Know Labs
Third Quarter 2024 Earnings Call
August 14, 2024

Presenters
Ron Erickson, Chief Executive Officer & Chairman
Pete Conley, CFO & SVP Intellectual Property

Operator
Greetings. Welcome to Know Labs' Third Quarter 2024 Earnings Conference Call. Please note this conference call is being recorded. I will now turn the conference over to Ron Erickson, Know Labs' Chairman and Chief Executive Officer. Please go ahead.

Ron Erickson
Thank you, Operator. Thank you, everyone, for joining us for today's conference call to review Know Labs' third quarter 2024 financial results and operating highlights. Joining me today is Pete Conley, our Chief Financial Officer and Senior Vice President of Intellectual Property, who will discuss our financial results. Missing today is Jordyn Hujar, who many of you have heard from, our long-term Chief of Staff. Jordyn is on maternity leave taking care of her new son and doing wonderfully well. If you have not seen today's financial results, press release, or 10-Q filings, they're available on the Investors page on the company's website at www.knowlabs.co.

Before providing an update on our activities, I'd 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 transitions 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. We recently completed a

new capital raise announced on August 7. Pete Conley will cover this event and will provide additional details throughout his financial update. However, as we are following SEC guidance and regulations, we won't have a question-and-answer session at the end of this call, as we are within what is known as the quiet period. I encourage you to join our annual shareholders meeting, now scheduled for September 26th at 1.30 p.m. Pacific Time, when the quiet period will be over and we can take questions from our investors.

With that, I will continue the call by reviewing the operating highlights of our third quarter for fiscal year 2024. Since our last earnings call on May 15, many milestones have been achieved. These milestones resulted from an accelerated work program we implemented at the beginning of 2023. Today, I'll provide a brief update on these milestones and the progress we've made against the core work streams we've previously articulated.

Workstream 1; hardware. A critical works name and 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 testing this device in and outside our lab, both in vitro and with humans. Data collected throughout these tests was compared to data collected with FDA-cleared glucometers, helping us to understand how our sensor performs in real-life settings.

Pulling from these findings, we continue to miniaturize the Gen1 prototype. These efforts resulted in the announcement of the KnowU on February 27th, 2024, only eight months after the introduction of the Gen1 research prototype. The KnowU is a wearable, non-invasive, continuous glucose monitoring device, or CGM. It is 85% smaller than the Generation 1 and is capable of 24-hour wearable data collection. It incorporates our proprietary technology and sensor, which we plan to submit to the FDA for clearance. We also introduced the KnowU's companion mobile application, making it a fully integrated system.

Since the announcement of the KnowU, we've been using it to accelerate data collection and determine the technology performance throughout continuous wear, in different locations on the body, and within more expansive glycemic ranges and diverse populations. The wearable format allows us to amplify the technology's testing and validation, launching 24/7 clinical trials inside and outside Know Labs R&D laboratory. We expect more work will be needed to prepare the KnowU for commercialization, including further miniaturization and adjustments based on inputs from clinical trials and human factors testing.

Workstream 2 is clinical testing and data gathering. Clinical testing continues to be an important area development for the company. Since our last earning calls, we've completed additional testing, including an IRB approved internal trial with more than 30 participants with pre-diabetes or Type 2 diabetes.

The data collected in this trial was presented and published in the following conferences. Clinical research results were presented at the American Diabetes Association’s 84th scientific sessions

in Orlando. A mean absolute relative difference, or MARD, of 11.8% on the test dataset was achieved. Data from 22 participants with Type 2 diabetes or pre-diabetes were included in this dataset.

Clinical research results were presented at the 2024 American Association of Clinical Endocrinology Annual Meeting in New Orleans. The test dataset achieved a mean absolute relative difference, or MARD, of 11.1%. Data from 10 participants with Type 2 diabetes or pre-diabetes were included in this data set.

Clinical research results were presented at the American Physiological Society Summit in Baltimore. A mean absolute relative difference or MARD of 10.8% on this data set was achieved. Data from 13 healthy participants were included in this data set.

Clinical research results were presented at the 17th International Conference on Advanced Technologies and Treatments for Diabetes in Florence, Italy. A mean absolute relative difference, or MARD, of 11.1% on the test dataset was achieved. Data from 10 participants with Type 2 diabetes or pre-diabetes were included in this dataset.

