S&P Global
Market Intelligence

PAVmed Inc. NasdaqCM:PAVM

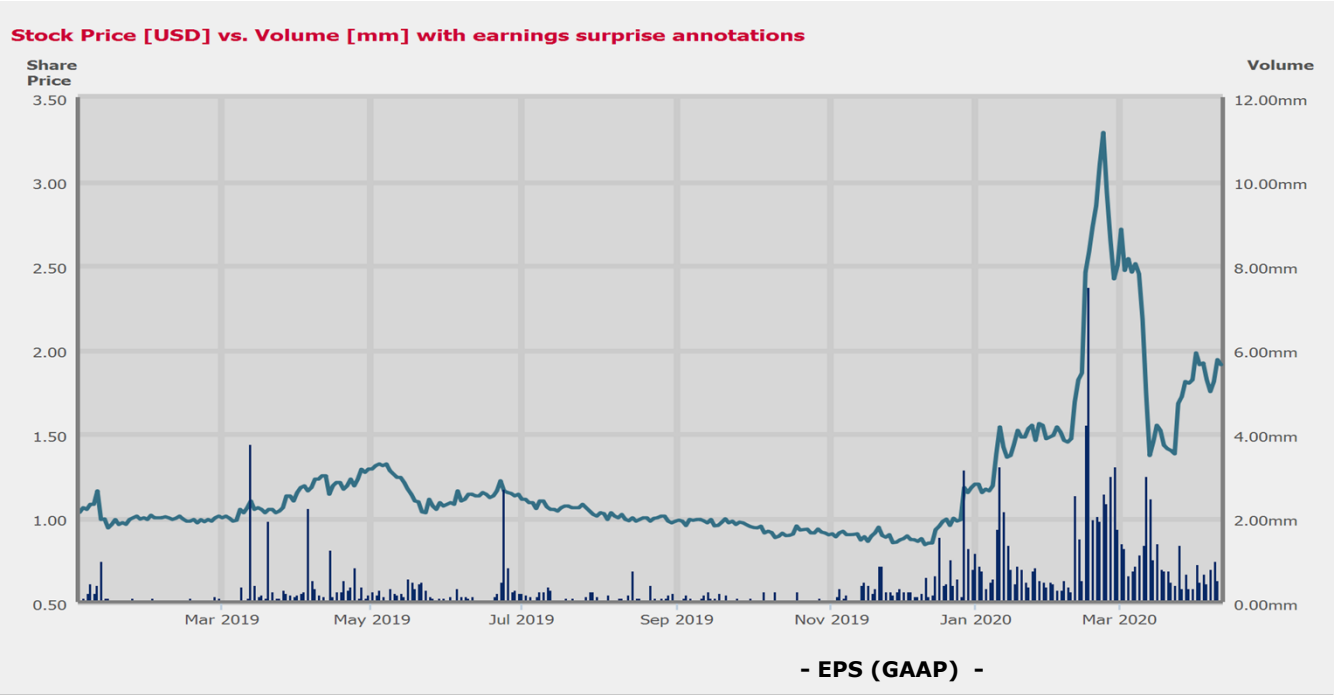
FQ4 2019 Earnings Call Transcripts

Thursday, April 09, 2020 8:30 PM GMT

S&P Global Market Intelligence Estimates

	-FQ3 2019-			-FQ4 2019-		-FY 2019-	-FY 2020-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	SURPRISE	CONSENSUS	CONSENSUS
EPS (GAAP)	(0.10)	(0.10)	NM	(0.11)	NM	(0.48)	(0.38)
Revenue (mm)	0.00	0.00	0.00	0.00	0.00	0.00	7.04

Currency: USD
Consensus as of Feb-25-2020 12:35 PM GMT



- EPS (GAAP) -

	CONSENSUS	ACTUAL	SURPRISE
FQ4 2018	(0.14)	(0.27)	NM
FQ1 2019	(0.13)	(0.13)	NM
FQ2 2019	(0.13)	(0.13)	NM
FQ3 2019	(0.10)	(0.10)	NM

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Call Participants

EXECUTIVES

Dennis M. McGrath
President, CFO & Secretary

Lishan Aklog
Chairman & CEO

Mike Havrilla
Director of Investor Relations

ANALYSTS

Anthony V. Vendetti
Maxim Group LLC, Research Division

John Andrew Levin
Levin Capital Strategies, L.P.

Unknown Analyst

Presentation

Operator

Greetings, and welcome to the PAVmed Inc. Business Update Conference Call. [Operator Instructions] As a reminder, this conference is being recorded.

I would now like to turn the conference over to Mike Havrilla, Director of Investor Relations for PAVmed. Thank you. Please begin.

Mike Havrilla
Director of Investor Relations

Good afternoon, everyone. This is Mike Havrilla, PAVmed's Director of Investor Relations. Thank you all for participating in today's business update conference call. Joining me today on the call are Dr. Lishan Aklog, Chairman and CEO; Dennis McGrath, Chairman -- sorry, President and Chief Financial Officer.

Before we begin, I'd like to caution that comments made during the call by management will contain forward-looking statements regarding the operations and future results of PAVmed. I encourage you to read the company's filings with the Securities and Exchange Commission, which identifies specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements. Factors that may affect the company's results include, but are not limited to, the uncertainties inherent in research and development, including the cost and time required to advance products to regulatory submission; whether and when products are cleared by regulatory authorities; market acceptance of products once cleared and commercialized; company's ability to raise additional capital; and the competitive environment.

