Know Labs (OTCX-BB: KNWN) - Buy
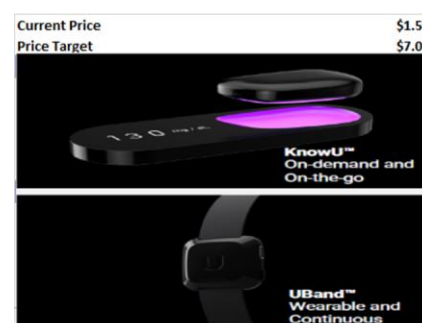
A Paradigm Shift in How We Measure: Targeting the Low Hanging Fruit, or Should We Say Sugar?

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Know Labs is driving what could be a significant paradigm shift in how we measure everything from glucose levels to alcohol to O^2 levels in the blood, instantly and with a high degree of accuracy. All via a blue-tooth wearable device like a watch. This technology has the potential to change "everything." Internal clinical; testing is underway, setting the stage for rapid clinical development and potential FDA approval via the De Novo pathway.

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

Current Price			$1.59
Price Target			$7.00

Source: Know Labs

Stock Data			
52-Week Range	$1.22	-	$4.83
Shares Outstanding (mil.)			36.0
Market Capitalization (mil.)			$57
Enterprise Value (mil.)			$47
Debt to Capital			0%
Book Value/Share			NA
Price/Book			-
Average Three Months Trading Volume (K)			NA
Insider Ownership			26.7%
Institutional Ownership			0.1%
Short interest (mil.)			-
Dividend / Yield			$0.00/0.0%

Know Labs, Inc. (KNWN)
Source: FactSet Prices

Please find Important Disclosures beginning on Page 12.

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**
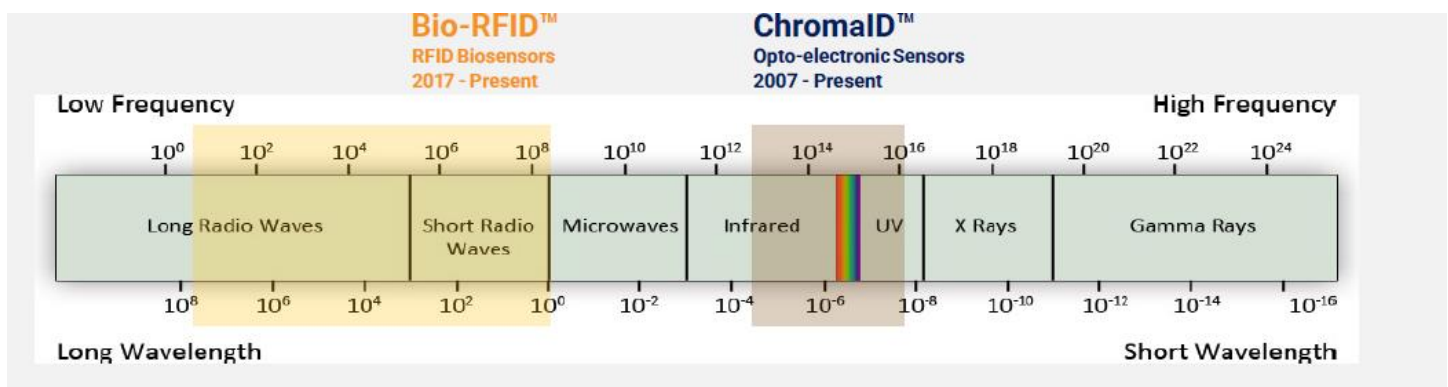
Source: Know Labs

