Well, today everyone, I'm really pleased
to welcome back Envision executive director
and co-founder Mr. Scott Kirkland.
We've spoken to Scott a few times in the past,
but it's been a little while, the last chat in late 2023.
So this is, uh, a well overdue catch up
if you are new to the business.
Uh, envision is developing a portable brain imaging device
that uses electro, uh, uh, magnetic imaging rather than MRI.
The goal here is, uh, straightforward in concept, uh,
anything but in execution, of course,
but in concept, we want something
that's smaller, faster, and cheaper.
Something that can be deployed at, at the bedside, something
that can be deployed even in an ambulance.
And we are really focusing,
at least in the early stages here on, uh, stroke.
And stroke is just an absolutely pernicious, uh, condition.
This is something that'll affect one in four
adults over their lifetime.
I think, Scott, you might have mentioned previously about a
third of global medical spending is, is on,
on stroke related, um, uh, issues. So
I'm sure I've thrown some big
numbers out there in the past. Yeah, yeah.
It's a, it's a big deal. It's a really big deal.
And, and one of the things that we learned in the, in one
of the early conversations here is
that when you wanna look at someone's outcome post-stroke,

it's really how quickly that, um, you know,
the golden hour was the phase that was used.
How quickly can you sort of get to that person,
identify the type of stroke,
and apply the appropriate treatment.
So it's a big deal. Um, and vision is, is getting closer
and closer to the all important commercialization phase.
And, and just Scott, this morning I scrolled through the,
the A SX announcements,
and you guys have a ton of market sensitive, uh,
releases in this year.
So a lot is happening, um,
which I'm really keen to dive into.
We've got half an hour, uh, here today, so we'll,
we'll keep it, um, re reasonably focused.
Sure. Very quickly, just
before I, I, I welcome you properly to the screen.
Um, remember, none of this is financial advice
for anyone who's watching you know that.
And if you do have any questions,
we've had some good ones come through, pop them on
that Slido link and I'll, I'll put them
to Scott when I get the chance.
So yeah, good to see
You again. Okay. Likewise,
Andrew. Thanks. It's good.
It's good to be back. And I think you visited the
site probably, what, three years ago?

Two and a half, three years ago? We did, yeah. Yeah.

So look, it's changed. It's changed a lot.

In fact, we we're expanding,

we're taking over the adjacent premises

to build out a pilot production line

for our first responder device now as well.

So there's Awesome, there's a fair, fair more faces around,

uh, these days as well.

But, um, just for, for your, um, members that may not be

as familiar with the story,

I've actually got the two devices in the room with me.

So the EMU device Great, great.

Which is kind of, you hopefully see it over my shoulder.

Let me shut up this.

So, sorry, I'm, I'm talking, so it's, it's, it's

Focusing on me. So on the small box.

On the small box. Okay.

That's, there you go. It's okay. There you go.

So that's the, uh, that's the EMU device.

So that's our first commercial unit,

our bedside brain scanner that is, uh,

underway in a pivotal trial Yep.

To support FDA de Novo clearance. Yep.

In fact, we have our fifth site being activated at present

in, in New York, Mount Sinai, New York.

And, uh, we've also unveiled our first responder device.

So this is this unit.

I remember seeing a very early prototype of that. Yeah,

Yeah. Um,

it looks smaller. Normally these things get bigger from
the original concept images.
Uh, and in fact, I, I would think this is pretty bang on,
uh, it's about 10 kilograms
or so without the coupling liquid in the back, so, yep.
Uh, I don't get a lot of, uh, spare gym time,
unfortunately these days,
but it, it is genuinely very lightweight.
Yeah. And, uh, we've in fact take, we've took
that device out in March
with the Royal Flying Doctor service
for its first a medical testing.
Yep. And that is the hardest possible pre-hospital test
we can put a device through.
You can imagine altitude pressure, G-Force
Turbulence Yeah.
To, yeah. All
Those, um, yeah.
Temperature variants, all the, all those things.
And it, it, it survived, it thrived, it wasn't babied,
you know, it was kind of thrown
around in the cargo hold, so to speak.
Yep. Um, and that was with healthy volunteers and,
and shortly where handing over devices to the RFDS to run,
uh, a study with a medical retrieval patients.
Yep. So there's, I've actually, I've got a whiteboard
behind me or in front of me, rather.
Yeah. With all our clinical trials, uh,

over the next six to 12 months.

And, you know, you, you're referencing earlier,

there's been a lot happening.

It, it's only really ramping up in intensity. Yeah.

Uh, and I dunno, happy to go through those,

but maybe I'll be in your hands

to see what you'd like to discuss. Oh,

No, it's, no, it def definitely exciting to sort

of see things, um, uh, progress here.