PAVmed has not yet received clearance from the FDA or other regulatory bodies to market many of its products. New risks and uncertainties may arise from time to time are difficult to predict. All these factors are difficult and impossible to predict accurately, many of them are beyond the company's control. For a further list and description of these and other important risks and uncertainties that may affect future operations, see Part I Item 1A entitled Risk Factors in PAVmed's most recent annual report on Form 10-K filed with the SEC, any subsequent updates filed quarterly reports on Form 10-Q.

Except as required by law, PAVmed disclaims any intention or obligation to publicly update or revise any forward-looking statements to reflect changes in expectations or in events, conditions or circumstances on which those expectations may be based or that the likelihood -- actual results would differ from those contained in the forward-looking statements.

As a note, we have just submitted our press release, which should be distributed shortly by our partner and that will be forthcoming.

With that said, I'd like to turn the call over to Lishan Aklog. Dr. Aklog.

Lishan Aklog
Chairman & CEO

Thank you, Mike. Good afternoon, everyone, and thank you for joining us on this quarterly call to update you on our business and discuss our recent financial results. Those of you who have been keeping up with our press releases know that we have been extraordinarily active in the months since our last update, with many exciting accomplishments and even more milestones we look forward to in the upcoming months.

Let me start first with a few words about the enormous challenges we are all facing as a result of the COVID-19 pandemic, which, in just a few months, has exacted a tremendous human and economic toll on our industry, on our nation and on our Board. I hope and pray that all of you are weathering the level of storm as best you can and are keeping yourselves and your loved ones safe. I am deeply moved that many of you have taken the time to reach out to us to express your support and continued confidence in us as well as to express your concerns for our safety and health. Thankfully, all members of the PAVmed

family, including our employees and critical partners are healthy, safe and able to continue their important work. We are very fortunate that our corporate structure and culture are well suited to address these challenges with minimal short-term and no anticipated long-term disruptions to our strategic plan.

For example, our employees and partners are already dispersed over many states across the nation and are already proficient and productively utilizing modern remote collaboration tools, which they've been doing since our inception. In addition, our team has always embraced a sort of special forces type culture as all members able to operate autonomously when necessary and spontaneously collaborate to address short-term challenges as they arise, while still systematically advancing and executing on our long-term strategic plan.

Before providing you with updates on our product portfolio, I'd like to give you a general summary of how each area of our business has or has not been affected by the pandemic and how we are responding for those that are affected.

First, financial and administrative perspective. As we previously announced, and as Dennis will explain in more detail shortly, we recently completed the November 2019 convertible note financing, which strengthens our balance sheet and enables us to fund our full strategic plan for the foreseeable future as we advance through upcoming milestones. We are also confident that we'll be able to continue to finance our operations as required until we begin to generate meaningful revenue through commercial sales or non-dilutive financing through M&A activities.

Our executive leadership team has implemented a cash management plan focused on preserving cash in areas where activities are inevitably throttled as a result of the lockdown. Our full-time headcount remains lean, our employees and the unique expertise they bring to our efforts are understandably our most critical resource that we do not plan to trim payroll. This makes us eligible for the Paycheck Protection Program within the federal stimulus package. We have already completed the application and, if approved, will result in proceeds of approximately $300,000 structured as a forgivable loan.

On the product development and manufacturing side, we currently utilize over a dozen partners across the U.S. in the design, development, testing and manufacture of our product. All these partners are designated essential services, remaining fully operational with no meaningful disruption in their activities on our behalf. Our supply chain has also remained intact, and we believe it will continue to do so without any disruption. The only 2 components we source outside of the U.S. are 2 electrical parts of our CarpX device we sourced in China. Although we already had sufficient inventory of these parts to get us through initial CarpX commercialization, these manufacturers are already back online following a short COVID-19 disruption earlier this year.

What about on the regulatory front? We, with the help of our regulatory consultants, have multiple active engagements with the U.S. FDA, including for CarpX, PortIO, EsoGuard and EsoCheck. We also have extensive ongoing work with our regulatory consultants on other portfolio products that are not yet before the FDA.

I'm happy to report that none of this work has been materially impacted by COVID-19. Our regulatory consultants are fully operational using remote collaboration tools, the FDA reviewers assigned to our products are also working remotely, and based on ongoing informal communication, appear to have a bandwidth to work on our applications. Some initial concerns that assigned staff would be diverted to COVID-19-related work has not materialized. Most importantly, we have not received any formal or informal indication that we should expect any COVID-19-related delays in the review process.

Two areas where we have had to actively manage COVID-19-related disruptions are our commercial and clinical research activity. On the commercial side, the fundamental challenge that we and essentially all medical device companies are currently facing is that the health care system is obviously overwhelmed by the pandemic. The system has been forced to divert resources and drastically modify operations to care for COVID-19 patients while protecting health care workers. Nonemergency care, including surgical and diagnostic procedures have essentially come to a standstill. Although we can't predict when the engine will start-up again, it is reasonable to assume that non-COVID-19 health care will be among the first things to come back online since one cannot and definitely defer necessary but nonemergency procedures.