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.
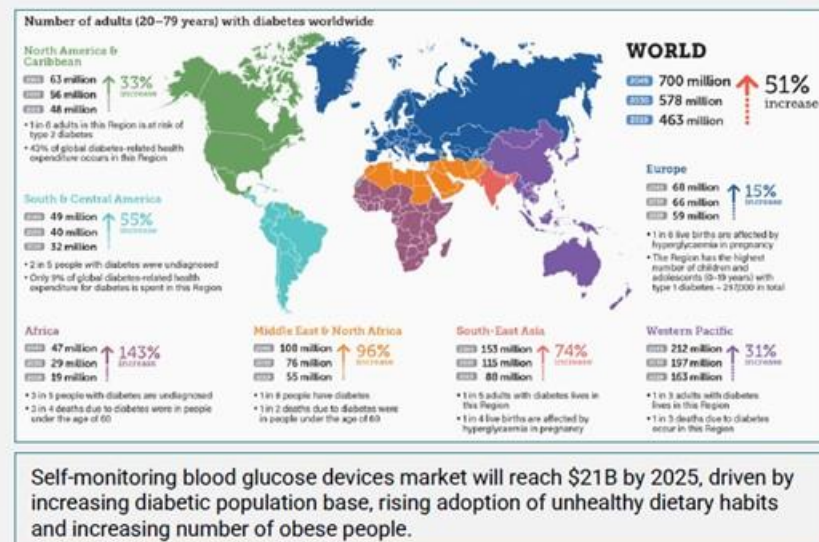
Financials: Know Labs reported $12M on the balance sheet and is spending approximately $2M per quarter. Over the next two years, we expect to see a modest rise in spending as the company initiates and completes its clinical program supporting a De-Novo filing with the FDA. We also note that the company created a subsidiary to work with the company's Artificial Intelligence (AI) Deep Learning Platform. That business raised approximately $4.2 million from Non-Fungible Token (NFT) sales. This revenue will be used to fund ongoing progress toward development of AI technologies for Know Labs' non-invasive glucose monitoring devices, KnowU™ and UBand™.

Exhibit 2. **What Can this Technology Do?** Measuring Glucose (Hb1ac) is just the beginning, but it's a BIG beginning.
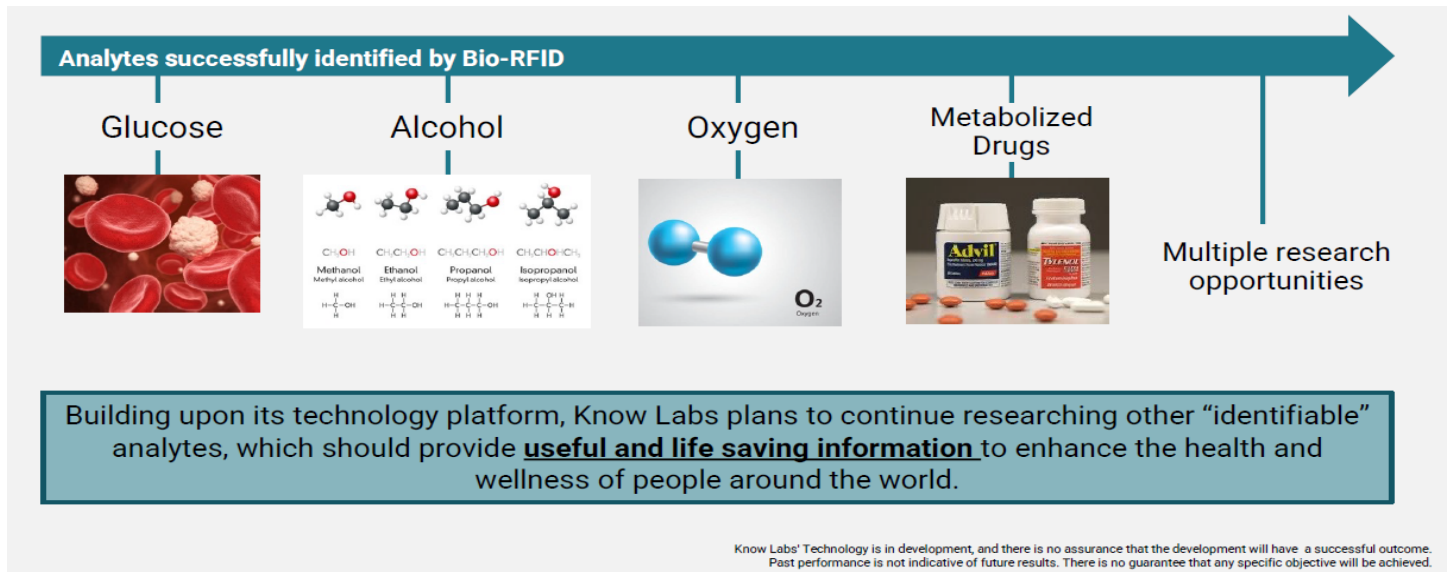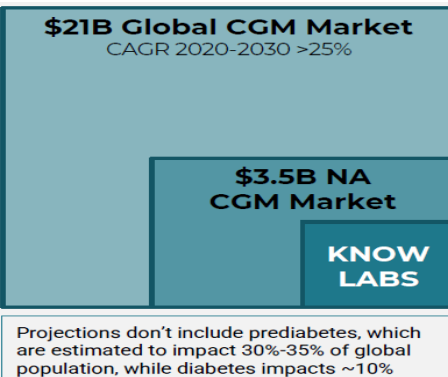