Maybe I, I just unpack for, for people here.

I mean, I, I, um, you, you're correct me if I'm,

if I'm wrong here,

but as a, as a de novo clearance denotes something

that they're looking to clear,

which has no precedent in the market.

In other words, this is entirely new as a category.

So it requires a few more, I, I suppose, um, uh, hurdles

More heavy lifting, more Heavy lifting.

Yeah. Um, yeah. What, what else can you sort of say there?

I mean, it's sort of, it's exci when,

when investors hear something like a big market opportunity

that's exciting when you hear no competition.

That's exciting. And I think anyone in this space also knows

that even if someone does have a pretty cool idea

and they're in the garage, it's a,

as you would know better than anyone, is a long,

is a long pathway to sort of get Yeah.

Get that into the hands. Yeah. So, yeah.

What, what else would you elaborate on there?

Yeah. And we've, I mean, we've been at it seven years,
you know, probably circa $60 million invested in the
development of the technology,
and that's Envision's existence.
And there was a decade before the University of Queensland,
so there's been a lot in big IP portfolio,
probably even bigger trade secret portfolio as well.
Yep. De novo's interest.
So it's, it's, you're, you're right,
it's no predicate device.
It, it is also for class two devices.
So those that are low to moderate risk. Yep.
And you, the manufacturer, are proving out safety
and efficacy from ground principles.
Yep. Interestingly, there are plenty of VCs domestically
and internationally when it comes to device investing.
They typically only invest in de novo
or sometimes PMA pathway products
because they know yes, there's more heavy lifting early on,
but, but it, it, it is far less likely
to become a, a commodity.
Yeah. As, as you know, as I mentioned, it's,
it's a first of its kind.
It's novel by, by inherent definition. Yeah.
So we met with the FDA late last year
to all align on the parameters
for this pivotal trial called Pivotal validation trial.
Yep. And we're enrolling up

to 300 suspected stroke patients, six sites.
We've announced five of those.
We are activating the fifth at, at the moment,
my colleagues in New York doing all that.
Uh, and they're fantastic centers.
You know, we've got, um, Mayo Clinic in there in Florida,
uh, UT Health Memorial, Herman, Texas Medical Center
in Houston, uh, Royal Melbourne, Liverpool in Sydney,
who we've worked with before.
And, uh, we have a, an alum site as well for the six
that we're, you know, preparing for as well.
So high volume sites, influential, uh,
clinical teams, the research teams are really engaged,
they're enthusiastic about the technology.
And that's one thing I was hoping to, um,
cover off in our chat is talk about the various different
applications of the technology.
Great. 'cause often what is viewed as, as,
as a holy grail for a lot of neurologists is the notion
of being able to give clot busting drugs.
So thrombolysis in particularly in the golden hour at
someone's home, for example.
Mm-hmm. That is the ideal scenario, you know,
in the golden hour when the clot is still softer, uh,
you know, the, the, the treatment is, is,
is far more effective,
functional outcomes improve less disability, less health,
economic burden, less societal burden, et cetera, et cetera.
Now, that is one objective of the technology

that we're working towards, and we believe it has the
potential to help open the door to, to that in the future.
Mm. But it is just one of several,
and our investment thesis
is not hinged on the one application, you know,
because to be frank, it is a very high reward,
but high risk, um, profile as well,
because it's that
that drug is contraindicated for hemorrhage.
Yep. So there's quite a few different areas.
So just to, just to rattle through them, you know, we went
through stroke, big burden time sensitive,
effective treatments.
The treatments for ischemia have come a huge way
in the last two decades.
And, you know, globally the mortality rates have come down
significantly as a result of those improvements in,
you know, what they call reperfusion, um, treatments.
You know, clot busting drugs, thrombectomy
to retrieve a clot.
Right. Hemorrhages is certainly lagging.
That mortality rate over the last 20 odd years is,
is barely improved.
There's other, you know, there's risk factors
and early identification of stroke
and other elements beyond just treatment.
But it's only in recent years that the treatment bundle,
and they call it a care package for cerebral hemorrhage,

is progressing and is now in, uh, the,
a American Heart Association guidelines.
So if you positively identify a patient with a hemorrhage,
which is, call it circa 20% of stroke cases,
you can intensively lower their blood pressure,
which improves functional outcomes.
You can reverse anticoagulants.
So if they're on blood thinners like warfarin,
if they have a bleed in the brain, you want
to reverse those anticoagulants.
And then some of those patients may be eligible
for neurosurgery.
So you wanna make sure you're getting
them to the right center.
And then if they're in the wards, they're in ICU,
they're in the stroke ward,
and you're worried about deterioration complications,
you want to keep a close eye on
them in that, in that setting.
So, yeah. And then finally ruling out there's no blood in
the brain in the same way that non-contrast CT does today
for suspected acute ischemic stroke.
Yep. To open the door to infilled thrombolysis.
So that's kind of, you know, four
or five different applications.
Yeah. Uh, that the clinician tell us all add a
huge amount of value.
We're, we're shooting ultimately for all of them.
But the point is, yeah.