I will discuss our EsoGuard commercial activities later, but I am proud to report that Shaun O'Neil, our Chief Commercial Officer, and his team have rapidly adapted to the situation on the ground in pretty remarkable ways. Recruitment of independent sales reps has been unaffected, and their sales training has actually moved virtual without missing a beat. So as sales calls with physicians who are -- which are also being held virtually. Many of the target physicians are, in fact, well positioned to participate in virtual sales call because they are working from home or from their offices using telemedicine and are not necessarily on the front line of the COVID-19.

They mentioned another area that we're managing is our clinical research activity. Life sciences companies face the same challenges with clinical research activities as with commercial activity. Nearly all non-COVID-related clinical research has come to a grinding halt nationwide, including intramural academic research trials and corporate-sponsored trials by large and small companies. We have active or soon to be active clinical trials involving multiple products, including EsoGuard, EsoCheck and PortIO, which are affected by this freeze. I will update these individually a bit later.

Although for the time being, patients cannot be enrolled and procedures cannot be performed, our clinical research team, led by Randy Brown, has done a similarly remarkable job of making sure that we continue to advance the ball where we can so that we are poised to make up for lost time when things eventually open up again. For example, all of these studies, we -- for all of these studies, we continue to work with IRBs on protocol approval and with medical centers on negotiating and executing clinical trial agreement. Some principal investigators continue to actually actively recruit patients so they are ready to officially enroll once we are back online.

Let's go through some of our recent accomplishments and upcoming activities and milestones. Let me start by highlighting some of these. In December, our majority owned subsidiary, Lucid Diagnostics, launched our EsoGuard Esophageal DNA test as the first and only commercially available DNA test to facilitate the detection of Barrett's esophagus with or without dysplasia as well as the esophageal cancer.

In January, we launched 2 multicenter clinical trials to support future regulatory clearance of EsoGuard and EsoCheck as an FDA-registered In-Vitro Diagnostic or IVD. The first patient was enrolled and underwent their procedures in February. Also in January, we held a successful presubmission meeting with the FDA on our PortIO product, focused on the design of a clinical safety study in support of a de novo application.

February brought many additional Lucid accomplishments. We are excited to receive FDA breakthrough device designation for EsoGuard and EsoCheck, which, in addition to validating their potential life-saving impact, provides priority expedited FDA assessment and review and potentially accelerated CMS coverage. We entered into successful -- sorry, we entered into sponsored clinical research agreements with 2 major academic centers: the Fred Hutchinson Cancer Research Center in Seattle, Washington; and the University of Pennsylvania in Philadelphia to evaluate EsoCheck in both Barrett's Esophagus progression and eosinophilic esophagitis.

We also announced a new product, our EsoCure Esophageal Ablation Device, a disposable single-use thermal balloon ablation catheter, which is designed to use our patented Caldus Technology to treat this dysplastic Barrett's before it can progress to highly lethal esophageal cancer and to do so without the need for complex and expensive capital equipment.

We also participated in 2 successful meetings with the Medicare contractor, Palmetto GBA, and its molecular diagnostics program, MolDx, one in February, focused on EsoGuard payment and another 2 weeks ago focused on EsoGuard coverage.

In March, the FDA accepted our 510(k) resubmission for CarpX -- for our CarpX minimally invasive carpal tunnel device, incorporating data from our first -- from our successful first-in-human CarpX clinical safety study. Also in March, EsoCheck was honored as a Silver winner of the 2020 Edison award.

This month, we completed training of our first cohort of 24 highly experienced independent gastroenterology sales representatives, covering a large swath of the country, who are now actively engaging with longtime physician partners on EsoGuard and EsoCheck. And just yesterday, despite the

pandemic and a massive regulatory backlog in Europe due to systematic changes, we received a firm date in June for the stage 1 audit of our quality system by our EU notified body, which allows us to restart our efforts to pursue EU CE Mark clearance of CarpX and PortIO.

Finally, as always, we continue to expand and advance our extensive intellectual property portfolio, which now includes 129 issued and pending patents, assigned or licensed to PAVmed and its subsidiaries. And we continue to have the success of securing allowances and advancing prosecutions.

We have many key upcoming activities and milestones for us to look forward to in the coming months. Here are a few highlights. We expect to receive a response from the FDA on our CarpX 510(k) resubmission sometime during their 90-day substantive review window, which extends into June. Despite the limitations imposed by COVID-19, we will be accelerating and expanding our commercial activities for EsoGuard, including virtual sales and professional education as well as aggressive marketing, targeting physicians and patients to strengthen brand recognition, generate awareness of underlying conditions and support the sales process. We will continue to aggressively pursue our discussions with Palmetto GBA and other Medicare contractors and hope to secure payment and coverage decisions for EsoGuard's CPT code as soon as possible.

Once the COVID-19 limitations begin to receive, we will restart both our commercial and clinical EsoGuard procedures and enrollment in our 2 IVD clinical trials. We'll also launch 4 additional clinical trials, involving EsoCheck and PortIO, which are currently on hold. We also have several very active M&A and partnership discussions involving NextFlo, EsoGuard, EsoCheck and DisappEAR, which I'll describe in more detail later, but which we hope to consummate in the coming months.

Finally, we still hope to achieve a critical accuracy milestone and benchmark in animal testing of our majority owned subsidiary, Solys Diagnostics, noninvasive laser-based blood glucose diagnostics device.

Now I'd like to now proceed to some more specific updates across our 4 divisions: GI Health, Minimally Invasive Interventions, Infusion Therapy and Emerging Innovations.