Source: Know Labs

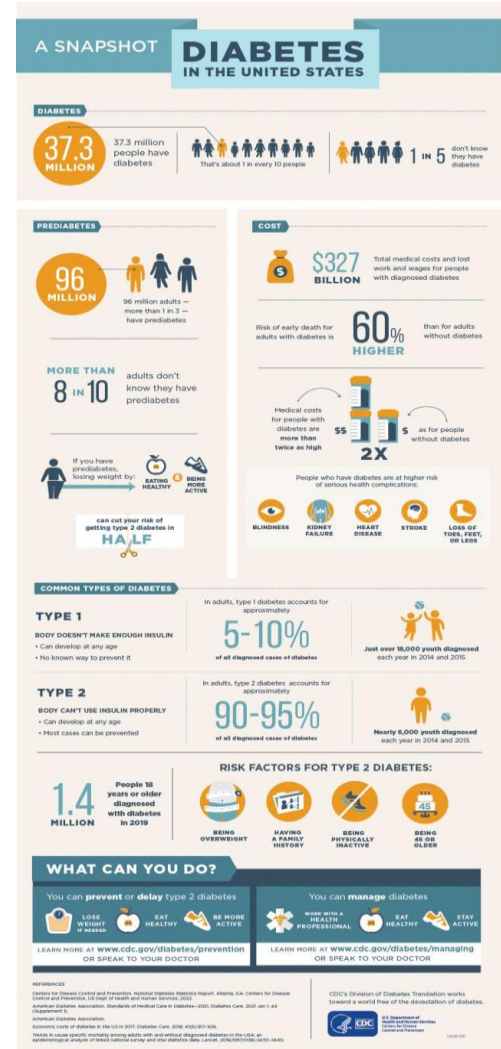**Exhibit 3. The Market for Glucose (Hb1ac) in Diabetes (Type II) is Large**

Exhibit 4. Just a Small Piece of the Market, is a Big Win for the Company

Source: Know Labs

Source: CDC

Exhibit 5. The KnowU (on demand) & Uband Platform (Wearable and Continuous) Devices

Source: Know Labs.

Exhibit 6. The Competitive Landscape

Source: Know Labs.