The investment thesis is, is not predicated on one singular
clinical use of the technology. So
Yeah, I was gonna ask you about that
because it, it, um, again, correct me if I'm wrong
because I'm well outside of my wheelhouse here,
but you've got the, the hardware
and the physics to contend with in terms of trying
to create an image.
But then I think as we chatted last time, a lot of the, the,
the secret source is in the algorithmic processing
of the imaging that comes through and,
and, uh, it's the new black, obviously in the market.
Yeah. I, you know, I, so I, I'm almost cringe
to bring it up, but it just feels
as though in this instance, it's particularly relevant
with all the development and AI image processing mm-hmm.
All of that kind of stuff. Yeah.
Is that, is, has the field moved favorably in, in that, on
that front from your perspective, given,
given you've got the hardware, the tech
and the physics sort of done?
Yeah. So, so, and I'm sure we talked about this,
this previously to some degree.
The, the common AI use in medical imaging is a
post-processing solution.
And it's, uh, that they're usually triage notification tools
that have been trained on maybe thousands of tens
of thousands cts or MRIs,

and it send an alert to the radiologist
or the clinician, look at this area,
there's an abnormality here.
Yeah. And I've mentioned previously the,
the value there is often not in the algorithm spotting the
abnormality, but in the alerts that are sent
to the interventional team, for example, in stroke
to improve workflow, save 20, 30 minutes, whatever it's Yep.
That, that's post-processing,
that's the FDA has approved over a thousand of those.
Mm-hmm. We don't do post-processing.
So we, within our headset, you know, if we go back
to the first responder
and there's 28 antennas, we will send, we,
the antennas will send a signal, there's transmission,
there's reflection, there's scatter.
That interaction is incredibly complex.
And the compu computational, I guess, power required
to make sense of that interaction 10, 15 years ago,
it was just, you couldn't really do
it in any reasonable time.
Right. That's why the technology was kind
of still stuck in a lab.
Yeah. Um, the value proposition is portable fast,
not portable, and oh,
we've gotta wait five hours, you know, to make sense.
So now we can make sense of those signals.
And, and we have a really powerful,
we call it a neurodiagnostic model,

and that's the core diagnostic feature of the product.
It looks at these signals
and looks at are they representative of a patient
that has a stroke or not,
based on what's in our training library,
and if so, is it a suspected hemorrhage
or a suspected ischemia?
And those are the two features
that we've been, um, validating.
In our previous study, the mvu, so we reported
for hemorrhage and auto sensitivity of 92 and 85%.
Yep. Test cases was around surface 60 test cases. Yep.
And then for ischemia, uh, most recently,
95% sensitivity in 80% specificity.
So Wow. Good. They're good, good, good numbers.
Certainly clinically relevant. It's a smaller sample.
And, and the intention of the pivotal trial is
to validate in a statistically significant manner,
you 95% confidence intervals, those, the performance
and the primary endpoint is hemorrhage
or not, which is our strongest performing feature,
which is the one that clinicians have, you know,
really encouraged us to focus on from the outset.
And we have a, um, secondary feature of ischemia
or not, um, which we can apply to the same, uh,
validation dataset. Yeah.
And, and, and what's what, um, interesting.
There you talk about sort of the training libraries,

but obviously, uh, as this goes out into the wild,
you'll be collecting more data, more information.
Mm-hmm. And it's always nice, one of the nice features
of this kind of tech is, is that
that positive flywheel kind of effect.
Mm-hmm. Um, is, is that something to take note
of in the sense that it, it, like,
it they're pretty high specificities.
Yeah. But I imagine they're only,
they're only gonna go in one direction, right? Yeah.
Yeah. I I I, I would hope so.
And, and there is,
at some point there's gonna be a limitation of the hardware.
I don't think we're not there yet.
Sure. Uh, In the first instance, we are focused on
how can we collect data quickly, cost effectively, that's,
that's relevant for our immediate applications being stroke
and traumatic brain injury.
So in parallel to the pivotal trial, we have
what we call a continuous innovation study running at two
sites in Australia, princess Alexandra in Brisbane, uh,
and, uh, John Hunter Hospital, Newcastle region.
And we'll continue to collect data.
That data goes into our training library,
but we're also ex, we've expanded the protocol
to include patients with traumatic brain injury.
So we'll be scanning patients that we've never seen
before, collecting that data.
And that the, the view is