Our GI Health division is building a portfolio of complementary products designed to diagnose and treat conditions of the esophagus, including a spectrum of conditions arising from chronic heartburn or gastroesophageal reflux disease leading to esophageal cancer as well as a prevalent inflammatory condition called eosinophilic esophagitis. Two products, EsoGuard and EsoCheck are commercially available. We hope to commercialize another product EsoCare in 2021. In addition, there are other potential pipeline products, which are the subject of active research programs within this division.

Now let's start with EsoGuard and EsoCheck. We continue to make excellent progress on these 2 groundbreaking products less than 2 years after licensing them from our partners at Case Western Reserve University. EsoGuard and EsoCheck are designed to facilitate early detection of conditions leading to esophageal cancer in patients with chronic heartburn. It's important to understand these -- that these conditions lie in a spectrum. So chronic heartburn can lead to benign changes in the surface cells of their lower esophagus of Barrett's esophagus, which can transform into precancerous changes or dysplasia, which in turn can lead to highly lethal esophageal cancer.

These are truly groundbreaking products. The National Cancer Institute highlighted them as one of the year's significant advancements in cancer's prevention in its 2020 reported progress. And as I mentioned, the FDA granted breakthrough device designation, which validates its potential life-saving impact. And EsoCheck, as I mentioned, was also recently recognized as a game-changing innovation and among the best new medical device products of the year by the Edison Awards honoring Thomas Edison.

So briefly, how do they work? EsoCheck is an FDA-cleared cell collection device, which can perform targeted and protected sampling of cells from the lining of the lower esophagus as part of a 5-minute noninvasive office-based procedure. It serves as an alternative to an invasive upper endoscopy performed under anesthesia in a hospital or dedicated endoscopy center. EsoGuard is a highly accurate next-generation sequencing diagnostic assay, which detects methylation changes of 31 sites on 2 genes, which occur in patients along with Barrett's Esophagus to esophageal cancer spectrum. EsoGuard has performed

on samples collected with EsoCheck and is commercially available in the United States as a Laboratory Developed Test or LDT.

Although professional society practice guidelines recommend screening in over 10 million high-risk GERD patients to detect and treat Barrett's before it progresses to cancer, fewer than 10% actually undergo screening using invasive upper endoscopy. The tragedy of these conditions is that the vast majority of patients diagnosed with esophageal cancer are not aware that they have underlying Barrett's and that the progression of cancer could have been prevented through careful monitoring and treatment if the Barrett's had been diagnosed earlier. Sadly, over 80% of these esophageal cancer patients will die within 5 years of diagnosis.

Based on very modest penetration of U.S. GERD patients currently recommended for Barrett's screening according to published guidelines and on a Deloitte market assessment we commissioned, we believe that the estimated addressable domestic market opportunity for these products is several billion dollars.

The most important update for these products is on the commercial front. We are commercializing EsoGuard using a hybrid model with internal sales management, marketing and professional education, working closely with independent sales representatives across the country. And in addition to Shaun O'Neil, our Chief Commercial Officer, we have hired 2 outstanding regional sales managers covering the Eastern and Western U.S. and a fantastic Director of Marketing and Communications. As I previously mentioned, last week, we completed training of the first cohort, these 20 highly experienced sales reps cover most of the country. They are all senior professionals, averaging at least a dozen years in the field, calling on physicians on behalf of well-established leading companies in the space. Most bring deep long-standing relationships with gastroenterologists in their territories. They currently had access to their physicians through virtual sales calls despite the lockdown, and we are confident they'll be first in line once things open up.

Several accounts that completed training had product on the shelf have performed procedures on patients before the shutdown of nonemergency procedures. Since then, our sales teams have been in discussions with well over 100 accounts who will be in an excellent position to begin performing procedures once things open up.

As I mentioned earlier, we have initiated an aggressive marketing campaign of the professional journals and social media, targeting physicians and patients to strengthen EsoGuard and EsoCheck brand recognition. Engagement with these activities has been excellent, and the feedback has been very positive. We're also making solid progress on the reimbursement and coverage front. As we've previously mentioned, EsoGuard received a CPT code last year. We successfully advanced it through CMS process. We were granted gap-fill designation, which permits us to proceed with payment and coverage, discussions with designated Medicare contractors and private payers. As I mentioned, we had 2 successful meetings with Palmetto GBA and MolDx. We're working with our consultants to finalize a detailed dossier in support of our payment and coverage request and look forward to further discussions culminating in a successful outcome.

There are many additional exciting developments and future activities in this division. As I mentioned, we're excited about the progress we're making on a EsoCure Ablation Device. This, as I mentioned, is the disposable single-use thermal balloon ablation catheter, designed to advance through the working channel of a standard endoscope and uses our patented Caldus Technology to ablate the esophageal tissue. Once cleared and commercialized, EsoCure will allow physicians to treat dysplastic Barrett's before it could progress to cancer and do so without the need for complex and expensive capital equipment like current technologies from Medtronic and others do.

