Know Labs
Second Quarter 2024 Earnings Call
May 15, 2024

Presenters
Jordyn Hujar - Chief of Staff
Ron Erickson - Chief Executive Officer
Peter Conley - Chief Financial Office

Operator
Greetings. Welcome to Know Labs's Second Quarter 2024 Earnings Conference Call. Please note this conference call is being recorded. I will now turn the conference over to Jordyn Hujar with Know Labs's Chief of Staff. You may begin.

Jordyn Hujar
Thank you, operator. Thank you, everyone, for joining us for today's conference call to review Know Labs's second quarter 2024 financial results and operating highlights. If you have not seen today's financial results, press release, or 10-Q filing, please visit the Investors page on the company's website at www.knowlabs.co.

Before turning the call over to Ron Erickson, Know Labs' Chairman and Chief Executive Officer, I would like to remind you that ,during this conference call, the company will make projections and forward-looking statements regarding future events. Any statements that are not historical facts are forward-looking statements.

We encourage you to review the company's SEC filings, including without limitation, the company's forms 10-K and 10-Q, which identify specific risk factors that may cause actual results or events to differ materially from those described in these forward-looking statements. These factors may include, without limitation, risks inherent in the development and/or commercialization of potential diagnostic products, uncertainty in the results of clinical trials or regulatory approvals, the need to obtain third-party reimbursement for patients' use of any diagnostic products the company commercializes, our need and ability to obtain future capital and maintenance of IP rights, risks inherent in strategic transactions such as failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, greater than estimated allocations of resources to develop and commercialize technologies, or failure to maintain any laboratory accreditation or FDA certification.

Therefore, actual outcomes and results may differ materially from what is expressed or implied by these forward-looking statements. Know Labs expressly disclaims any intent or obligation to update these forward-looking statements except as otherwise may be required under applicable law.

A Q&A session will follow this call. Your questions can be submitted through the webcast portal, which can be accessed through our website. We will not be taking questions over the phone during today's call.

With that, I'll turn the call over to Ron Erickson, Know Labs' CEO.

Ron Erickson
Thank you, Jordyn. Welcome, everyone, to our conference call to review the financial results and operating highlights of our second quarter for fiscal year 2024. Joining me today is Pete Conley, our Chief Financial Officer and Senior Vice President of Intellectual Property, who will discuss our financial results.

Since our last earnings call on February 14th, many milestones have been achieved. These milestones resulted from an accelerated work program we implemented at the beginning of 2023.

Now I'll provide a brief update on these milestones and the progress we've made against the four core work streams that we previously articulated. Work stream number one, hardware - a critical work stream in an area with a lot of progress has been hardware development. In June 2023, we announced the completion of our portable Generation 1 prototype device for non-invasive glucose monitoring. We spent the next several months with this device undergoing sensor characterization to better understand how our sensor performs in a completely wireless unit and answer questions surrounding battery life, signal quality, and temperature.

These tests included testing in and outside of our lab, both in vitro and with humans. Data collected through these tests was compared to data collected with FDA-cleared glucose monitors, helping us to understand how our sensor performs in real life settings.

Following from these findings, our product team, alongside our hardware for more electrical engineering and industrial design partners, continued to miniaturize the Generation 1 prototype further. These efforts resulted in the announcement of the KnowU, our Gen 2 device, on February 27th. The KnowU is a wearable, non-invasive, continuous glucose monitoring device, or CGM. It incorporates our proprietary technology and sensor, which we plan to submit to the FDA for clearance.

This sensor has now been tested and proven stable and accurate. By including it in a wearable format, we can amplify the technology's testing and validation outside the lab. The KnowU can be worn with an adhesive, allowing the user to clip the sensor on and off or on the arm or forearm with a strap. The device, significantly smaller and lighter than the Generation 1 prototype, includes onboard computing power and built-in machine learning capabilities.