that may help us expand the indication in the future
for the device, not just stroke,
but, you know, there's a lot
of traumatic brain injury events.
Yeah. Um, you, you know, one of the tidbits
or insights that I, they got in the states from one
of the major centers over there, we're engaging with, uh,
as senior clinician who describes scenarios whereby any,
any, any patients with a suspected head knock
that are on blood thinners,
and she'll say, maybe call it a quarter
of the population over the age of 55 over there.
Right. Has to get a head CT
to rule out there's no bleeding in the brain.
That's the protocol. Yeah.
And the cost to transport these patients to hospital,
call it 1500 us, another thousand to see the triage nurse,
another circa 1500 for a ct.
They haven't even seen a doctor at this point.
You know, by the time they see a doctor, it's maybe five,
six k, assuming they're not admitted.
And for many, many of these patients, it's,
it's unnecessary ionizing radiation.
Yeah. So, um, you know, TBI from falls,
car accidents, assaults,
and then military is really interesting.
So that's something we're actively Yes. Pursuing as well.
Yeah. Um, there's lots of interest in, in that.

So, so we keep getting the collect, uh, the,
the additional data through this innovation study.
And then, you know, to your, to your question around,
once it's out there, you can set up something called a
registry, which will allow us to, um, collect data,
but we, we want matching ground truths and,
and, you know, if we just get sent random scans,
we need some matching, whether it's CT
or an M mri, to really make sense of that, that, that data.
But that could be very effective.
So cost effective parallel data collection.
And then once it's in the field, establishing registries
to keep building out the data set.
Now the FDA don't want you, you, you,
you're not updating your algorithm in the background.
Sure. That is a big no-no. Yes.
You have an algorithm that's been approved by them. Right.
And then you have a, you know, X amount of months,
whatever time it is, we wanna then put in a five 10 K
to, to update that.
Yep. Gotcha. Yeah.
Um, gosh, the time is racing by,
but, uh, I'll go to some questions in a, in a moment.
Yeah, sure. Sure. But one, one thing I,
I caught my attention, actually,
someone posted it on our forums.
Mm-hmm. And this has been really, I, I can imagine
other peers in this sort of space
of the A SX look at you guys with a little bit of envy,

because one of the things you always notice
with early stage med tech development is just
costs a lot of money, right?
Yeah. And, and you're pre-commercial. Yeah.
But you guys have managed to,
you get these pretty cool funding deals.
It's sort of like, there's very little
strings attached to it.
And I saw a $5 million grant come through recently.
Um, do you just wanna speak to that a little bit too?
Because it, it feels as though I, I I, I guess it's the,
the, the focus on stroke that sort of opens the door to,
to more funding than what might be available
for more niche sort of, uh mm-hmm. Issues. Mm-hmm. But,
Or maybe I'm wrong. Yeah.
What, what would you say? Um, well, well,
I was gonna say that the grants are fantastic.
We also don't spend a lot either.
So I was gonna show you the blinds at the back
of the boardroom that are broken, you know?
Okay. And,
and for any of your, um, members that,
that are shareholders have been to our Ag gm, uh, they can,
they, you know, we we're not over,
over investing in fit up, put it that way.
Uh, the old saying, Scott, is that I think it was Yeah.
Fit of the carpet. Think of the dividends. That's it.
That's it. Get there. Um, pardon me.

So yeah, look, the grants are fantastic.
And if you look at, we have a really active kind of grant
strategy, you know, um, indication expansion,
the two devices, retaining, manufacture, whatever we can do
to accelerate with non-diluted funding, we, we, we do.
So, uh, and you look at the, the, the programs
and the criteria things they're looking to fund, you know,
innovation, tackling big health, economic burdens, uh,
creating engineering roles, you know, STEM jobs, uh,
retaining manufacturer of high value,
high margin medical product.
So it's like, okay. But, but they are competitive.
There's a lot of work that goes into them.
Uh, we're really happy with that recent win.
We have a very active portfolio like pipeline beyond that.
That one we don't forecast obvious for obvious reasons. Yep.
Grants and grants are not in a cash flow
until you secure them.
Sure. But, um, it, you know, ones that we're eligible,
we go, you know, full, full, full steam, full steam for, um,
but, you know, our cash cash position end
of March is about 12.7.
And, uh,
quarterly expenditure is round 3 million on average.
You know, payroll's the largest single component about
1.7 mm-hmm.
Outside of that, it's running trials, right.
Running trials, building machines, you know,
and the, the us interestingly, the US trial cost per patient