We expect to complete development and FDA 510(k) submission to be secured by early 2021 and hope to have it commercialized later that year. As previously noted, we've launched these 2 international multicenter clinical trials, ESOGUARD-BE-1 and BE-2 to support future PMA submission for FDA registration of EsoGuard and EsoCheck as IVDs. One of the studies is a screening study of high-risk GERD patients, and the other is a case-control study of patients with known Barrett's or a more advanced condition. We have over 60 sites in the U.S. and Europe. Clinical trial enrollment has paused after the first patient was enrolled and underwent procedures last month. We have a couple of patients scheduled for

later this month, but do not expect to be in full swing until clinical activities resume in the coming weeks and months across the country and in Europe.

Meanwhile, our clinical research team is continuing to secure IRB approvals and complete contracts so we can make up for lost times when things open up. As I mentioned, we have 2 other additional EsoCheck clinical trials on hold with Fred Hutch one and the one with the University of Pennsylvania, and they are both -- we look forward to advancing those as things open up.

Finally, we have 2 active partnership discussions involving GI Health products. We have a strong interest from an established diagnostic company outside the U.S. to perform and market EsoGuard in that region. We also have been offered the opportunity to license highly accurate eosinophilic esophagitis biomarkers from a major academic medical center for commercialization as an LDT. I expect this license agreement to be consummated soon.

Let's move on to Minimally Invasive Interventions and our CarpX product. CarpX is our patented single-use disposable minimally invasive device, designed to treat carpal tunnel syndrome while reducing recovery times. The balloon catheter device is inserted under the scarred ligament, tensioning it while pushing the nerve and tendons away. When activated, bipolar radiofrequency electrodes precisely cut a ligament from the inside out in a matter of seconds. We believe CarpX will dramatically reduce recovery times compared to traditional open surgery, targeting an estimated $1 billion immediately addressable domestic market opportunity.

We are seeking FDA 510(k) clearance to commercially market CarpX for minimally invasive carpal tunnel release. The FDA recommended a clinical safety study to support 510(k) resubmission, and we consulted closely with them during the development of the study protocol. As we've previously announced, the clinical safety study was successfully completed and incorporated into a 510(k) submission, which is currently under FDA review.

Briefly, 20 carpal tunnel syndrome patients in New Zealand underwent successful CarpX, minimally invasive carpal tunnel release. All patients met the study's prespecified effectiveness endpoint, which was clinical device technical success, defined as the endoscopic confirmation of complete division of the transverse carpal ligament. CarpX consistently cut the ligament clearly and precisely without evidence of thermal spread beyond the targeted tissue cutline. Procedure times fell after a short learning curve, indicating that the procedure can be performed in the same or less time as traditional open surgery.

Two weeks and 90-day postoperative follow-up rates were 100% and 95%, respectively, exceeding the targeted 80% rate recommended by the FDA. The only loss to follow-up was a patient who was documented to be back to normal with resolution symptoms at 6 weeks. He opted not to return to the study site for his 90-day follow-up visit because he was traveling a significant distance away and was overall satisfied with the procedure's outcome.

All patients who completed follow-up met the study's prespecified primary safety endpoint, which was defined as device safety with no serious device-related adverse events. Patients underwent additional prespecified outcome assessments at baseline and during postoperative follow-on visit. These assessments use well-established, standardized and validated measures to assess patient satisfaction as well as changes in symptoms, motor and sensory function and neurophysiologic parameters following the procedure. The excellent results of these prespecified outcome assessments following CarpX were similar to or better-than-expected results from traditional open surgery.

Since the FDA accepted our 510(k) resubmission application, we've received some informal communications with them and look forward to their formal response this quarter during the 90-day substantive review window, which extends to June.

Now next, some brief highlights from our Infusion Therapy division, which includes PortIO and NextFlo. PortIO is our implantable intraosseus vascular access device, which allows direct access to the bone marrow to deliver medications, fluids and other substances. We are seeking an initial short-term implant duration indication through the FDA's de novo pathway. In January, we participated in a successful

presubmission meeting with the FDA focused on the clinical protocol for a single -- for a small single-center clinical safety study in New Zealand and on the target population in our proposed label.

The short-term clinical safety study as well as a long-term study we had planned to perform in Colombia, South America are both on hold due to travel and clinical limitations. We're continuing with the necessary administrative work, so we can proceed immediately to training and enrollment once these -- once things open up. And we're also exploring whether it might be advantageous to move the clinical safety study to the U.S. as an IDE study.

Our NextFlo infusion system, just a brief comment about that. This system delivers highly accurate gravity-driven infusions independent of the height of the IV bag and seeks to eliminate the need for complex and expensive electronic infusion pumps for most of the estimated million infusions delivered in the United States each day. We are successfully advancing the NextFlo infusion test through design control development and testing with the goal of a 510(k) submission later this year.

An exciting development that arose from M&A discussions with key strategics in the space has been an expansion of the applications using NextFlo as a platform technology. These are applications that we had always contemplated and are now pursuing at the request of these strategics. These applications include disposable infusion pumps for home use, packaged drug infusions, military and pharma applications and intravenous nutrition. Our M&A discussions remain active with several large companies in the space, and we look forward to consummating a deal as soon as possible.

I wish I had more time to update you on exciting projects we're working on in our Emerging Innovations division, again, a few brief highlights. Our DisappEAR resorbable pediatric tubes, which are manufactured from aqueous silk and seek to revolutionize the care of the estimated 1 million children who undergo bilateral ear tube placement each year. We are very close to securing a commercial development and manufacturing relationship with a large multinational company, which has developed expertise and processing scope for commercial use. Their technique allows the ear tubes to be injection molded instead of machined, which greatly enhances the commercial potential of this product. And then as I briefly mentioned, our -- in our subsidiary, Solys Diagnostics, the research and development plan for our noninvasive laser-based blood glucose monitoring technology is progressing very well, and we expect to complete bench top and animal testing in the coming weeks.