The KnowU is designed to optimize the customer experience, which is expected to last for years, ultimately getting rid of -- eliminating costly disposables and connecting with an easy-to-use companion mobile app. More work will need to be done to prepare the KnowU for commercialization, including further miniaturization and adjustments based on inputs from clinical trials and human factors testing, and most important, what works best for the patient user. Through 2024, the KnowU device will support accelerated data collection, including determining the technology's performance through continuous wear in different locations on the body and within more expansive glycemic ranges and diverse populations. If you haven't seen it, I encourage you to watch the video we published on our website with specific details on the KnowU features.

Work stream number two involves clinical trials and data collection. Clinical testing continues to be an important area of development for the company.

During the first half of our fiscal year 2024, we completed an IRB-approved internal trial with more than 30 participants with pre-diabetes or type 2 diabetes. 80% of the data collected from our sensor was randomly selected to train our algorithm. The remaining 20% of the data was then applied to the trained algorithm and compared to a paired venous blood glucose reference value, resulting in a Mean Absolute Relative Difference, or MARD, of 11.1%. This was the first time we implemented a clinical research protocol involving people with diabetes using venous blood as a comparative reference, the gold standard expected by the FDA. That's very important.

Dr. Somers, Virend Somers from the Mayo Clinic was an author and a co-investigator on that research protocol. Dr. Somers presented and we announced on March 6th the interim results of this study titled, “non-invasive blood glucose monitoring in people with diabetes using an RF sensor and venous blood comparator.” This he did at the 17th International Conference on Advanced Technologies and Treatments for Diabetes, or ATTD, in Florence, Italy.

This trial has been completed and enabled the R&D team to collect more data in the hyper and hypoglycemic ranges. In previously published studies, most of the data collected was within the normal glycemic range, 70 to 100 milligrams per deciliter, and glucose values from a popular CGM were used as a comparative reference. By including participants with type 2 diabetes, this study increased the number of data points outside the normal glycemic range. Demonstrating similar accuracy across all ranges is an essential milestone in our technology development roadmap.

While many devices typically underperform outside the normal glycemic range, our sensor delivered consistent accuracy across the hyper, normal, and hypoglycemic ranges in this study. The MARD for these ranges were 11.5%, 11% and 9.5% respectively. These results suggest that our sensor, paired with our trade secret machine learning AI algorithms, holds considerable promise for non-invasive blood glucose measurement.

A core focus of our next series of trials will be enrolling a more diverse population, including people with type 1 diabetes. This is necessary to collect more data in the very low hypoglycemic range of 40 to 70 milligrams per deciliter and the very high hyperglycemic range of 350 to 400 milligrams per deciliter. The FDA is focused on these ranges, and accuracy is critical for those managing diabetes.

The wearable nature of the KnowU will also enable continuous data collection and yield a large volume of data that machine learning algorithms require to improve accuracy across all intended use cases. This increase in data will be used to further refine and inform our algorithm development.

Our work stream three is algorithm development. We leverage all the data that's collected during our sensor characterization work in vitro tests and clinical trials for algorithm development. As we continue refining the algorithm, we learn exactly what data is needed to increase accuracy. This includes a wider range of glycemic ranges, along with data from a more diverse population, and data that takes into account temperature, location on the body, and other interferences. Our goal is to achieve an algorithm with a mean absolute relative difference, or MARD, of 10% or less.

More importantly, we also need to meet the FDA's requirements for accuracy in varying glycemic ranges and over different periods of time, all of which we're considering during our algorithm development.

The goal of our data science and algorithm development efforts during fiscal 2024 includes building personalized models for each user following a calibration period. The outcome will be an algorithm that can develop an accurate glucose value estimate for those individuals whenever they are wearing the KnowU device.

Building personalized models is an early step toward a generalized algorithm, but the ability to create these models may themselves prove to be viable in an FDA-cleared commercial device. The current version of our algorithm performs well within a known population from data collected in our lab in Seattle. We're first focused on understanding performance in different settings outside of the lab and expanding our population of study to those with type 1 diabetes. As we move forward, new approaches such as device calibration will be tested.

Our fourth work stream involves intellectual property. With respect to intellectual property, we continue to grow our portfolio. At the end of this quarter, we had over 300 patents issued, pending and in process, reflecting our very high continuing rate of innovation.