is actually very comparable with our earlier study
that we wrapped up last year
with 300 patients at three sites.
Okay. But there's some efficiency,
I hate using the word optimization,
but that's the reality that certain things that we've,
we've, we've done, you know, there was a whole lot of data
that we're collecting that wasn't necessary.
You know, someone's blood pressure on day six, you know,
that kind of stuff, uh, to, to make it more cost efficient.
And so, you know, funded for the Pivotal trial,
then we've got these grants, you know, the 5 million grants,
r and d rebates, uh,
and then yeah, like I said, act active grant portfolio.
And then the other thing that happened since we last chatted
about was, uh, strategic investor Keysight.
Yes, yes. Yeah. Yeah. Expand on that a little bit.
Yeah, sure. So, not, not a name that many people in,
in the Aussie market are familiar with, uh,
but they were, they were spun out of Agilent, which was,
was, uh, spun out of Hewlett Packard.
And so I believe they listed on the New York Stock Exchange
over a decade ago.
They, they, the market caps CI haven't checked recently,
it's probably around 28 billion us, something like that.
Okay. That they're a leader in test and measurement,
and they have very successful telecommunications, aerospace,
defense, automotive, semiconductor categories.

Mm-hmm. And they're very motivated to grow healthcare.
It's an emerging, they do 5 billion,
approximately 5 billion revenue per annum.
US healthcare's a small component.
They're very motivated and excited to, to grow that. Today.
A lot of that healthcare category may be selling equipment
to the major manufacturers to test, call it, you know,
RF coils in an MRI machine, for example, in our situation,
we have a collaboration going back to, um, 2019
where they've customized their components
and they now live in the device.
Right? Yeah. So they're embedded, they sit
behind our antennas, help us submit and measure signals.
They, uh, our addressable market, you know,
when we say we're going after 60,000 road air ambulances in
the us that our TAM becomes their TAM effectively.
Yeah. So, um, we're, you know,
they put in 15.3 Aussie at 2 0 5 to acquire 8.7.
Got a great relationship. You know,
we have constant communication with 'em.
In fact, a number of them are coming up next,
early next month, which is great.
We're also Coex exhibiting in Medica in November. Okay.
Um, at the, it's like one of the largest,
it's probably the largest medical device conference, uh,
and event they get, um, uh, 80,000 attendees.
So yeah. Good, good relationship.
And I think, you know, from a commercialization perspective,
'cause that's another thing we're building out at the

moment, is go to market strategy.

Yep. And which we, I think we've touched on in the past.

You know, it's very much a US focused FDA first strategy

and then come back to Australia, TGA recognize FDA

with minimal review, and then we'll tackle Europe, CE mark

and parts of Asia, South Korea, Japan, et cetera.

Yeah. Us, you know, we do expect to have a, uh,

direct sales force on the ground, um,

whose mortgage repayments count on selling Envision product.

Okay. Uh, be because it is a new technology. Yep.

It w we feel it's something that you need to know how

to sell yourself before someone else a

third party can sell it. Right.

So no, no li no, um,

licensing arrangements with third parties

Or definitely no licensing.

Yeah. I can tell you that, that we, we,

we can do hybrid models where we may work

with a distributor in certain markets

and that, that, that may very well still be the case.

But the reality is a distributor, you know,

as you appreciate, they often have 20 other

competing products in their portfolio.

Yeah. Uh, and you know, you really have need

to have nicely aligned incentives to ensure your Yeah.

Your, um, you know, your products being,

being, you know, appropriate service.

It's not just the incentives,

but is it the right division within some
of these larger organizations as well? Yeah.
We've come up against it with a few other guests as well.
Yeah. On, on one hand it's a much cheaper path to market,
but you lose all the control so that,
that's the compromise you're, you're dealing with
Yeah. Control
and that intel and, and,
and are you doing the education process,
the clinical demonstration process, justice?
Yeah. I, I, I think the other important fact is when we talk
about launching in the us, you know, again,
I mentioned we're building out the go to market
and we'll report on that to the market,
but as a principal, you're not trying to do all the us.
So for us, you know, an area that may make a lot of sense,
for example, is the southern states which have the highest
incident rates of stroke compared to,
you know, the national average.
And we've got some great reference sites in there.
You know, we've got, we're in Texas, we've got Mayo
and Florida around that southern stroke belt.
Yeah. Uh, so, you know, that's the kind of targeted,
you know, there's plenty of relevant centers from the,
you know, the smaller rural remote,
what we call critical access hospitals that,
that are more interested in earlier front door potential
usage versus the large tertiary centers
that are particularly interested in,