Exhibit 7. Bio-RFID vs. Accu-Chek Fingerstick
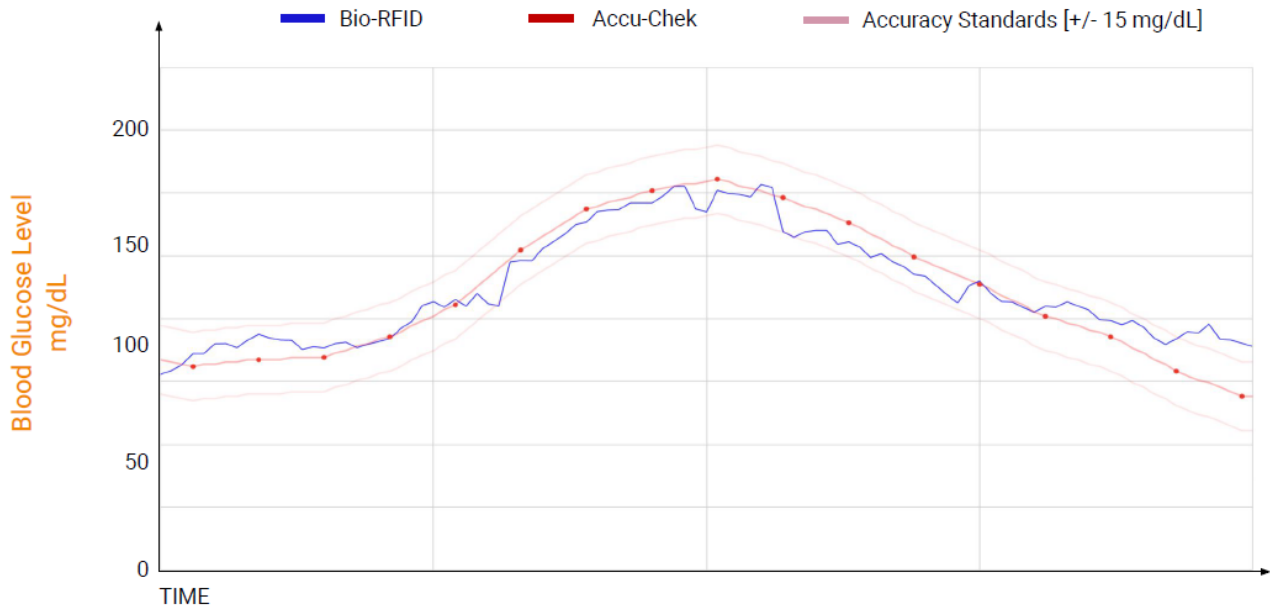
Source: Know Labs.

Exhibit 8. Bio-RFID vs. FreeStyle Libre 14-day
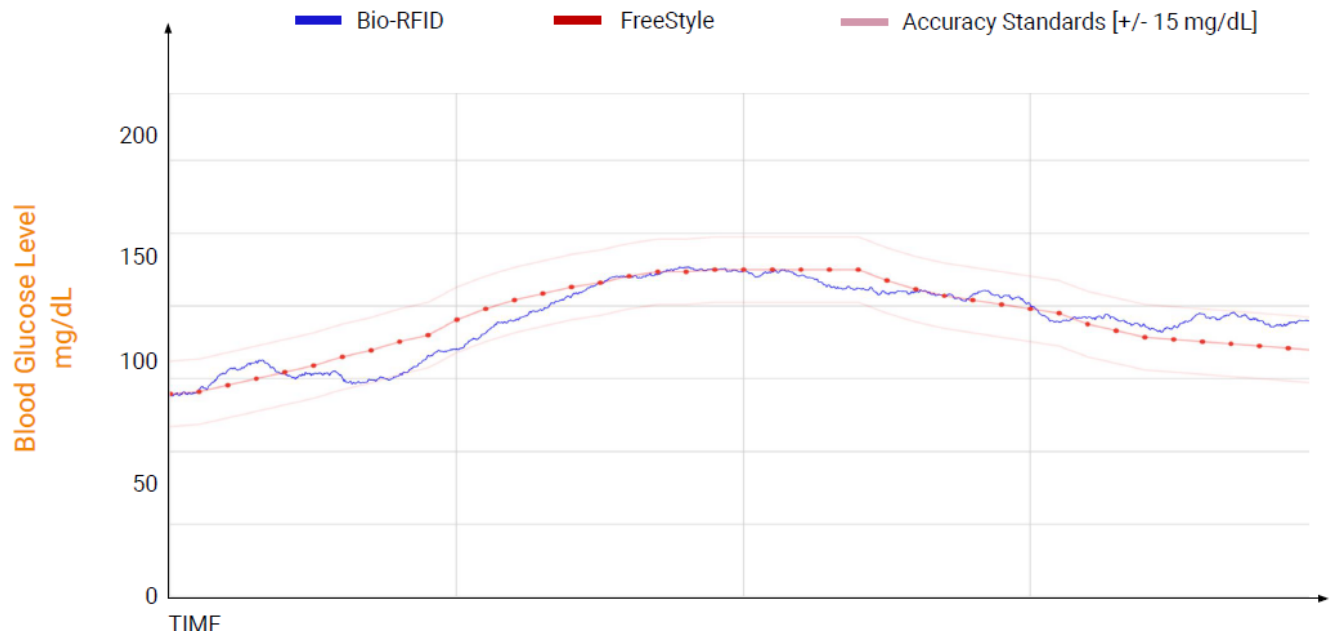
Source: Know Labs.