Our Emerging Innovations team is also working on several exciting products, including products in the ECMO cardiopulmonary support and ventilation areas. Both of these areas are highly relevant to the treatment of COVID-19 patients and other respiratory conditions.

I'll now pass the mic on to Dennis for a review of our financial results.

Dennis M. McGrath
President, CFO & Secretary

Thanks, Lishan, and good afternoon, everyone. I'll be brief as our financial results for the quarter and year ended December 31, 2019, were reported in our press release that was published just prior to the beginning of this call.

Our annual report on Form 10-K will be available at sec.gov and our website early next week. The complexities involved with accounting for the noncash charges related to our fourth quarter convertible debt financing, coupled with lawyers, auditors, consultants and staff working remotely, made the extension unavoidable. You'll recall that even as late as just last week, we completed the second half of the November 2019 financing, which Lishan spoke to, which also impacted the related registration statement that was filed in December and amended on March 30. The elongated registration process was impacted in part by the SEC's availability challenges as they were working at home as well. Nonetheless, the financial results I will be providing today are consistent with the preliminary results reported on March 30 as available to you and reported on Form 12b-25 extension filed at that time.

So with regards to the financial results, research and development expenses for the fourth quarter of 2019 were $2.3 million, up from about $1.4 million for the same period in 2018 and about $700,000 higher sequentially. The year-over-year increase reflects incremental hiring of Chief Medical Officer, Chief

Operating Officer and Engineer PAVmed as well as clinical trial-related expenses, many of which Lishan just went through for CarpX and particularly EsoGuard is the early setup cost for the IVD clinical trial began in earnest in the fourth quarter.

General and administrative expenses were $2.3 million for the fourth quarter of 2019, compared with $1.9 million for the same period in 2018 and were higher by about $600,000 sequentially. The sequential increase reflects the financing transaction costs in the fourth quarter related to the November convertible debt financing. The year-over-year increase reflects an increase in compensation-related costs, particularly stock-based compensation, increased IP legal costs and an increase in Investor Relations activity.

PAVmed reported a net loss attributable to common stockholders of $6.3 million or a loss of $0.19 per common share. However, our press release provides substantially more detail related to the noncash charges occurring in the current and prior periods. Also, the press release provides a table entitled Non-GAAP Measures, which highlights these amounts along with interest expense and other noncash charges like depreciation, stock-based compensation, financing-related costs, should enable you to have a better understanding of the company's financial performance. You'll notice from the table that after adjusting the GAAP loss by these charges, the company reported a non-GAAP adjusted loss for the 3 months ended December 31 of $3.9 million or about $0.12 per common share.

PAVmed had cash of $6.2 million as of December 31, 2019. Subsequent to the year-end and just last week, the company received net proceeds of approximately $6 million from the prepayment of the investor notes received in the November private placement transaction with 2 institutional investors. You will recall, the company entered into a Series B senior secured convertible note with each of the Series A investors that gave us this option for an additional $6 million. That funding, last week, was in connection with these previously announced Series B investor notes.

Our cash balance at March 31 is approximately $8.5 million, and we're very confident that we will continue to have access to additional funding to finance our ongoing operations as needed, which Lishan has alluded to earlier in the prepared remarks.

Furthermore, as of January 2020, we accumulatively paid down approximately $7.7 million of the previous December 2018 senior convertible debt, which had an initial balance of just under $8 million at the outset and leaves a remaining balance of $50,000.
So with that, operator, we could open it up to additional questions from our audience.

Question and Answer

Operator

[Operator Instructions] Our first question comes from the line of Anthony Vendetti of the Maxim Group.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Dennis, Lishan, thanks so much for doing the call and also for going over the COVID-19 impact across all facets of your business. Seems like most of -- well, all of your business is continuing to operate. And you've been operating, and they have had experience operating remotely. So that side of the business seems fine. It's the commercial side that and the delay some of the trials and so forth, but that's to be expected. I was wondering if you could just talk a little bit more about CarpX. Obviously, this is a resubmission. So you've had a lot of conversations -- many conversations with the FDA over this time period. Do you -- I mean, if it wasn't for the COVID-19 situation, do you believe they would have needed the full 90 days? And with the current situation, is it hard to gauge whether you think they will take the full 90 days to review? Or what -- based on your conversations with them, where are they at in terms of the review process?

Lishan Aklog
Chairman & CEO

Sure. That's a great question. And obviously, we have to be careful about predicting anything, but I can make -- I can provide some insights that you alluded to. One of them is that we've been involved with the FDA on this product. This is a resubmission, as you noted. And what I did mention was that we have the same lead examiner, who was very supportive of our application at the beginning. So that was -- we were fortunate to have that, that's not guaranteed, as you may know.

So yes, for the same people who work with us on developing the preclinical testing and documenting the lack of thermal spread and the thermal safety, the preclinical setting in animals and cadavers, the same people who worked with us to develop the protocol for the clinical study are now reviewing this.

As I mentioned, we don't really have any sense that they're being affected by the epidemic -- by the pandemic there. They acknowledge receipt. They've -- they quickly proceeded with the acceptance checklist. I've mentioned, we've had some informal communications that indicate that they're deep into the weeds of the application.