in ward opportunities in ICUs and stroke wards.
Uh, so there's still a lot of centers under that bracket.
And then for, you know, the first responder, it's really
there, there's a subcategory called in the US advanced Life
support fleet.
They tend to be kind of more highly trained paramedics,
more frequently going out to suspected cardiac events
or neurological events.
Uh, that's kinda circa 25, 30% of the fleet, you know,
we call them micro ambulances back here, back here,
typically mobile intensive care unit ambulances.
So, okay. Um, that
and aeromedical are really the, the, the,
the expected earlier adopters with the product. Yeah.
Yeah. Gosh, time is racing away. I've,
I've got, I've got another five 10, so, oh, okay.
Okay, cool. Um, I, I,
I'll throw some quick fire questions at you.
Some of them have been lodged and you,
and you've touched on them, so if you've,
if there's nothing else to say, there's nothing else to say,
but I'll, I'll, I'll throw them at you anyway.
Yeah. Um, just to be complete, um, sure.
What is the current thinking around cash, cash funding
to address funding requirements
between now and commercial launch?
You, you gave a lot of detail there.
Is there anything else to say?

Um, I think, well, we have like optionality, grants
strategics, uh, we have, you know, good mark,
good relationships in, in the market.
Um, we, I mentioned we're funded for the Pivotal, so we're,
you know, we got flexibility.
That's Yeah. That's, that's the good thing. Okay.
And you know, when,
when we did do a transaction in back in July, 2020,
it was very much a demand driven transaction.
Yeah. Right? Yeah.
So that's what you ultimately want for those things.
So, um, you know, the cost base
I mentioned is very product development engineering, and,
and that's how we expect it to stay over the next kind of
circa nine to 12 months.
But of course, we expect next year we'll be building out our
sales, marketing, service, customer support function.
Yep. And that, but, but we take a very conservative approach
to how we manage our capital.
We don't like, you know,
and we've talked about this Yeah, yeah.
We avoid dilution unnecessary, you know, un you know,
dilution that doesn't add value, all those things. Yep.
And that, that's really the clear point.
I, it's something I continue to raise
because I feel as though investors, we see a capital raise
as instantly negative and it's sort of like, well, maybe
and often, you know, but, but not necessarily.
It depends what the money's being used for. Right.

Like that, that's, that's always the, the, the thing
that I try and encourage people to focus on.
If, if I've got an, an, an opportunity to get a insane RO, I
then give me as much money as you can. Right?
Yeah. Yeah. And, and, and it depends,
you know, who, who is it?
Yeah. And, and, uh, are they getting everything they want
or are they, you know, that's the other element.
Are they getting everything they want or are they gonna have
to try and get the rest on market? Right.
A hundred percent. Yeah.
Yeah. Yeah. Yeah.
But again, well funded for the pivotal, so you, you,
you know, we've got that flexibility.
We're not in any, any pressing need.
Yeah. Fantastic. Uh, question from Alex is curious in
to know what the FDA has been like to, to deal with.
Are there any changes in how they interact this year?
I guess new administration and all of that stuff?
Yeah, it's a good question.
So our engagement with the FDA around
that pivotal trial alignment
really happened before all these changes.
Okay. So I can't, it's harder to speak to person.
I've been speaking with peers
and others that have had more recent engagements,
and most of the feedback has been,
they've had reviews responded to in, in time as per their,

you know, their guidelines are all very much public.
Great. Uh, I'm aware of one peer that's had some challenges
recently for something that was kind of, I guess,
non-mission critical.
You know, I think they deferred it,
but in general,
the feedback is all the mission critical stuff is,
is still kind of business as usual.
Oh, that's good to hear. Okay. Yeah.
Great to hear another one from Alex.
Assuming you do go to market,
what are the influences over the rate of uptake
of the two products in Australia and U and the us?
Yeah, so the, there,
so there's a few elements to this.
So, so the engagement with key opinion leaders,
so influential clinicians that have that drive change,
that drive, you know, improvements to guidelines, et cetera.
So we've got some great engagement there.
Bunch in the US bunch domestically, bunch in Europe as well
that we engage with.
Yeah. Podium strategy.
So we have, we have,
from the data we de generated in our clinical trials,
both the, the recently completed
and the, the, the ones we're going through now, we have, uh,
papers that come out of those that we're targeting
for high impact journals, clinical focus,
biomedical engineering focus,

and then we have podium presentation opportunities at the
major conferences that we're targeting as well.
And often it's not us giving a presentation,
it's a clinical collaborator.
Right, right. That's the ideal scenario.
That's nice. Yeah. Yeah,
Yeah. I mean it
yeah, you, you, you,
you're much better shot at these major events if it's not an
industry, you know, it's a a hundred percent a clinician, a,
a, a, you know, investigator or a study
That that's true of any product.
What it's like a review from a customer is better than any
from a, you know, uh, from the company.
Sure, sure. Yeah. Yeah, yeah. Um, so, so there's that.
And then, you know, the purchasing cycle, we,
it's a new product, we don't know yet,
that's the bottom line, but,
but based on our, you know, capital equipment price point,
there's obviously consumables and service in there.
Yep. Uh, and other kind of new technologies been introduced
that sales cycle could be anywhere six to 12 months,
you know, from lead generation to
doing clinical demonstrations, you know,
budget negotiations, um, you know,
installation, training, et cetera.
Yeah. So, um, it's really
leveraging those reference sites, leveraging the KOL KOLs

and not trying to bite off more than we can

chew, be really targeted.

