIs and to primary care physicians? Sure. But it's not like we've been struggling to get that message across without it, with the prior guidelines.

Ross Osborn

Okay. Got it. Thanks for taking my questions and congrats again.

Operator

Our next question comes from the line of Mike Matson with Needham and Company; please proceed with your question.

Lishan Aklog, M.D.

Hi Mike.

Joseph

Hey guys, this is Joseph on for Mike.

Lishan Aklog, M.D.

Hi Joe. How are you?

Joseph

Quick question around, Phase 2. I'm doing very well, thank you very much.

In terms of Phase 2 for the launch of the nine additional sites, is this a full launch in 2022, you have nine additional sites that will be up and running and completing EsoGuard tests? Part two to that, is there a certain cadence that you guys are expecting, or is this going to be one lump sum of site additions as we saw in Phase 1?

Lishan Aklog, M.D.

Great, thanks for the question. This definitely is a 2022 plan, so our goal and our ramp-up with regard to sales reps that will be driving cases to these test centers is consistent with a ramp culminating in the fourth quarter of this year. The cadence is we're moving forward on all nine simultaneously. In some locations it's easier to add, to find, to identify and hire nurse practitioners and reps than others, and so this is a parallel path across all nine states simultaneously, in contrast to what we did in stage one, where we started with Phoenix, then we did three and then we did another three.

Joseph

Okay, great. Since you guys really only need a small office at the end of the day, there hasn't been any trouble finding space in these metro cities, correct?

Lishan Aklog, M.D.

No, we have high standards, we look for nice space in nice locations that are convenient for patients to—based on traffic patterns and so forth, but there are plenty of these. These are not big locations, they're two or three offices, and they're not hard to find.

Joseph

Okay, great, and then maybe just one around revenue per test, a big drop off sequentially. Was this all based on cash collection timing, or did this have anything to do with the coverage, the inclusion of coverage from the MediNcrease health plans? I don't know if you guys have already started receiving payments for that …

Lishan Aklog, M.D.

It has nothing to do with—I'll just briefly comment and have Dennis add to it. It has nothing to do with the reimbursement issues around Medicare or otherwise. It's entirely timing with regard to the transition between the model where we were collecting a fixed amount of—fixed payments from ResearchDx, which was the provider of record and the billing entity going into February, and that transitioned to us billing directly. It's entirely based on that, it's not—there's no issue with regard to blips in volume or in reimbursement or anything like that.

Dennis, do you want to maybe elaborate on that a little more?

Dennis M. McGrath

Yes, sure. Joseph, it was purely formulaic. We had been collecting $100,000 per month from ResearchDx, $189,000 recognized, was $100,000 for January, and 25 of 28 days in February times $100,000 gives you $89,000. The tests that we can bill after February 25, because of our own lab, have all been delayed until we have our own revenue cycle provider up and running, so all of the tests that were done in March, which were significant, will be billed and that will occur. It's creating obviously a timing delay, but they will be billed, and we will collect, if it's at the out of network rates, use the—the past as an indication of what the out of network rates are, it's somewhere between $1,000 and $1,300 per test. We expect to be able to collect that. Purely formulaic in terms of the past arrangement and the transition from using a third-party lab provider to our own lab.

Joseph

Okay, great, yes, that makes perfect sense. That's all from us. Thank you guys so much and congrats on the quarter.

Lishan Aklog and Dennis McGrath

Thanks, Joseph.

Operator

Thank you, and our next question comes from Kyle Mikson with Canaccord Genuity. Please proceed with your question.

Lishan Aklog, M.D.

Kyle, good afternoon.

Dennis M. McGrath

Hi Kyle.

Adrian Miller

Kyle, you may be on mute.

Operator

Kyle, your line is live if you are there?

Okay, I guess he is not with us at the moment. Our next question comes from Ed Woo with Ascendiant Capital. Please proceed with your question.

Lishan Aklog, M.D.

Ed, good afternoon.

Edward M. Woo

Thanks for taking my question. In terms of there's a lot of discussions about inflation I'm sure is hitting everybody including you guys. How often do you guys get to change your reimbursement rate? Is this something that is revisited annually? Do you think that's going to have any impact with rising costs, especially for personnel, nurses or whatnot, for your business?

Lishan Aklog, M.D.

That's a great question. I think just at a high level, historically, set reimbursement from payers, whether it be Medicare or private payers, are really not indexed for inflation, and we don't have the luxury of going back to the well on an annual basis. Fortunately, we have really healthy margins with these rates, and we'll be in a position—as it relates to our COGS, hasn't been the cost of goods—sorry, there hasn't been much in the way of an impact there. Although we do see supply chain challenges on parts and subassemblies and things like that. That's something we monitor carefully, and we try really hard to order long leadtime items well in advance.

But on the payment side, we're lucky to get what we get, and we have a healthy margin built in, so.

Edward M. Woo

Great, and then if you tell us a little bit about maybe some of your medical supplies, you don't see any impact near term, because you guys have been able to order early enough in order to get whatever you need to …

Lishan Aklog, M.D.

We do our best, yes. We have had some challenges that I've talked about on PAVmed calls in the last couple of quarters, but with regard to Lucid, it's really fairly—we haven't had any issues. The EsoCheck manufacturing, we have ordered plenty of long leadtime items, our team is very meticulous about that. I didn't mention it in our call, but we are making progress towards wrapping up the transition to our high-volume EsoCheck manufacturer, Coastline, in the coming months. Hasn't been an issue, and with regard to the laboratory itself, reagents and so forth, that hasn't been a challenge either yet. Fingers crossed it'll stay that way.