Exhibit 9. Bio-RFID vs. Dexcom G6
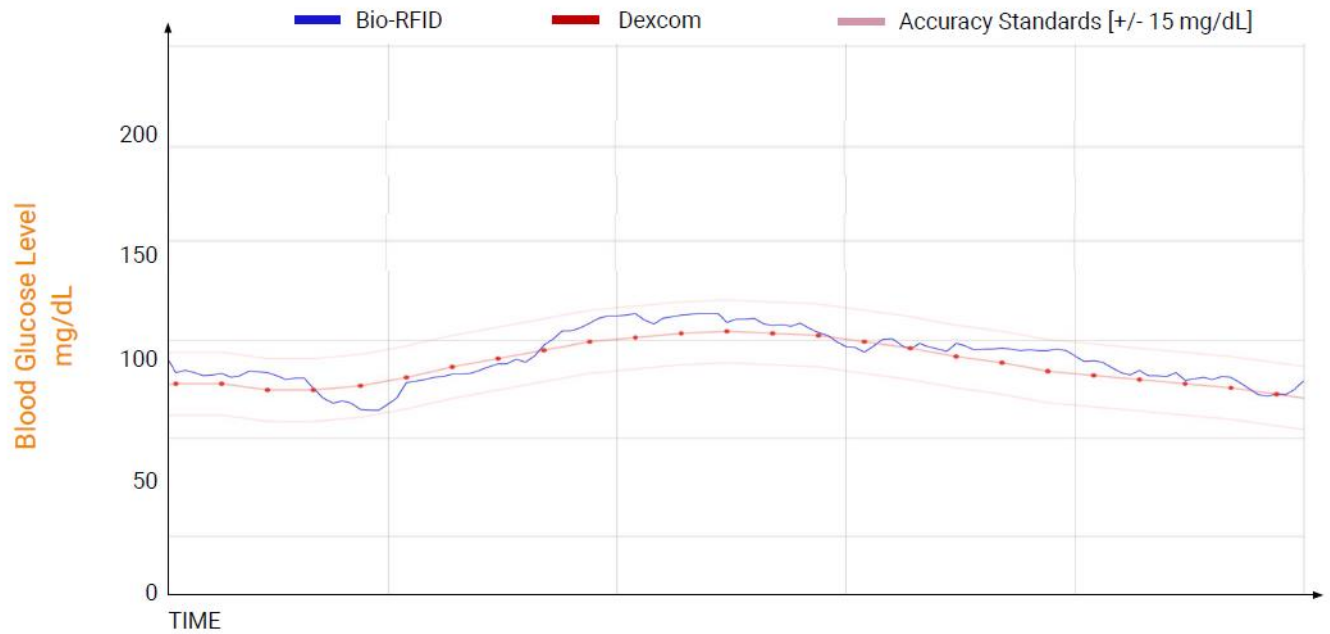
Source: Know Labs.