In general, 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 the mean absolute relative difference, MARD, presented at these conferences. This was the first time we implemented a clinical research protocol involving people with diabetes and using venous blood as a comparative reference, the gold standard expected by the FDA.

Dr. Virend K. Somers from the Mayo Clinic has been an avid contributor to our research as an author and co-investigator. Dr. Somers has personally presented these results at global conferences, most notably at the 17th International Conference on Advanced Technologies and Treatments for Diabetes in Florence, Italy, and the 84th American Diabetes Association Scientific Sessions in Orlando.

We also recently published a paper in a leading diabetes journal. Our study entitled, "A Glycemic Status Classification Model Using a Radio Frequency Non-Invasive Blood Glucose Monitor," was published in Diabetes Technology and Therapeutics, a leading peer-reviewed journal covering all aspects of diagnosing and managing diabetes with cutting edge devices, drugs, drug delivery systems, and software.

This study demonstrated that our proprietary noninvasive radio frequency dialectic sensor and trade secret machine learning algorithms correctly classified an individual's glycemic status as hyperglycemic, normal glycemic, or hypoglycemic with a 93.37% accuracy compared to venous blood glucose values serving as an early proof of concept for a novel non-invasive diabetes screening device.

Expanding the potential application of the KnowU Beyond non-invasive blood glucose monitoring means our technology can support underserved global populations by facilitating early identification and intervention as a non-invasive screening device. A core focus of our next series of trials will be enrolling a more diversified population, including people with Type 1 diabetes. This is necessary to collect more data in the very low hypoglycemic range and the very high hyperglycemic. 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.

Workstream 3 is algorithm development. We leverage all the data that is collected during our sensor characterization work, in vitro trials, 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 levels along with data from a more diverse population and the 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 will also need to meet the FDA's requirements for accuracy in varying glycemic ranges and over different periods of time, all of which we are considering during algorithm development.

The goals of our data science and algorithm development efforts in 2024, including 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 these 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 with an unknown population from data collected in our lab in Seattle. We are first focused on understanding performance in different settings outside of the lab and expanding our population study to those with Type 1 diabetes. As we move forward, new approaches such as device calibration will be tested.

Workstream 4, intellectual property. With respect to intellectual property, we continue to grow our IP portfolio. At the end of the quarter, we had over 330 patents issued pending and in process, reflecting our continuing high rate of innovation. Know Labs' rate of innovation is roughly two times faster than the overall non-invasive glucose monitoring IP market growth rate.

The issued and pending patents cover fundamental aspects of our radio frequency spectroscopy technology and several unique applications. Intellectual property will continue to be a focus for the company, and we'll work to build and reinforce a defensible IP moat around our technology.

We remain focused on maintaining our position as the worldwide IP holder leading in this non-invasive blood glucose monitoring space.

Trade secrets are also critical. So we launched an initiative to identify and qualify them and quantify them. As a result of this exercise, we've gathered and codified in excess of 600 trade secrets which provide a proprietary working element of the Know Labs platform technology. This is very important.

Lastly, in May, 2024, we created the Know Labs' Skunkworks to pursue IP monetization and a global patent licensing program. We believe there is large opportunity to work with potential strategic partners and customers and drive revenue from non-core fields of use of the Know Labs' platform technology in both the US and the rest of the world.

With regards to corporate update, on the corporate side, we launched several initiatives focused on maximizing shareholder value and increasing our chances of success. For instance, we expanded our medical and scientific advisory board, appointing four new members with extensive clinical diabetes management and FDA expertise, and expanded our board of directors, appointing three new directors with deep sector expertise.

We also joined the Children with Diabetes Industry Advisory Board and the Industrial Participant Program of the Wyss Institute for Biologically Inspired Engineering at Harvard University. Both of these programs increase Know Labs' exposure to thought leaders in the healthcare space, allowing our team to leverage their expertise and apply their experience to our product development, accelerating time to market.

