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Know Labs (ASE: KNW) – Neutral

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Know Labs Announces Positive Interim Results

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Know Labs assessed the accuracy of its radiofrequency (RF) dielectric sensor measuring blood glucose in participants with prediabetes and Type 2 diabetes using venous blood as a comparative reference – resulting in an overall Mean Absolute Relative Difference (MARD) of 11.1%. “Achieving this level of accuracy in the first study using a blood reference device is truly remarkable,” said Larry Ellingson, former Chair of the Board of the American Diabetes Association, Founding Member of the Diabetes Leadership Board and current member of Know Labs’ Board of Directors.

Investment Highlights:

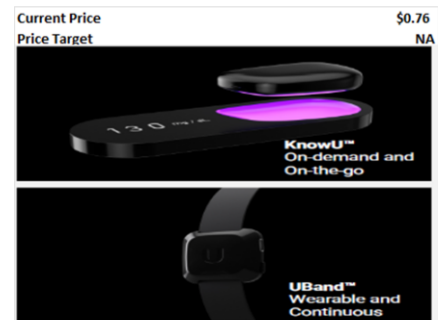
Study Design: (press release): This is Know Labs’ first clinical research protocol involving people with diabetes and using venous blood as a comparative reference. The proprietary RF sensor employed in the study measures glucose levels using dielectric spectroscopy by rapidly scanning a large range of RF frequencies and recording voltage values detected at each frequency to quantify, with trade-secret machine learning (ML) algorithms, and real-time continuous blood glucose levels. The sensor continuously scanned participants’ forearms during 21, three-hour sessions involving a 75g Oral Glucose Tolerance Test. Venous blood samples were collected using a peripheral intravenous catheter every five minutes and analyzed using an FDA-cleared blood glucose hospital meter as a reference device. Data was preprocessed using smoothing techniques and an 80/20 split was performed to create model training and test datasets, respectively. Know Labs trained a Light Gradient Boosting Machine model on data consisting of 520 paired RF and reference blood glucose values, then tested on 130 held-out paired values. These early results are part of a larger, now completed clinical trial with up to 100 participants focused on a population with diabetes and prediabetes, conducted September 2023 through February 2024.

Results: On the held-out test dataset, blood glucose was estimated with a MARD of $11.1 \pm 2.1\%$ relative to venous blood. Similar accuracy was observed in normoglycemic ($11.0 \pm 2.7\%$) and hyperglycemic ($11.5 \pm 3.1\%$) ranges.

Funding Secured: Management recently announced a funding agreement for an investment of up to \$12 million, of which it has executed a \$4 million with Lind Global Fund II LP.

Valuation: We have lowered our rating from Buy to Neutral, and as such, we remove our 12-month price target. Our model is projected out to 2030. We apply a 30% success probability to our projected revenues in our product model, which is in addition to our 30% risk rate applied in our Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models, which are then equal-weighted and averaged and rounded to the nearest whole number to derive a target valuation.

Risks to our thesis include: 1. Regulatory Approvals 2. Clinical Science 3. Dependence on OEM suppliers 4. Development of the target markets 5. Intellectual Capital 6. Dilution



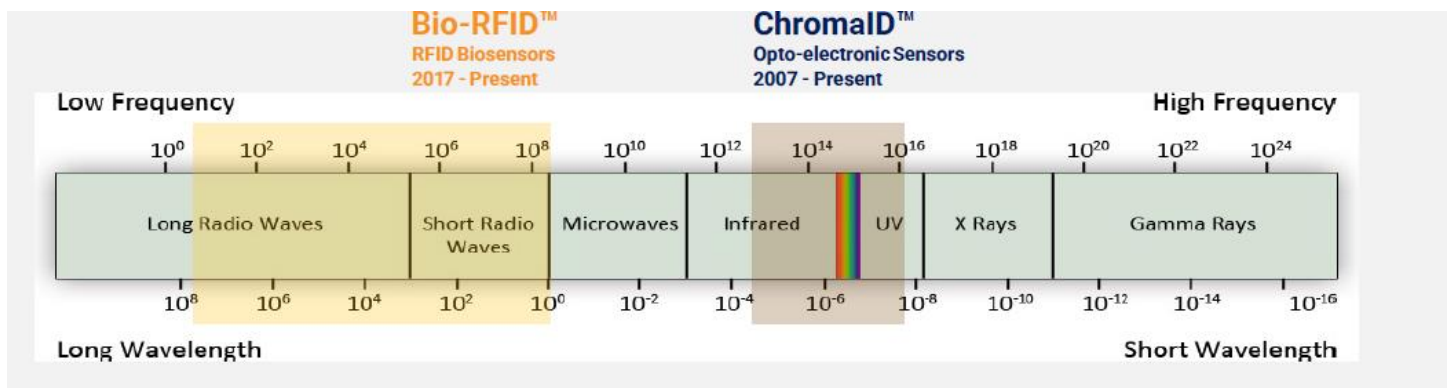
Stock Data Sept. YE			
52-Week Range	\$0.23	-	\$1.48
Shares Outstanding (mil.)	81.3		
Market Capitalization (mil.)	\$62		
Enterprise Value (mil.)	\$56		
Debt to Capital	0%		
Book Value/Share	NA		
Price/Book	-		
Average Three Months Trading Volume (K)	NA		
Insider Ownership	31.9%		
Institutional Ownership	2.9%		
Short interest (mil.)	0.3%		
Dividend / Yield	\$0.00/0.0%		