Exhibit 10. Does it Work?
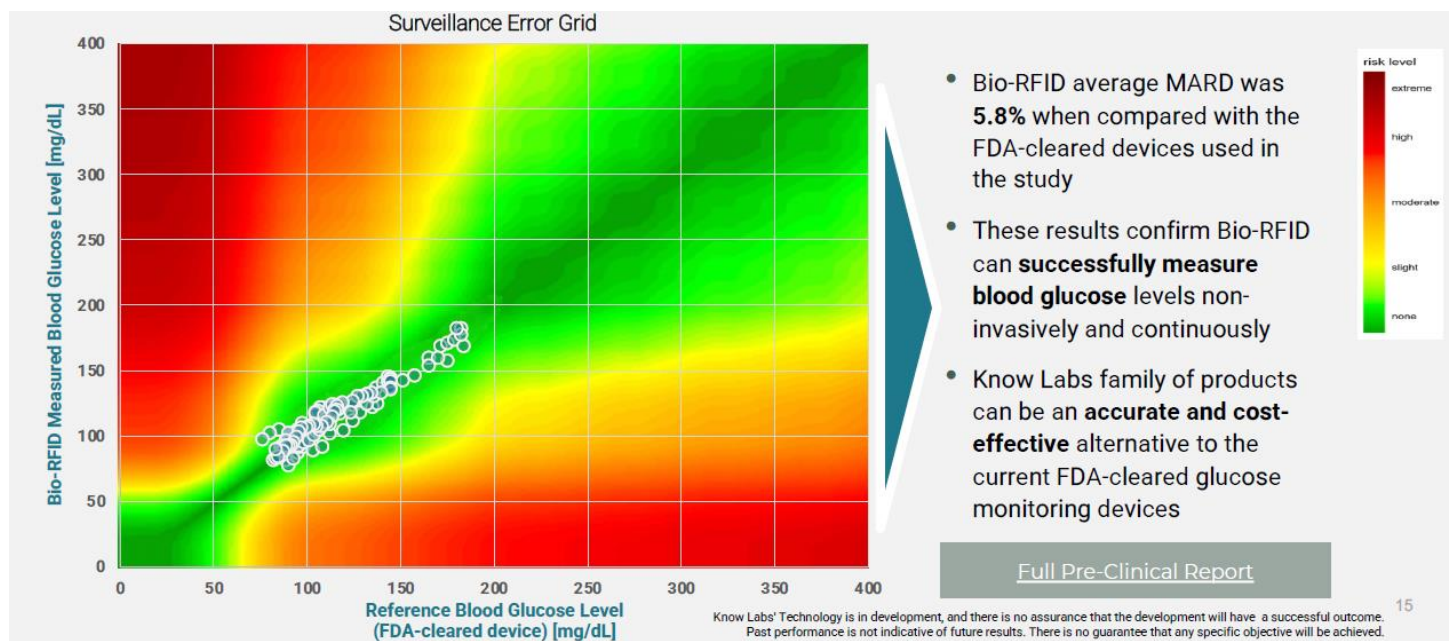
Source: Know Labs

Exhibit 11. Test Results Summary

MARD [%] = Mean Absolute Relative Difference, Bio-RFID vs. Reference Device; lower is better