The issued and pending patents cover fundamental aspects of our radiofrequency spectroscopy technology in several unique applications. Intellectual property that includes patents and trade secrets will continue to be a focus for the company, and we will work to reinforce a defensible

intellectual property moat around our technology. We'll remain focused on maintaining our position as the leading worldwide IP holder in non-invasive blood glucose monitoring.

Finally, a corporate update - as I already mentioned, our team was in Florence, Italy in early March to attend the 17th International Conference on Advanced Technologies and Treatments for Diabetes. The industry calls it ATTD, and it's the number one worldwide show each year on the subject.

We displayed the KnowU to attendees and presented the results of our recent clinical study. We also had meetings with companies in our space and physicians leading critical diabetes research around the world.

We co-hosted a luncheon event with Children with Diabetes, a well-known nonprofit organization dedicated to providing education and support to families living with type 1 diabetes. This luncheon was attended by more than 60 physicians who were prominent thought leaders in the diabetes management field. This group had the opportunity to learn more about our company, our technology and our technology roadmap. Many medical and technical questions were addressed, and new clinical collaboration opportunities were discussed, and we continue to follow up on those.

The ATTD organization also awarded us an emerging technology grant as an outstanding startup company presenting an innovative product. As a part of this grant, we participated in the International Fair of New Technologies with two scheduled presentations and an exhibition hall booth that allowed us to display our progress to the more than 5,000 attendees at the conference.

We will continue to attend, present and engage with the medical community at other conferences that are important for the diabetes space, including American Association for Clinical Endocrinology, where we just presented May 9 to 11 in New Orleans, the American Diabetes Association Scientific Sessions, June 21 to 24 in Orlando, and the ATDC conference on practical targets for diabetes care from July 10 to 13 in Keystone, Colorado, and there are many others. These conferences have proven to be valuable in our continued efforts to pursue collaboration agreements with other companies and to engage with preeminent clinicians from around the world.

Lastly, we entered into a funding agreement for an investment of up to $12 million. This agreement was executed with Lind Global Fund II LP, an investment entity managed by the Lind partners. This investment will enable us to accelerate development across our four core work streams that I've enumerated, including hardware development, expanded data collection, algorithm development, and our IP.

It'll allow us also to reinforce our team in areas that are critical for our development roadmap and our desire to start generating revenues from our robust IP portfolio. In this arena, we

recently brought on board Chris Somogyi as President International. Chris has an academic and career background in biomedical engineering and over 40 years of experience in commercializing innovation across related industries. Chris will play a pivotal role in identifying global opportunities to license our extensive intellectual property portfolio and will focus on securing strategic development partnerships as we look at opportunities in the rest of the world. You'll see a more comprehensive overview on Chris and his areas of focus in a press release that we'll issue tomorrow morning prior to the market open.

It's important as we approach the market with what we call the next generation of the glucose monitor to do so in the context of the progress that's been made over the last 40 years. Glucose levels were historically determined by testing urine. In the early 1980s came the introduction of the finger stick with its enzymatic determination of glucose levels from blood drawn from the finger. In the early 2000s, companies came to the market with the first continuous glucose monitors utilizing their own enzymatic determination of blood glucose from interstitial fluid. The Know Labs' noninvasive glucose monitor is the next generation, whether used in a continuous form or in a spot check screening manner.

I'm very proud of our team's achievements during the last quarter. We remain committed to delivering an accessible, affordable and accurate solution that improves the current standard of care and enhances the quality of life for those living with diabetes. The recent milestones such as the KnowU product brings closer to a future where equitable care and diabetes management can become a reality. I encourage you to visit our investor relations website at ir.knowlabs.co to stay updated with our progress.

And now, I'd like to turn the call to Pete Conley, who can review our financials. Pete?

Peter Conley
Thank you, Ron. We detailed the financial results in today's second quarter of FY 2024 earnings release, which as noted by Jordan, you can find on our website, but I'll share a few key line items.

For Q2, fiscal 2024, Know Labs reported an operating loss of $4.73 million compared to an operating loss of $4.81 million in Q2 fiscal 2023, a reduction in operating loss of 1.7%. This translates to earnings per share of a loss of $0.07, better than the prior year earnings per share loss of $0.10, an improvement of 30% before preferred stock dividends. In Q2 fiscal 2024, we also recorded a non-cash charge to earnings of $976,000, principally related to stock-based compensation of $617,000 and issuance of common stock for services of $251,000.