Company Description: Know Labs is an advanced technology company that is currently focused on developing “Bio-RFID”. The Bio-RFID sensor employs electromagnetic energy to detect, record, identify, and measure a unique signature of the target. The results are then analyzed using proprietary algorithms combined with its artificial intelligence (AI) Deep Learning platform.

How Does it Work? Bio-RFID utilizes spectroscopy at higher wavelengths to span radio wave and microwave segments of the electromagnetic spectrum. The technology, which is highly patented, utilizes electromagnetic energy along a wide range of the electromagnetic spectrum from visible light and infrared to radio and microwave wavelengths to perform analytics which allow the user to accurately identify and measure materials and analytes depending upon the specified targets or endpoints and field of use. A critical competitive differentiator for Bio-RFID is its ability not only to identify a wide range of organic and inorganic materials and analytes but to do so concurrently and in real-time, which potentially enables new multivariate models of clinical diagnostics and health and wellness monitoring. The company has been able to non-invasively measure blood glucose levels in humans with a high degree of accuracy and specificity. The company notes that its ability to obtain exacting results from the data obtained from its Bio-RFID sensor technology, also referred to as Radio Frequency Spectroscopy or RF Spectroscopy is a consequence of the application of the Company’s proprietary algorithms.

Exhibit 1. The Technology and the Spectrum



Source: Know Labs

It's not just the sensor but its AI Artificial Intelligence & Machine Learning, too. The company has developed AI and Machine Learning that drives the accurate pattern recognition of its algorithms which has led to the development of a robust AI Deep Learning Platform at the company. The initial indication is pattern recognition for Bio-RFID’s exacting determination of blood glucose levels. The company notes that the same sensor/technology can provide the data recognition for blood alcohol and blood oxygen levels too. We note that the company sees value in its AI Deep Learning Platform and has structured this part of the business as a subsidiary, AI Mind, Inc.

How Well Does It Work, How Does it Compare to What’s on the Market Now? The company announced the results of laboratory-based comparison testing between its Bio-RFID technology and the leading continuous glucose monitors from Abbott Labs (Freestyle Libre®) and DexCom (G6®). These results provide evidence of a high degree of correlation between the Bio-RFID technology and the current industry leaders and their continuous glucose monitors. In addition to internal testing, the Company engaged a world-renowned research institution to perform third-party validation testing of the Bio-RFID technology. The purpose of the independent research was to confirm that Know Labs’ Bio-RFID technology is able to precisely and non-invasively measure and identify a variety of analytes in vitro by detecting their unique radio frequency spectral responses.

What’s the Pathway to the Market? The company intends to seek a De Novo approval versus the alternative, a traditional 510(k) pathway. Recall that the 510(k) submissions rely on a predicate device that must prove substantial equivalence for market clearance; De Novo submissions begin with a clean slate and don't use any existing equivalence criteria as a basis for approval of a device. And it is for this reason that some companies consider the De Novo pathway.

Exhibit 2. Model Assumptions

1. Our model is a simplified prevalence model where we assume a timeline, market share, and a price in the Type II diabetes markets in the U.S., we remove Europe for the moment as the company is capital-constrained.
2. We assume annual pricing of just \$1,000, which we note is well below competing devices now in use in the marketplace.
3. The market size is quite large; as such, almost any market share translates into commercial success.
4. We apply just a 30% probability of success. We believe this is conservative as the device has already demonstrated proof of concept and equivalence to other products in the marketplace. As we see clinical progress, we anticipate raising this probability which then has the effect of driving a higher suggested valuation.