So we've had no indication that there is a slowdown. And we've always been hopeful that because -- and now because it's the same group, that because this is a resubmission, that there would be an opportunity for things to move quickly. But there's no way we can really predict that. I mean this is the counterargument to that is that we are submitting a clinical trial, even though it's small and there's 20 patients. It's a substantial amount of data and information that they have to go through. So I wouldn't want to presume that things will move more quickly than normal. But I can say that I don't think we're slowed down by COVID. We're very fortunate that we have the same group reviewing it. And we've had some informal communications that indicates that they are well into their -- so they're deep into their review of the application.

Anthony V. Vendetti
Maxim Group LLC, Research Division

No, that's very helpful, Lishan. And if you could just give a little bit more color on EsoGuard in terms of feedback from KOLs during your initial commercial launch here. How is that going...

Lishan Aklog
Chairman & CEO

Yes. Sure. I mean, it's been -- I mean, I'm just going to sound cheerleader-ish a little bit, but it's not absolutely remarkable. I mean, the feedback has been excellent. We have really solid people on the ground. Our Eastern sales manager is a long-time veteran of the GI space. And the people who are -- the independent reps who are already on the phone and on e-mail contacted to doctors are having these conversations, and these conversations are going very well. I mean, we have them well trained with objection handling to handle all the various tasks that these conversations can take about how it relates to their existing endoscopy business and so forth. And the feedback we're getting, and I receive a lot of these is that people ultimately get it. They understand that there's an opportunity here to enlarge the funnel and to bring more patients that are not in this group of sort of 90% of the patients should be getting screened who were not getting screened as a way to expand the funnel and to ultimately both benefit patients and benefit their practice.

The practice -- some of the larger practices already have a subset of their physicians who run esophageal clinic, they run motility and VH clinic. And any concern we had about sort of where this would fit in within their practices, it's probably not material. The feedback has been, yes, let's get started and let's get rolling and get these patients into these clinics. So I really can honestly say the feedback has been extremely positive. And once we -- once they're actually able to do procedures, we expect -- we have to be pretty quick and substantial.

Anthony V. Vendetti
Maxim Group LLC, Research Division

Yes. It's great. And so just obviously, the commercial launch is going to be stalled by COVID-19, do you think there'll be some pent-up demand as you're having these conversations?

Lishan Aklog
Chairman & CEO

Yes. No, definitely. Yes. It started to wrap. But yes, exactly. That's the point I was trying to get across, which is that there is still a lot of activity. And because of the existing relationships of these reps, they are able to pick up the phone and talk to their long-time physician colleagues about this technology and begin that process. So all of that activity has really been -- it's somewhat affected, but it's been proceeding pretty aggressively. The only thing we can't do are actually procedure, right? And so I think the way you describe it is exactly right, but there will be pent-up demand and that will make up somewhere for lost time because of the activities that are currently ongoing.

Operator

[Operator Instructions] Our next question comes from [Asif Ahmed].

Unknown Analyst

Just I want a quick follow-up on Lucid and since you guys have all the stuff lined up. Would there be any chance -- you don't have to go into details if there something is confidential, obviously, but any chance that you guys are spinning off running Lucid as a separate entity? I mean, has there been any plans or anything? We just want to -- obviously, many of the guys that I'm working with, they would like to know and are really interested in if there's anything you can say that, that is obviously safe and secure to say.

Dennis M. McGrath
President, CFO & Secretary

That's a great question, and it's one that is a frequent inquiry made of us. And so I'm not going to answer your question very specifically because it is a strategic plan that the Board will mull over continuously. I'm going to give you a more broad answer. Our plans this year include a bunch of activities that Lishan thoroughly went through that we'll modulate our burn rate from where it is now and where are the clinical trials once they ramp up. And there are many access points for us to finance that business. We can finance as we have at the parent level. We can finance with debt. We've been creative with that.

Fortunately, we'd evolve to a level of sophistication that the early days of PAVmed's immaturity had different types of financing structures. One, as you suggest, is a financing inside the subsidiary in

whatever form that takes private or public financing. It's a tool, a proceeds from an M&A transaction on one of our assets and revenues for the second half.

So your question, although I can't specifically answer because no firm decision has been made about that, the ability to finance inside a subsidiary and treat that as its own separate entity. Right now, we look at this as a single segment with 4 divisions. But what you're suggesting is something that could be available to us in the future. And as it continues to evolve, we'll be opportunistic that -- and take action in best interest of shareholders.

Operator

Our next question's come from the line of [Robert Wileman].

Unknown Analyst

It's in regards to -- I believe there's a provision in the latest round of convertible notes that speaks about the requirement of a sale of an asset by the end of June to provide a source of nondilutive financing. Is that something that we expect to still come to fruition? Is that a provision that is -- that could be sort of renegotiated if an acceptable terms for sale of an asset don't present themselves? Just could you provide as much context as you can around that?

Dennis M. McGrath
President, CFO & Secretary

Yes, sure thing. Let me expand your comment just a bit to add context. When we completed the -- engaged in the November financing, you'll recall there were 2 pieces of that puzzle. The Series A financing are notes that we got -- received $7 million. And the Series B, that was an additional $7 million of debt, $6.3 million of net proceeds. Available option to us that had prerequisite conditions to be achieved, one of them is what you just outlined that a nondilutive financing at a certain level would occur before a certain date. And that condition was waived as indicated by the financing last week. I mean, investors are so delighted with the progress of the company, the continued involvement of our value, but we waive that condition.