Research and development expense for Q2 fiscal 2024 was $2.18 million as compared to $2.56 million in Q2 fiscal 2023, a decrease of 15.1% year-over-year. The decrease in R&D expense was related to decreased personnel and the use of external consultants to reduce the cost of product development.

Selling general and administrative expense for Q2 fiscal 2024 was $2.55 million, which was higher by $308,000 than the $2.24 million in the year ago period, an increase of 13.7%, reflecting key hires made in the quarter as well as an increase in legal expenses related to IP and financing activities.

Turning now to the balance sheet, as of March 31, 2024, we had cash and cash equivalents of $4.71 million compared to $8.02 million at the end of September 30, 2023. Net cash used in operations for the first six months of FY '24 was $7.05 million compared with $6.34 million in the six-month period of fiscal 2023.

During the year ended September 30, 2023, the company made adjustments to its fixed expenses, and the impact of those adjustments has significantly reduced our monthly burn rate. Given the significant reduction in fixed expenses, the company believes it has enough cash and flexibility with its operating expenses to operate until at least October 31, 2024.

As we have stated in our fiscal 2024 10-Q, we expect to raise additional funds through the issuance of equity, preferred stock, and convertible debentures. To that end, on March 20, 2024, we entered into an at-the-market offering agreement with the Benchmark Company, pursuant to which we may, from time-to-time offer to sell shares of our common stock through or to the Benchmark Company as our sales agent or manager in an aggregate amount of up to $5 million.

In addition, we have an $18 million S3 shelf registration statement, which was subsequently declared effective on January 11, 2024, to facilitate our liquidity needs. Finally, shareholder equity for Q2 fiscal 2024 was a negative $1.75 million versus $3.74 million in fiscal 2023, ending September 30, 2023. We are actively taking steps to address our negative shareholder equity through the conversion of convertible debt to equity as well as new equity issuance, as previously mentioned.

That concludes my review of our financial highlights, and I'll return the call to Ron for closing remarks.

Ron Erickson
Thanks, Pete. We'll now dedicate the next 10 to 15 minutes to questions submitted through the webcast portal. And bear with me a second as I take a look at the screen.

Let me start here as they come in, they scroll in. The first question is what is the status -- one of our work streams we've talked about is over time in joint development agreements, and we've talked about those with medical device manufacturers, big pharmaceutical companies, consumer electronic companies. One thing that I have said in the past, we don't mention who those companies are. I would say that we continue to engage in dialogue with those companies, and as those evolve over time, there will be an opportunity to let the market know who those

companies are and what our transactions involve. But at this point in time, I'll say we're just continuing to nurture a number of relationships that have the potential to be very significant.

One of the questions is what happened to the wrist worn device similar to a smartwatch. We've -- as I indicated, we've been going through a process of miniaturization. The KnowU, our Generation 2 device is significantly smaller than the Gen 1. We think between here and delivering that product to the FDA for FDA clearance and FDA approved clinical trials, there will be future miniaturization. Among other things, I've talked to people about the fact that this device, the KnowU, has an off the shelf battery. The battery is larger than (inaudible). We can have a custom battery. I think there's some other opportunities for miniaturization there.

Between here and a wrist worn device that's much, much smaller would be the need for an ASIC. That takes time. That takes money. So I think there's a transition period to where we are now, future miniaturization, and ultimately getting to something that is literally watch-like. But meanwhile, the current product, the product that we announced and showcased in Florence, Italy in early March is a wearable product, can be worn, as I indicated, with an adhesive or wristband. So the process of miniaturization is ongoing, but we have a wearable today.