Yeah. That's, that's a good point. Yeah. Yeah.

Yeah. And, um,

By, and by the way, that was, that was one

of the key pieces of advice from, um,

Sam Hubbard at Promus who's had a very successful journey

when it comes to tackling the US being super considered

and targeted and how you go about accessing that market

because you can fit all of Europe in the US

and you have room for California leftover, it's

Amazing. And

Yeah. You, you,

yeah.

You burn a lot of cash just flying around. Yes.

Yeah, absolutely.

Uh, it's a saying, I'm fond of actually grow yourself broke

because you, you can get, it's very easy to do for the best

of reasons, to get over your skis and,

and who knows what the market environment's like

six, 12 months from now.

And, you know, so I mean, I guess, I guess the,

the other thing that's really interesting about, um,

well, companies in a lot of different spaces,

but certainly in med tech, is that you go from this,

this stage of, Hey, look,

we've got some really cool kit here

and you've really gotta bang the drum, you know, and,

and they say science progresses one funeral at a time.

And, and I'm sure like a adoption of new technologies.

I haven't heard that one, but Yeah.

Oh, it's a great, it's a, it's a great one.

Um, which just, it just, it just, you know,

PE people become very wedded to their preferred workflow,

their preferred solutions.

Sure, yeah. And when you're dealing with the human body Yes.

That's an, that's an extra, yeah. Yeah.

CC clinicians are inherently conservative.

They're taught to be from, it's the first thing in medical

school, you know, this is the tri, which is

Good, which is good, Right?

Yeah, exactly. This is what we want. This is the most, and,

and people, you know, forget that medical devices, one

of the biggest hurdles is of getting these things

to market is documentation.

Yeah. You know, it's like the aviation industry.

We want it to be like that. Yes.

What what we're really trying to focus on is settings

where we're not asking them to replace something existing.

Yeah. You know, this is not displacing CT MRI. Yeah.

We're filling a gap. Yeah. Because these are the settings.

You need information, you don't have access to them. Yeah.

And the example I would give is like in the neuro ICU

for example, we, we, um, had the opportunity to part,

present and participate at a conference in Houston

that had about 60 physicians there, most

of which were neurointensivists

and then a bunch of neurologists
and a few neurosurgeons as well.
You know, they were telling us some of their,
like their tertiary centers usually have
around circa 18 bed neuro ICU beds.
And if a patient is very unwell,
the nurse may do OB observation rounds every
one to two hours of that patient.
Right. And they'll look at their pupils
and they'll use a tool tool called a ter,
and that's kind of, that's the neurological assessment.
Yeah. If they're stable, maybe that's every,
you know, two to four hours.
But, but the point is they're really flying blind when it
comes to deterioration complications.
There's not so, so an incremental, you know, non-ionizing,
the nurse can do a quick scan, takes five minutes.
Yep. We're not really asking 'em
to change a whole lot in their workflow,
but they can spot a problem
that's gonna cause a whole lot more problems down the track
if they don't address early, um, you know, quicker.
So, yeah. You know, and, and,
and we, we do describe the clinicians
as co-designers of the product.
Yeah. Um, like since they, even
before I, I arrived on the scene
and that it was the professors
and the research team at the University of Queensland,

they had a bunch of clinicians out at the Princess Aandra
hospital there were in there, focus on this, focus on that,
you know, really making sure this thing's gonna be useful.
So, um, that was going back to my other point as well.
We're identifying all these use cases of value
that they tell us of, of value, um,
and, you know, we'll do a staggered kind of approach to kind
of nailing them all off.
It's so interesting. And, and you,
it's funny you mentioned ProMedica where I was sort of going
before was that you, you do go from this hard to get,
you know, I can't get arrested kind of thing.
Why ast, you know, to where the, it's more of,
it's more the inquiry start becoming inbound.
And that, and that is a really interesting inflection point,
um, uh, uh, to, to, to witness.
And it's, it's why those reference sites
and the material is so important.
When you say you knock on the door, it's like,
we've got this brain scan, it's really cool.
It's like, who else uses it?
Well, no one, but you could be the first.
And it's sort of like, uh, when you say, oh no,
the Mayo Clinic's using it, oh,
DARPA is involved and, and you know,
It's, We just, we're social species
and it's just, that gives it that, uh, for one of a, I mean,
it's, it's be, it's more thorough than that obviously,

but there's a social proof dimension to it.