Bio-RFID vs. Finger Stick
- 94% within +/- 20%
- 94% within +/- 15%

Average Bio-RFID MARD 6.7%

Bio-RFID vs. Free Style
- 100% within +/- 20%
- 98% within +/- 15%

Average Bio-RFID MARD 5.4%

Bio-RFID vs. Dexcom G6
- 100% within +/- 20%
- 100% within +/- 15%

Average Bio-RFID MARD 5.3%
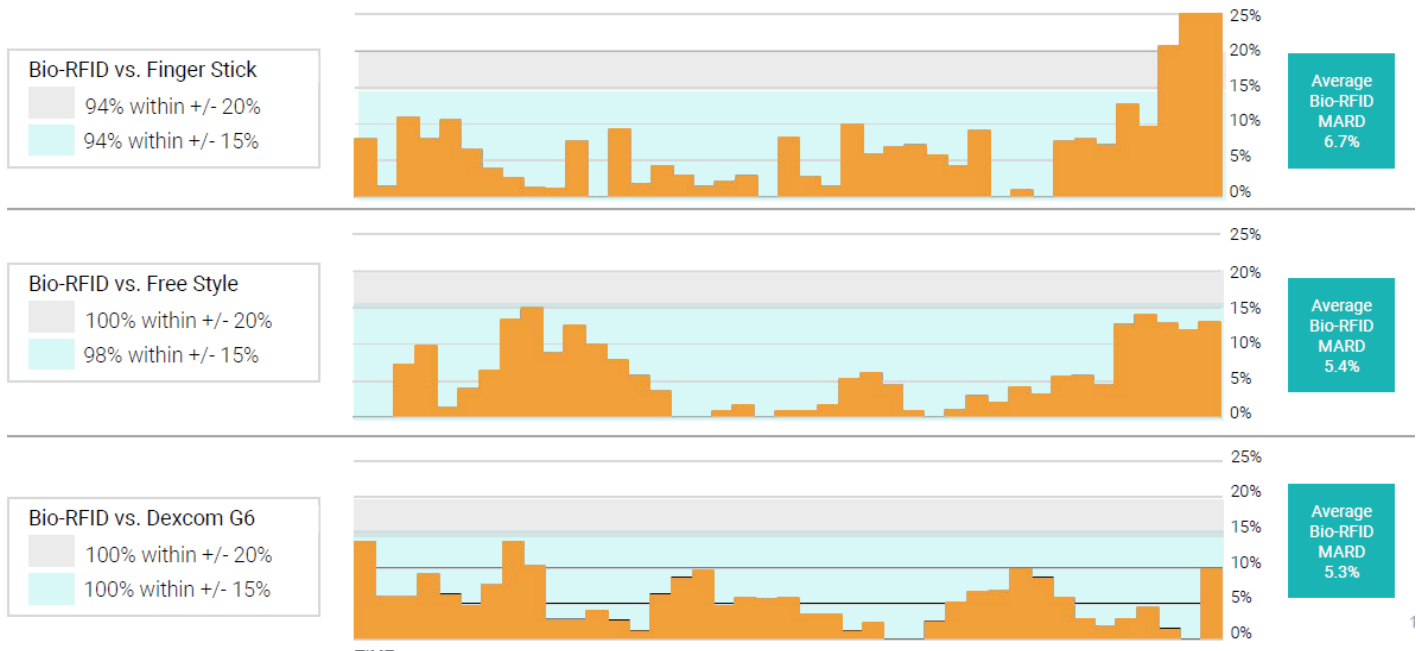
Source: Know Labs.

Exhibit 12. Bio-RFID Expected Path to Market

PRE-FDA STUDIES				FDA CLINICAL TRIALS	COMMERCIAL RIGHTS & PRODUCT LAUNCH
INTERNAL VALIDATION		SCIENTIFIC RESEARCH VALIDATION			
IN VITRO	IN VIVO	IN VITRO	IN VIVO		

PROGRESS TO DATE

Know Labs conducted hundreds of internal tests validating the Bio-RFID technology and comparing its accuracy to other FDA approved devices.

Completed *in vitro* validation with world renowned academic medical center.

In vivo external validation of Bio-RFID glucose monitoring technology to be kicked off soon.

FDA multi-site clinical trials and application submitted.

FDA clearance .

Product manufacturing and commercialization.

Source: Know Labs.