This is a good question because we have a lot of inquiries about this. And the inquiries deal with the fact that there are many, many wearables, wrist type wearables in the marketplace being advertised in the marketplace as doing non-invasive blood glucose monitoring. I've seen them for as little as $29.95. They -- very inexpensive. Just a couple of months ago, the FDA issued an advisory warning that none of these devices are FDA approved. None of these devices meet the FDA medical device clearance criteria. So I'd say there's a lot of confusion in the market around that. They I think are acknowledged by the FDA, by clinicians and others that these do not have a degree of accuracy that is sufficient to allow a person to manage their diabetes. They're simply a marketing effort of a very inexpensive and inaccurate device.

Are you pursuing an alternative financing to eliminate lends and obtain less dilutive terms? Pete Conley, you want to take that one.

Peter Conley
Yes, Ron. We are -- as disclosed in our 10-Q and on this call, have indicated we are seeking additional equity financing. And we are very, very sensitive to deletion for several reasons. One of them is our shareholder base who has seen us through multiple rounds of funding since 2019, six rounds in total -- will -- are a foundation to our shareholder ownership. And we are very mindful of their loyalty to us and our support of us. And so deletion is something we take very seriously.

So while we are currently seeking additional equity financing, I'll state for the record, we will not do any sort of structured finance. There won't be any penny warrants or anything of that nature which could potentially harm our current investors. We are in the process and have

been in the process of talking to institutional investors, long only, fundamentally focused, and that is where we intend to raise equity capital.

Ron Erickson
Here's a question that said that we had announced a (inaudible) 100 clinical trial to be completed end of February. When can investors expect to see the result of the (inaudible) 100 study? Well, this is really -- this is an interesting one because the IRB protocol, as you know, when we send these out, these are independently approved, our protocols are independently approved. So it was independently approved for up to 100 participants. Once we got into the study and collected the data and analyzed the data from 30 participants in 85 sessions, we -- and we looked at all that data, we saw that the performance was satisfactory and at a level that was significant enough for us to shift our attention to testing with our Gen 2 KnowU.

So basically, we were approved to go to 100. We got great data using our Gen 1 because, you know, as you recall, the IRB was approved before we had the Gen 2, and so we made great progress and loved the data, and so we didn't have to do the whole 100, and then made the decision to shift our focus on testing to the KnowU, the Gen 2 device that we had in our hands starting early March.

Peter Conley
Ron, I might add, we have presented interim results at the ATTD and last week, the American Association for Clinical Endocrinology annual meeting. The results can be found on the research and development page of our website. And as the analysis concludes, we will continue to publish accordingly.

Ron Erickson
There's a question about international markets. As I indicated, during my formal remarks, we will be announcing tomorrow morning the hiring of Chris Somogyi. Chris' title is President International, and given Chris's background, as you'll see from the materials that we released tomorrow morning, he's going to be focusing on international and also focusing on monetization of our intellectual property in fields of use outside of diagnostics. So he's got a big area of responsibility, but his title is President International, and that's going to be a core focus of his.

Here's a great question. This is an unusual question. One of the individuals -- are you feeling fatigued? Are you getting enough rest, work, family balance? That's a rare question from a shareholder, and I'm going to say we appreciate -- I can't mention the individual's name unless it can be seen out there by everybody, but I want to appreciate the empathy. I think that, truth be known, we are so energized and excited about what we're doing, about the developments that we have internally, the way things are going -- now, I'm going to say, listen, we don't -- I know that people would like to see more press announcements. We make it a -- sort of the way we operate, we don't like to do press announcements unless we have something material to talk about that is really important.

But I'll just say that our level of energy and excitement and enthusiasm internally is really tremendous. So short answer, we're not fatigued. I think always there's that -- when you're building a business and everybody's moving fast, we're all alert to that work family balance. And I would say that we make sure that that happens, right? We really make sure -- that would be -- that's one of the core values of this company. We really care about our people. We care about their lives. We care about the work they do. We care about their commitment to the vision for the enterprise. And that vision is to create up a noninvasive diagnostic device with a first focus on glucose that literally can make a difference in the world and make a difference in people's lives. And the whole team's committed to that. And so that we get 100 percent, you've got to have that work-life balance. And I think we work hard toward that. So thanks for the question, by the way.