Now that's not an indication that we have lost sight of that. As Lishan indicated in his remarks, we are actively engaged in M&A-related activities, including our NextFlo with multiple parties. So although we're not prepared to speak specifically to that at this point, rest assured, there are ongoing discussions related to that. So hopefully, that answered your question.

Unknown Analyst

It does. That was helpful. And in terms of NextFlo, is -- we're talking with multiple parties, and I would imagine, gauging their interest. In the background, are we also progressing towards the FDA clearance for that device where presumably the value of that would go up substantially?

Lishan Aklog
Chairman & CEO

Yes. Sorry, I wasn't clear about that. I did try to mention that in my comments. So the answer is yes. The way -- the best way to understand that is to think of NextFlo as a platform technology, as I mentioned, with multiple applications. So the application that we had always focused on and the one that was the center of most of our commentary was this infusion set to replace electronic infusion pumps. And that product is, in fact, as you asked, advancing through our design control development process, and we're looking to have submission to the FDA before the end of the year. So that is moving along, and we are definitely keeping the parties that we're talking to informed about that.

What's interesting is that they would come back to us and express interest in these other applications beyond the infusion set new patient refusing to that. And it's because of their inquiries around this that we have started to pursue these other applications, which is disposable infusion pumps and particularly that and the prefilled drug infusions. And that's actually enhanced our ability to have these conversations. So the way this ultimately could evolve would be that we enter into agreements that start with 1 particular

application with milestones or time lines that extend for other applications. And even in theory, have multiple transactions with different parties where we're licensing or they're acquiring the technology for certain applications. Does that make sense?

But yes, the simple answer is we absolutely are moving the products along both because we would like to eventually commercialize them, but also, as you said, because that does, in fact, enhance the value.

Operator

[Operator Instructions] Our next question comes from the John Levin of Levin Capital.

John Andrew Levin
Levin Capital Strategies, L.P.

Lishan, Dennis, congratulations on all you're doing, it's really terrific. The presentation was wonderful. EsoGuard and EsoCheck -- I'm outside, so it's hard to hear me, forgive me.

Lishan Aklog
Chairman & CEO

We can hear you fine.

John Andrew Levin
Levin Capital Strategies, L.P.

Why are you not able to sell any -- what?

Lishan Aklog
Chairman & CEO

We can hear you fine, sorry.

John Andrew Levin
Levin Capital Strategies, L.P.

Why are you not able to -- okay. Why are you not able to sell any of it yet? I understand COVID is an impediment, but is there some technical reason that you're in pre-K? You may have said and I missed it. What is the impediment to getting [indiscernible] sales?

Lishan Aklog
Chairman & CEO

Yes. The impediment is simply that there are no procedures being performed. So for us to effectively sell EsoGuard and EsoCheck, the physician has to perform a procedure, get a sample, send the sample to our -- to the laboratory for performance and for billing, right? So because there are no nonemergency procedures being performed, there's no sort of stocking inventory right now. It's just we have to wait for procedures to come up. So we are building up demand. There's no doubt about that. And once we're -- things open up, so we'll be able to sell it.

John Andrew Levin
Levin Capital Strategies, L.P.

Yes. Perfect. I understand. I would have assumed for their most vulnerable or their most favorite patients, they would have said, "oh, sneak into our office, and we'll get one done to you."

But I guess that didn't happen, right?

Lishan Aklog
Chairman & CEO

Yes, there really is none of that right now. I mean, we've actually had some creative conversations about moving them with equipment as cars passed by and so forth. But for all classical purposes, it has to wait till that comeback. But don't come back sooner than you might think because you can't wait forever.

John Andrew Levin
Levin Capital Strategies, L.P.

I understand. I was just trying to make sure there was no regulatory or procedural or some kind of...

Lishan Aklog
Chairman & CEO

No, no, no. Not at all. We were off to the races, and then things came to a hold. Yes.

John Andrew Levin
Levin Capital Strategies, L.P.

Well, let me follow that up, if I may. When you're offer the races, in patients -- what percentage of the -- how many -- when you were at the races, how many horses ran? And what was the result with the horses that ran?

Lishan Aklog
Chairman & CEO

Yes. We were just getting started. So we only had a handful of patients at 2 sites, before we -- before things shut down. But those cases went fine. Those physicians and their staff were trained. They were able to perform the procedure. The samples were sent. So everything was successful in that regard. But it was only a handful before the elective procedure started to end. But as I mentioned, we have 100 -- over -- we are in contact with well over 100, maybe close to 200 accounts right now as we speak. So those conversations were -- they're priming and gearing up to go once things open up.

Operator

We have reached the end of the question-and-answer session. I will now turn the call back over to management for any closing remarks.

Lishan Aklog
Chairman & CEO

Thank you all for joining this afternoon and for your questions. We look forward to keeping you apprised of our progress via our news releases and periodic conference calls such as this one, encourage you to continue to stay in contact, which many of you have with Mike directly with any questions at jmh@pavmed.com. Thank you for joining us today. You have a great day, and stay safe.

Operator
That concludes today's conference. You may disconnect your lines at this time. Thank you for your participation, and have a great evening.