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Know Labs (OTCX-BB: KNWN) - Buy

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Updates IRB – Internal Trial of Non-Invasive Glucose Monitoring, Reports 2nd Quarter Results

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Know Labs released a video update on the IRB-approved internal trial the Company has been conducting at its laboratory in Seattle. The video can be found here. [Click Here for the Video](#). Know Labs is driving what could be a significant paradigm shift in how we measure everything from glucose levels to alcohol to O₂ levels in the blood, instantly and with a high degree of accuracy. All via a Bluetooth wearable device like a watch. This technology has the potential to change “everything”.

Know Labs reported 2nd Quarter results. The company spent \$3M in the quarter and ended the period with \$8.3M in cash.

A Paradigm Shift in How We Measure – Radio Frequency Coupled with Artificial Intelligence (AI). The technology utilizes electromagnetic energy across a wide range of the spectrum from visible light and infrared to radio and microwave wavelengths to perform analytics (AI processing) which accurately identifies and quantitates its target. The first selected indication is set targeting the glucose levels (HbA1c) in type II diabetic patients.

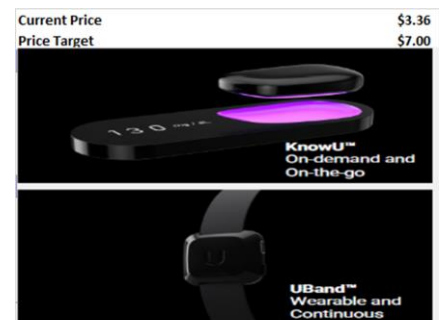
What is the Opportunity? With a competitive product and just a tiny piece of the market, the company can succeed. In just Type II diabetes in the U.S. alone, the CDC estimates there are 37M target patients. The numbers are even more significant in Europe.

Does it Work? The company has run hundreds of internal proof of concept studies and recently completed *In Vitro* validation at a world-renowned academic medical center. An *In Vivo* Study of Bio-RFID glucose monitoring is expected to begin soon.

What’s the Timeline & Pathway to the Marketplace? The company will be busy over the next two years as they complete product refinements and finalize the KnowU production units. Management is preparing to initiate a clinical program based on input from regulators. A pre-submission meeting with the FDA is the next step. Multiple variables predict the timeline. Management intends to use the De Novo pathway. This pathway does not rely on comparisons to a predicate device where equivalence must be shown. As the technology behind the KnowU band is novel, it may provide an accelerated path to market.

Valuation: We project our model out to 2030. We apply a conservative 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 our 12-month projected price target of \$7.0.

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



Source: Know Labs

Stock Data			
52-Week Range	\$1.15	-	\$4.00
Shares Outstanding (mil.)	43.8		
Market Capitalization (mil.)	\$147		
Enterprise Value (mil.)	\$137		
Debt to Capital	0%		
Book Value/Share	NA		
Price/Book	-		
Average Three Months Trading Volume (K)	NA		
Insider Ownership	20.2%		
Institutional Ownership	0.4%		
Short interest (mil.)	-		
Dividend / Yield	\$0.00/0.0%		



Exhibit 1. 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. and Europe.
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 2. Product Model

U.S. Type II Diabetse 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%	1%	2%	3%	6%	8%	10%	12%	14%	15%
Annual Fee	-	-	52,920	111,132	175,033	367,569	514,597	675,408	851,014	1,042,493	1,172,804
Annual Fees - Price	-	-	\$1,000	\$1,020	\$1,040	\$1,061	\$1,082	\$1,104	\$1,126	\$1,149	\$1,172
Revenues (M)	-	-	\$53	\$113	\$182	\$390	\$557	\$746	\$958	\$1,197	\$1,374
Probability of Success	-	-	30%	30%	30%	30%	30%	30%	30%	30%	30%
Annual Revenues - Millions	-	-	\$16	\$34	\$55	\$117	\$167	\$224	\$288	\$359	\$412

ROW Type II Diabetse 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%	-	-	1%	3%	5%	7%	9%	10%	11%
Annual Fee	-	-	-	-	71,715	225,902	395,328	581,132	784,529	915,284	1,057,153
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	\$75	\$240	\$428	\$642	\$884	\$1,051	\$1,239
Probability of Success	-	-	30%	30%	30%	30%	30%	30%	30%	30%	30%
Annual Revenues - Millions	-	-	\$0	\$0	\$22	\$72	\$128	\$192	\$265	\$315	\$372