Peter Conley
Ron, if I could just amplify on what you're saying, part of what drives our excitement and enthusiasm literally every day is not a week goes by when we don't learn something new. And I'll give an example of that. Two weeks ago, the first week of May, in the Journal of Diabetes, Science and Technology, the peer review publication, a publication was included in the journal comparing the performance of the Dexcom G7 in the Abbott Freestyle Libre. And we learned, contrary to Dexcom's stated MARD of 8.2%, that in the study, the overall rate was 15.1%.

Now, we look at what we're doing, our most recently disclosed MARD is in the 11% range. And then we come to realize that there's a very high failure rate of the Dexcom G7 - depending on the source, in that same peer review publication, indicated the failure rate was 35%, call it one in three. We have seen from other postings and other sources, failure rate of 23%, call it one in four.

When you combine those facts with the fact that, in the world, nearly 600 million people have diabetes, and the combined install days of Dexcom, Abbott, and Medtronic is only about 4 million, you realize the CGM penetration worldwide is less than 1%. So when you look at accuracy, reliability, and the fact that 99% of the world still doesn't have a viable solution, that gets us very excited and very energized to bring the next generation of CGM to the world.

Ron Erickson
Thanks, Pete. So here's the question is are non-invasive technology a trade secret or patent? And what countries is it patented pending in, aside from the USA? Pete, by the way -- as everybody knows, Pete's our senior VP of Intellectual Property and has core responsibility for that. So, Pete, would you respond to this, please?

Peter Conley
Sure. As of March 31st, 2024, we have 332 patent assets that are either issued patents, pending patents, or in-process patents, meaning patents in the process of being filed. Of those patents, they are in 18 jurisdictions. The majority of them, 215 of the 332, are in the United States. And

then we have patent coverage through the PCT, Patent Cooperation Treaty, where we're able to file in multiple countries. We also have coverage in the EU, the UK, and literally a whole host of other countries - China, Japan, South Korea, and so forth. So we have global coverage. We have dominant coverage in our core technology of RF spectroscopy. And we look at this as a strategic asset that we plan to monetize in future discussions with potential JV partners and the like.

Ron Erickson
I would just want to add to that trade secrets. We have a significant body of trade secrets that may, by actual number, be twice the number of patents we hold. So, we don't talk a lot about trade secrets because they are secret. They're secret. We have them organized internally. We acknowledge they exist internally. I'm going to call it -- it's our secret sauce. And that is a significant part of our intellectual property. But what can I say? It's a secret, right? And it's a significant trade secret. That's a real big part of our intellectual property asset base.

I want to thank everyone for their questions. I do want to say there are a couple of questions that ask -- that are very precise questions. And as a consequence of being precise and asking for some things are really we can't disclose, I'm not able to respond to some of those more detailed questions. And I apologize for that. Those are the kinds of things that I could only disclose if we had a non-disclosure agreement with people.

There is one final question that has to do with the FDA and the FDA process. We have already started the process of, I'll say, socializing our technology with the FDA. And the next step will be a pre-submission meeting with the FDA, which we hope to have during fiscal year '24. And thereafter, with the final product, the refined Gen 2, if you will, that's a product that we take to the FDA and go through clinical trials with them, sort of organize with and through them pursuant to our protocols. And so that's an undertaking that we are eager to get underway and have already begun, as I indicated, this process of socializing our technology with the FDA, which is the most appropriate thing to do.

All that being said, I want to thank everybody for all your questions. Thank you for your engagement. We try to be available. I will say we've been extremely busy lately, so if we've been unresponsive to some of you, as some of you, it's not because we don't care. It's just that we've been very, very busy. So thanks so much for your continuing support; really appreciate it. And with that, that concludes our Q&A. I want to thank you for joining us. It's a lot to look forward to in the balance of fiscal 2024. We're excited to report today on our progress. We look forward to telling you more. Meanwhile, thanks to you, thanks to the efforts of all our employees, our board members, our advisors, our strategic partners, and candidly, diabetes clinicians and people in the world suffering from type 1 and type 2 diabetes who get in touch with us daily, who are eager for this noninvasive solution. We're here to work for them, to work for all of you. And I want to thank you. Have a great day and all the very best.

Jordyn Hujar

The conference call replay will be available on our website in the coming days. Thank you for your participation.

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