Exhibit 3. Product Model

U.S. Type II Diabetese Market	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
US Market Prevalance	48,000,000	50,400,000	52,920,000	55,566,000	58,344,300	61,261,515	64,324,591	67,540,820	70,917,861	74,463,754	78,186,942
Assume 10% - Proactive & Insured	4,800,000	5,040,000	5,292,000	5,556,600	5,834,430	6,126,152	6,432,459	6,754,082	7,091,786	7,446,375	7,818,694
Market Share	0%	0%	0%	0%	1%	2%	3%	3%	4%	4%	4%
Annual Fee	-	-	-	-	58,344	122,523	192,974	202,622	283,671	297,855	312,748
Annual Fees - Price	-	-	\$1,000	\$1,020	\$1,040	\$1,061	\$1,082	\$1,104	\$1,126	\$1,149	\$1,172
Revenues (M)	-	-	\$0	\$0	\$61	\$130	\$209	\$224	\$319	\$342	\$366
Probability of Success	-	-	30%	30%	30%	30%	30%	30%	30%	30%	30%
Annual Revenues - Millions	-	-	\$0	\$0	\$18	\$39	\$63	\$67	\$96	\$103	\$110

ROW Type II Diabetese Market	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
US Market Prevalance	59,000,000	61,950,000	65,047,500	68,299,875	71,714,869	75,300,612	79,065,643	83,018,925	87,169,871	91,528,365	96,104,783
Assume 10% - Proactive & Insured	5,900,000	6,195,000	6,504,750	6,829,988	7,171,487	7,530,061	7,906,564	8,301,892	8,716,987	9,152,836	9,610,478
Market Share	0%	0%	-	-	-	-	-	-	-	-	-
Annual Fee	-	-	-	-	-	-	-	-	-	-	-
Annual Fees - Price	-	-	\$1,000	\$1,020	\$1,040	\$1,061	\$1,082	\$1,104	\$1,126	\$1,149	\$1,172
Revenues (M)	-	-	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Probability of Success	-	-	30%	30%	30%	30%	30%	30%	30%	30%	30%
Annual Revenues - Millions	-	-	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

Source: Dawson James

Risks Analysis includes: (1) Regulatory Approvals; (2) Clinical Science (3) Dependence on OEM suppliers; (4) Product Development (5) Intellectual Capital & IP (6) Competitive Landscape (7) Dilution and or Financing Risks.

Regulatory risk: Know Labs must be able to obtain the approval of the FDA before commercial sales of the product candidates commence in the United States. The timing of these approvals is uncertain.

Clinical Science risk: The trials may take longer than expected and the design may face challenges. The company plans to pursue the De Novo pathway but there can be no guarantees that this will be viable versus another pathway such as the FDA's 510-K.

Dependence on OEM suppliers: The company must rely on others to manufacture its devices.

Product Development risk: The company is still in early stages of finalizing its products and software.

Intellectual Capital & IP: The company is still small with a select group of internal people able to understand and develop the technology. The company's ability to expand may be dependent on its ability to retain existing employees and recruit new people to join the organization. The company has a defined patent estate but there can be no guarantees that the company patents are valid and or may be challenged.

Competitive Landscape: The medical device market is intensely competitive. Know Labs must compete with existing and new treatment methods, as well as new technologies for its disease targets. In addition, the company faces intense competition, including well-capitalized devices companies and other emerging technology companies, most of which are well financed.

Dilution and or Financing risk: Know Labs is not a profitable company. While the company has a cash balance today, it is likely that it might need to raise additional capital prior to commercialization. The company's ability to do so could be critical to keeping the current programs moving forward and providing a value-creation event in the future.