Source: Dawson James

Valuation: Our valuation for Know Labs is based on our assumptions. The most critical of which is the timeline. We assume the company can leverage the De Novo pathway and, with one modestly powered trial, submit the device for approval. In our therapeutic model, we apply a 30% probability of success factor. This could prove conservative. The subsequent revenues are then fed into our income statement. To the income statement metrics, we then model a target valuation. We assume the company does raise additional capital, and as such, our valuation math is based on the 2030 fully diluted share count. We apply a 30% risk rate in these models, which is in addition to the probability of success factor in the therapeutic model. The risk rate is then set to 30% in our free cash flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP). We select 30% for micro-capitalized growth companies, and this represents our highest risk rate. The result of these three models is then equal-weighted and averaged and rounded to the nearest whole number to provide a 12-month target price.

Exhibit 3. Free Cash Flow Model

Average	\$	7
Price Target	\$	6
Year		2023

DCF Valuation Using FCF (mln):

units ('000 - Cnd\$)	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(25,360)	(7,779)	(8,100)	(13,202)	68,224	168,666	254,964	362,542	620,753	727,522
Tax Rate	0%	0%	0%	0%	0%	0%	10%	15%	20%	25%
EBIT(1-t)	(25,360)	(7,779)	(8,100)	(13,202)	68,224	168,666	229,468	308,161	496,602	545,641
CapEx	(300)	-	-	-	-	-	-	-	-	-
Depreciation	203	-	-	-	-	-	-	-	-	-
Change in NWC	-	-	-	-	-	-	-	-	-	-
FCF	(25,457)	(7,779)	(8,100)	(13,202)	68,224	168,666	229,468	308,161	496,602	545,641
PV of FCF	(33,094)	(7,779)	(6,231)	(7,812)	31,053	59,055	61,802	63,844	79,142	86,957
Discount Rate		30%								
Long Term Growth Rate		1%								
Terminal Cash Flow		1,900,336.90								
Terminal Value YE2030		302,850								
NPV		670,659								
NPV-Debt		9191								
Shares out (thousands)		108,668	2030E							
NPV Per Share	\$	6								

Source: Dawson James estimates

Exhibit 4. Discounted EPS Model

Current Year	2023
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	\$ 5.02
NPV	\$ 8

		Discount Rate and Earnings Multiple Varies, Year is Constant					
		2030 EPS					
Earnings Multiple		5%	10%	15%	20%	25%	30%
		2	\$7.14	\$5.15	\$3.78	\$2.80	\$2.11
5	\$17.84	\$12.88	\$9.44	\$7.01	\$5.26	\$ 4.00	
10	\$35.68	\$25.77	\$18.88	\$14.01	\$10.53	\$ 8.00	
15	\$53.52	\$38.65	\$28.31	\$21.02	\$15.79	\$ 12.00	
20	\$71.37	\$51.53	\$37.75	\$28.02	\$21.06	\$ 16.00	
25	\$89.21	\$64.41	\$47.19	\$35.03	\$26.32	\$ 20.00	
30	\$107.05	\$77.30	\$56.63	\$42.04	\$31.59	\$ 24.00	
35	\$124.89	\$90.18	\$66.06	\$49.04	\$36.85	\$ 28.01	

Source: Dawson James estimates

Exhibit 5. Sum-of-the-Parts Model

Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MMs	Term Val
Type 2	1%	30%	2	70%	\$1,374	\$4,738
NPV						\$7.22
Other	1%	30%	4	70%	\$250	\$862
NPV						\$0.78
Net Margin						40%
MM Shrs OS						109
Total						\$8

Source: Dawson James estimates

Risks Analysis include: (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 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 6. Income Statement