Sure. Um, which has become very interesting. Yes.

When that happens. But

By the way, every week I get a new inquiry from somewhere

in the world from clinician interested

in technology Oh, interesting. Every week. Every week.

Interesting. Yeah. Um, so the challenge is, you know,

some of those markets can't just sell one, you know, one bit

of kit to one clinician in wherever.

We gotta have considered, considered launch

for all these markets, but the clinician interest is really,

really strong, which is great.

The, I think the other element we

didn't touch on was reimbursement.

So, yes. Yeah. Um, for, for, for strokes,

the way CMS reimburse it is they have these things called

disease related group payment buckets

or DRG payment buckets.

Mm-hmm. And they vary depending on the type of stroke, uh,

whether it is treated or not, what treatment

and if there are complications, and how severe.

So for example, an ischemic stroke treated

with a thrombectomy

with mild complications might be 30 grand us is the payment

just, I, I dunno the exact number.

It's just a guess, right? Yep.

And then the hospital then determines how

that 30 grand is utilized to care for, as part of that,

you know, including bedtime and equipment

and et cetera, et cetera.
That that payment bucket is determined on prior usage data
and it's updated annually.
And if you are a new technology,
you have no prior usage data.
Yep. So the, the CMS have created this scheme called new
technology add-on payment,
and a, a company that some of your, um,
colleagues will be familiar with that,
that I believe is secure.
That is EBR systems, which it's designed for first
of its kind novel, you know, newly approved, um, technology
that, uh, can demonstrate meaningful clinical improvement.
And there's a period of up to three years
of guaranteed additional, it's an incremental payment on top
of that payment bucket.
The example there is vis ai,
which is a triage notification tool for CT
to help spot a particular type of stroke
or large vessel occlusion.
Yeah. It's about a thousand dollars per patient per scan
that hospitals receive through the N tap for that product.
Incremental. So it becomes a revenue generator.
It's not about cost saving, it's, well,
hopefully there are some cost savings,
but it's revenue generation tool.
So we plan to pursue intap as part
of our regulatory strategy.

And yeah, I mentioned the criteria,

new certain cost criteria, clinical benefit.

Interestingly, if you have breakthrough device designation,

you don't need to satisfy clinical benefit. Oh,

Okay. Right, right.

Um,

I've pushed my luck on the time, so I'll just

No, no, no, that's fine. Yeah.

I'll, I'll finish by saying, um,

well, I'll leave it to you.

What, what's, what's the message that you'd like

to leave, uh, our members with?

Um, geez, we, we've got a, uh, okay.

Since last time we chatted, I,

I think we can genuinely say we're exiting that r

and d phase, anding that genuine commercialization phase.

Yep. You know, we have a trial running for,

for FDA clearance.

Yep. I think that's pretty, pretty, pretty critical.

And when I look at my whiteboard of the various studies,

you know, we have two key trials for the emu,

we have the Pivotal trial, we have the, um,

continuous innovation, so we are able to communicate,

you know, activation of those sites, recruitment progress,

uh, final readouts insights, these kinds of things.

Then with the first responder,

we have three separate pre-hospital trials.

These are all running this year, you know, um,

Royal Flying Doctor service,

mobile stroke unit in Melbourne, standard road ambulance,
and then substantial equivalence testing to demonstrate
that device is as good or better than the emu.
So to support a FDA pathway, the five 10 K for that.
So like, just, there's a lot, there's a lot, there's a lot
of meaningful catalyst that we'll be able
to communicate over the next six to 12 months. Yeah.
The phrase that comes to mind, Scott, is, is gradually,
then suddenly and, um, yeah.
Yeah. Yeah. And,
and, um, I, I, I, I saw in the chat you've got a couple
of existing shareholders here, so I'm really,
really glad we've got a few people on, on, on the,
the journey and then those
that have been kinda sitting on the sidelines, I think,
you know, we've, we've really turned the corner in terms of
where we're at in that commercialization
journey, so, wow. It's
Been, look, it's been fascinating to stay on top
of the journey and, and it really is getting
to an exciting phase.
So we won't leave at 18 or 20 months.
Uh, between, between the next chat,
Um, you, you can come out for next time you're come out
for another visit, we, that
Might take you up on that for sure. Yeah.
Yeah. We can do some demos for the device. Awesome.
Awesome. How's that? How's that content?

That's very cool content for the, yeah.

Fantastic. I love it. Okay.

I, I'll let you get back on with it. Alright, pleasure.

Thanks Andrew. Good catch up. Thank you. Cheers. Thanks.

Cheers. Thanks a lot. See you guys.