Exhibit 4. Income Statement

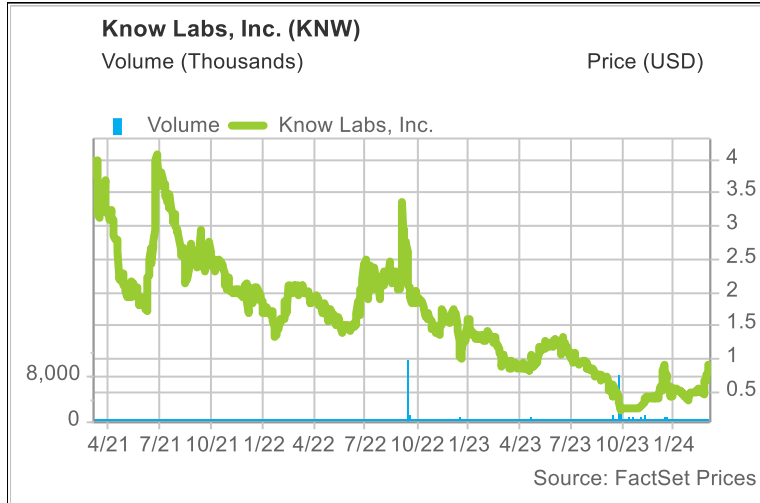
KNW, Inc. Income Statement (\$000)															
YE Sept. 31		2021A	2022A	2023A	1Q24A	2Q24E	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue (\$000)															
US Type 2 Diabetes			-		-	-	-	-		18,210	39,007	62,664	67,113	102,643	109,930
ROW Type 2 Diabetes										300	300	300	300	300	300
Other Platform Services												25,000	50,000	75,000	100,000
Total Revenues			4,369	-	-	-	-	-	-	36,721	78,313	125,629	134,527	205,585	220,160
Expenses															
COGS			-	-	-	-	-	-	-	5,141	7,831	10,050	9,417	12,335	11,008
% COGS										14%	10%	8%	7%	6%	5%
Gross Profit			4,369	-	-	-	-	-	-	31,580	70,482	115,578	125,110	193,250	209,152
Research & Development	868,584	3,970	2,779	7,727	1,440	1,500	1,500	1,560	6,000	12,000	12,240	12,485	12,734	12,989	13,249
General & Administrative	994,221	6,476	5,000	6,570	1,608	1,675	1,675	1,742	6,701	10,000	15,000	15,300	15,606	15,918	16,236
Marketing & Business Development			-	(274)	480	500	500	520	2,000	4,000	15,000	25,000	25,500	26,010	26,530
Total expenses		10,446	16,764	14,023	3,528	3,675	3,675	3,822	14,701	26,000	42,240	52,785	53,840	54,917	56,016
Operating Profit		(10,446)	(12,395)	(14,023)	(3,528)	(3,675)	(3,675)	(3,822)	(14,701)	5,580	28,242	62,794	71,270	138,333	153,137
Oper Margin															
Interest Income (expense)	-5228	(14,914)	(364)	127					-	-	-	-	-	-	-
Other Income			259	-											
Pre-tax income		(25,360)	(15,795)	(15,289)	(3,528)	(3,675)	(3,675)	(3,822)	(14,701)	5,580	28,242	62,794	71,270	138,333	153,137
Pretax Margin															
Income Tax (Benefit)			-	-	-	-	-	-	-	-	-	6,279	10,690	27,667	38,284
Tax Rate			0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	15%	20%	25%
Dividends				(5,153)											
GAAP Net Income		(25,360)	(15,795)	(20,443)	(3,528)	(3,675)	(3,675)	(3,822)	(14,701)	5,580	28,242	56,514	60,579	110,666	114,852
GAAP-EPS		(0.86)	(0.41)	(0.34)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	0.03	0.15	0.30	0.32	0.58	0.60
Non GAAP EPS (dil)		(0.86)	(0.16)	(0.20)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	0.03	0.15	0.30	0.32	0.58	0.60
Wgtd Avg Shrs (Bas) - '000s		29,371	42,553	49,581	98,473	98,670	98,867	99,065	98,769	99,562	100,360	101,166	101,977	102,796	103,621
Wgtd Avg Shrs (Dil) - '000s		29,371	94,946	100,981	183,890	184,258	184,626	184,996	184,442	185,737	187,040	188,353	189,675	191,006	192,347

Source: Company reports and Dawson James

Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and rating changes over the past three years:

- Initiated – Buy – February 8, 2022 – Price Target \$7.0
- Update Report – Buy – February 15, 2022 – Price Target \$7.0
- Update Report – Buy – May 24, 2022 – Price Target \$7.0
- Update Report – Buy – September 7, 2022 – Price Target \$7.0
- Update Report – Buy – September 19, 2022 – Price Target \$7.0
- Update Report – Buy – December 21, 2022 – Price Target \$7.0
- Update Report – Buy – January 27, 2023 – Price Target \$7.0
- Update Report – Buy – February 17, 2023 – Price Target \$7.0
- Update Report – Buy – May 16, 2023 – Price Target \$7.0
- Update Report – Buy – June 2, 2023 – Price Target \$7.0
- Update Report – Buy – August 28, 2023 – Price Target \$7.0
- Update Report – Buy – December 8, 2023 – Price Target Drops from \$7 to \$4.0
- Rating Change Report – Neutral – February 20, 2023 – Price Target NA
- Update Report – Neutral – March 5, 2024 – Price Target NA
- Update Report – Neutral – March 7, 2024 – Price Target NA

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Current as of 27-Feb-24

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
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Market Perform (Neutral)	15	42.86%	2	5.71%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	6	17.14%

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