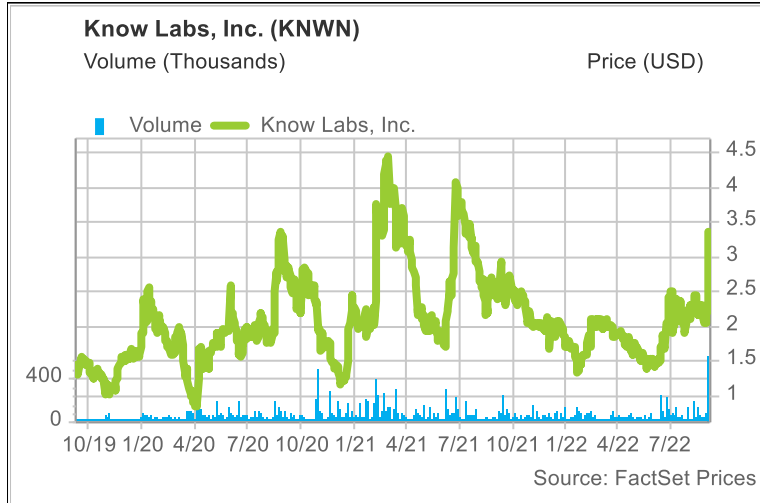
KNWN, Inc. Income Statement (\$000)														
YE Sept. 31	2021A	1Q22A	2Q22A	3Q22E	4Q22E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue (\$000)														
US Type 2 Diabetes		-	-	-	-	-			54,631	117,020	167,105	223,712	359,249	412,238
ROW Type 2 Diabetes									300	300	300	300	300	300
Other Platform Services											25,000	50,000	75,000	100,000
Total Revenues		9	-	-	-	9	-	-	109,563	234,340	334,510	447,723	718,798	824,776
Expenses														
COGS		-	-	-	-	-	-	-	15,339	23,434	26,761	31,341	43,128	41,239
% COGS		9	-	-	-	9	-	-	14%	10%	8%	7%	6%	5%
Gross Profit									94,224	210,906	307,749	416,383	675,670	783,537
Research & Development	3,970	1,249	1,273	695	(437)	2,779	3,000	6,000	12,000	12,240	12,485	12,734	12,989	13,249
General & Administrative	6,476	1,448	1,589	1,250	713	5,000	5,100	5,202	10,000	15,000	15,300	15,606	15,918	16,236
Marketing & Business Development		155	164	-	(319)	-	-	2,000	4,000	15,000	25,000	25,500	26,010	26,530
Total expenses	10,446	2,851	3,025	1,945	(43)	7,779	8,100	13,202	26,000	42,240	52,785	53,840	54,917	56,016
Operating Profit	(10,446)	(2,843)	(3,025)	(1,945)	43	(7,770)	(8,100)	(13,202)	68,224	168,666	254,964	362,542	620,753	727,522
Oper Margin														
Interest Income (expense)	(14,914)		(240)			(240)	-	-	-	-	-	-	-	-
Other Income		(3)	262			259	-	-	-	-	-	-	-	-
Pre-tax income	(25,360)	(6,141)	(3,003)	(1,945)	43	(11,046)	(8,100)	(13,202)	68,224	168,666	254,964	362,542	620,753	727,522
Pretax Margin														
Income Tax (Benefit)		-	-	-	-	-	-	-	-	-	25,496	54,381	124,151	181,880
Tax Rate		0%	0%	0%	0%	0%	0%	0%	0%	0%	10%	15%	20%	25%
GAAP Net Income	(25,360)	(6,141)	(3,003)	(1,945)	43	(11,046)	(8,100)	(13,202)	68,224	168,666	229,468	308,161	496,602	545,641
GAAP-EPS	(0.86)	(0.16)	(0.07)	(0.03)	0.00	(0.26)	(0.11)	(0.13)	0.65	1.60	2.16	2.88	4.60	5.02
Non GAAP EPS (dil)	(0.86)	(0.07)	(0.03)	(0.02)	0.00	(0.12)	(0.09)	(0.13)	0.65	1.60	2.16	2.88	4.60	5.02
Wgtd Avg Shrs (Bas) - '000s	29,371	37,872	43,761	63,848	63,976	52,364	71,812	74,903	75,504	76,110	76,720	77,336	77,957	78,582
Wgtd Avg Shrs (Dil) - '000s	29,371	93,000	93,186	113,372	113,599	103,289	100,981	104,202	104,933	105,670	106,411	107,158	107,910	108,668

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

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	Company Coverage		Investment Banking	
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