Edward M. Woo

Great. Well, thanks for answering my questions and I wish you guys good luck. Thank you.

Lishan Aklog, M.D.

Thanks, Ed.

Operator

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

Lishan Aklog, M.D.

Hey Kyle, welcome back.

Kyle Mikson

Hey. Sorry for that.

I'm just curious about the private payer coverage, efforts in the quarter. We saw the CMS updates, and then just there was definitely some—I don't want to say noise, but there was obvious some—it was an exciting quarter for your space in particular. How did private payers interact, or are you even having those discussions today?

Lishan Aklog, M.D.

Yes, we are having those discussions, and the MediNcrease contract is the fruits of that. We have more we're working on, and we expect to steadily, as I said before, the private side is blocking and tackling, door to door combat, not to be overly dramatic about it. But so, we've been—again, I think the proof is in our first commercial payer contract, which happened after the proposed LCD was published.

Kyle Mikson

Okay, and yes, apologies if you've mentioned any of this in advance, obviously I was having phone issues.

Lishan Aklog, M.D.

That’s okay.

Kyle Mikson

Maybe just with the test center expansion, and then as those ramp up, any incremental takeaways? Are you going to be making any changes to those centers going forward? Are you going to accelerate efforts? Just curious, if you take a step back what you think at this point? (Inaudible)

Lishan Aklog, M.D.

I tried to point out, but this maybe is a good opportunity to reemphasize a point that I did touch on in the comments, in my prepared remarks, which is that right now we're looking at a mid-level trajectory, right? As I said, we really feel like the model's well honed, the test center model works. Our training has become really good. We have some predictability now with regard to translating deployment of sales reps and opening of test centers to testing volume.

One of the trends we've noticed, we don't have enough data points to report this but we will in the coming quarters, is that we have seen a nice increase in the proportion of our cases that are coming through from primary care physicians and test centers, and that's an important metric of how that's working.

But we're trying to take a middle ground here. We want to obviously grow testing volume, to generate data for clinical utility, to support reimbursement, and to generally prove that the model works. But we are also cognizant of the fact that right now we don't have predictable reimbursement, we are starting to bring some of that in, but we're not at the stage where a large proportion of these cases are getting full reimbursements.

With an eye towards being protective of our cash and our capital, we're trying to take a middle of the road approach with regard to the throttle, to use a metaphor, but once we have more predictable reimbursement and we start getting more of these private payer agreements under our belt, then we have the ability to dial these up and to increase the cadence and so forth. But our plan really for the rest of this year is to stick with our targets with regard to the expansion of our sales force and the expansion of the test centers, to give us time to start getting more predictable reimbursement. Hopefully that makes sense.

Kyle Mikson

Sure. Maybe if I could ask another, just on the LCD, and maybe fully reflecting that they do not account for those guidelines yet, I just wanted to ask though, it seems like the EsophaCap type device is included in the LCD? I know the guidelines aren't included, maybe that can get EsoCheck in there. When is the next milestone or benchmark we should be looking for? I know there was a recent meeting, just curious what is on the horizon, and—yes; and what (inaudible)

Lishan Aklog, M.D.

There's a lot to clarify.

The guidelines recommend non-endoscopic biomarker testing with a capsule device. That includes EsoCheck, just to be clear, it's right there, there's a photograph of it, the results from the FMESTM (phon) paper are in there. Although EsophaCap is there as well, EsoCheck is featured, and we consider the guidelines supporting EsoGuard and EsoCheck. Don't want there to be any confusion about that. That's for the guideline.

The open meeting, I thought, went well. It was substantive, it was serious. We had plenty of opportunity, us and other stakeholders, to describe what we think are useful modifications to the LCD. The goal is to have the LCD really be an operational foundational LCD, so that the criteria are a bit clearer, and that, when we get the sufficient clinical utility data to submit as part of a technical assessment, it doesn't require revisiting and reopening the LCD. That was really the focus of our comments as well as others, and the written comments are going to really push that a lot harder from us, as well as multiple other stakeholders.

As I mentioned, the open meeting occurred yesterday, the written comments period for Palmetto end on Saturday, but we were also notified that Noridian, which is the Medicare contractor that covers California and covers the lab there and will be ultimately the contractor of record, also scheduled an open meeting and a comment period. The open meeting there is going to be on May 26, and the comment period ends on June 11. That gives us another bite at the apple to really make the case and make sure that the final LCD that comes of this really gives this, not just us but the field, the opportunity to get coverage for this really important, and now guideline-based, option to perform widespread testing in these at-risk patients.

Kyle Mikson

Okay. Yes, we're all looking forward to seeing how the guidelines impact the LCD hopefully, so we'll find out soon. Thanks, guys, appreciate it.

Lishan Aklog, M.D.

Okay. Thanks a lot.

Dennis M. McGrath

Thanks, Kyle.

Operator

Thank you. At this time, we have reached the end of the question and answer session, and I will now turn the call back over to Lishan Aklog for closing remarks.

Lishan Aklog, M.D.

Great. Well, thank you, everyone, for joining us today, and as always, great questions. As always, we look forward to keeping you abreast of our progress via press releases and these conference calls. The best way to keep up with Lucid news updates and events is to sign up for our e-mail alerts on the Lucid investor website, and to follow us on social media on LinkedIn, Twitter, and YouTube, as well as through our website. You can also contact Adrian Miller, our VP of Investor Relations, at akm@pavmed.com.

Thanks again, and have a great rest of your day.

Operator

This concludes today's conference. You may disconnect your lines at this time. Thank you for your participation and have a great day.