We're also making a targeted effort to spread our story and our work. Consequently, we presented our company at multiple investor and sector focused conferences such as the Third Annual Bernstein CGM Disruptors Conference, The Benchmark Company's Discovery Conference, the Emerging MedTech Summit 2024 by Life Sciences Intelligence, the Life Science Innovation Northwest 2024, and the Bio International Convention of 2024.

We continue to focus on our core objective, which is a successful development of the KnowU to obtain FDA approval. However, we believe we can achieve faster monetization of our technology through strategic collaboration with major players and the capitalization of our intellectual property assets.

We've increased our efforts on this front and we're continuing funneling resources into that arena. These work streams can help us maximize shareholder value while bringing disruptive technology to the market that can impact the lives of millions of people around the globe.
I'm proud of what we've achieved during the past quarter. We remain committed and the recent milestones bring us closer to a future where equitable care and diabetes management will become a reality. I encourage you to visit our Investor Relations website at ir.knowlabs.co to stay

updated with our progress. Now I'd like to turn the call to Pete Conley, so he can review our financials. Pete?

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

For Q3 fiscal 2024, Know Labs reported a net loss of $4.1 million compared to a net loss of $3.6 million in Q3 fiscal 2023, an increase of 13.9%. This translates to earnings per share of a loss of $0.05, better than the prior-year quarter earnings per share loss of $0.07, an improvement of 29% before preferred stock dividends.

It is important to note the net loss for the quarter included non-cash expenses of $1.58 million. The non-cash items include stock-based compensation of $1 million, amortization of operating lease right of use asset of $276,000, and interest expense for the extension of notes and warrants of $240,000.

Research and development expense for Q3 fiscal year 2024 decreased $531,000 to $1.35 million as compared to $1.88 million in Q3 fiscal 2023, a decrease of 28.2% year-over-year. The decrease was due primarily to the completion of hardware and software product development milestones and continued use of consultants to reduce the cost of product development.

Selling, general, and administrative expenses for Q3 fiscal 2024 increased $1.1 million to $2.49 million as compared to $1.36 million for the year ago quarter. The increase primarily was due to an increase of $276,000 in salaries related to several key hires, an increase in legal expense of $257,000 related to our financing activity, and further investment in our intellectual property assets and an increase in stock-based compensation of $479,000, and an increase in other expenses of $116,000. As part of the selling, general, and administrative expense for Q3 fiscal 2024, we recorded $99,000 and $63,000, respectively, of investor relation and business development expense.

Turning now to the balance sheet. We had cash and cash equivalents of approximately $2.13 million at June 30, 2024, as compared to $8.02 million at the end of September 30, 2023. The company is undertaking initiatives to significantly reduce our fixed expenses and monthly burn rate. Subsequent to the end of Q3 fiscal 2024, on August 9, 2024, as noted by Ron, we closed a firm commitment underwritten public offering of $3.445 million, which was a unit offering priced at $0.26 comprised of one share of common stock and one warrant exercisable for cash at $0.26, providing a path to an additional $3.4 million of future fundings.

This financing, along with the cash on hand, the company believes it has enough cash and flexibility with operating expenses to operate until at least December 31, 2024. As noted in our

Q3 of fiscal year 2024 10-Q, the company plans to seek additional funding under our effective S-3 shelf registration to ensure our operations well into 2025.

Finally, shareholding equity for Q3 fiscal year 2024 was a negative $4.6 million versus $3.74 million in fiscal year 2023, ending September 30. 2023. The company is actively taking steps to address its shareholder equity, including the conversion of debt to equity. This concludes my review of our financial highlights and I'll return the call to Ron for closing remarks.

Ron Erickson
Thanks, Pete. As already mentioned, we won't have a Q&A session at this call as we're in the quiet period imposed by SEC regulations due to our recent capital raise. I encourage you once again to join our annual shareholders meeting scheduled for the end of September when the quiet period will be over and we can take questions from investors.

This conference call replay will be available on our website in the coming days. In the meantime, thank you for joining and I appreciate it very much. There's a lot to look forward to in the balance of 2024 and we're excited to report on our progress. We appreciate the support of each of you, our shareholders. We appreciate the efforts of our employees, board members, advisors, and strategic partners. Thanks so very much. Thank you and have a great day. All the best.

Operator
This concludes today's conference. You may now disconnect your lines at this time. Thank you for your participation.