Exhibit 13. It's a Big Market with Big Valuations
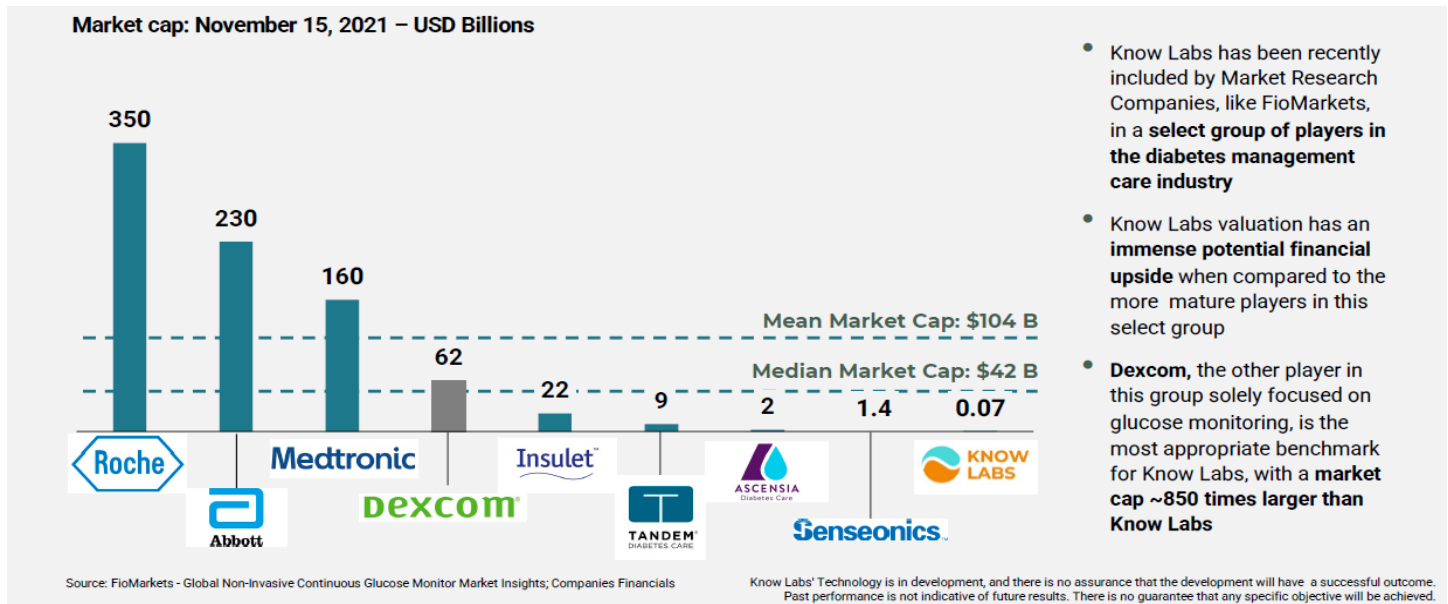
Source: Know Labs

Exhibit 14. Can the Company Make It – Know Labs has Established Multiple Manufacturing Partnerships

Source: Know Labs

Exhibit 15. Does the company Have Strong IP?

62 patents issued and pending build and protect Know Labs' technology platform	2012	First patent approval for sensor technologies developed from ChromaID™ laboratory studies
	2017	Bio-RFID™ developed by leveraging the core technology and IP of ChromaID™
	2019/20	Development of new IP in the RF short and long radio wave spectrum - 14 issued and 24 pending electro-magnetic energy spectrum patents
	2020	USPTO grants US patent 10,548,503 "Health Related Diagnostics Employing Spectroscopy in RF and Microwave Band Frequencies" with a priority date of May 8, 2018 and expiration date of May 7, 2039
	2021	USPTO grants US patent 11,033,208 "Fixed Operation Time Frequency Sweeps for an Analyte Sensor" with a priority date of February 5, 2021 and expiration date of February 5, 2041

Source: Know Labs

Exhibit 16. 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 17. 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 18. 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 19. 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					
		5%	10%	15%	20%	25%	30%
Earnings Multiple	2	$7.14	$5.15	$3.78	$2.80	$2.11 $	1.60
	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 20. Sum-of-the-Parts Model

Sum of the Parts	LT Gr	Discount Rate	Yrs. to Mkt	% Success	Peak Sales MM's	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.
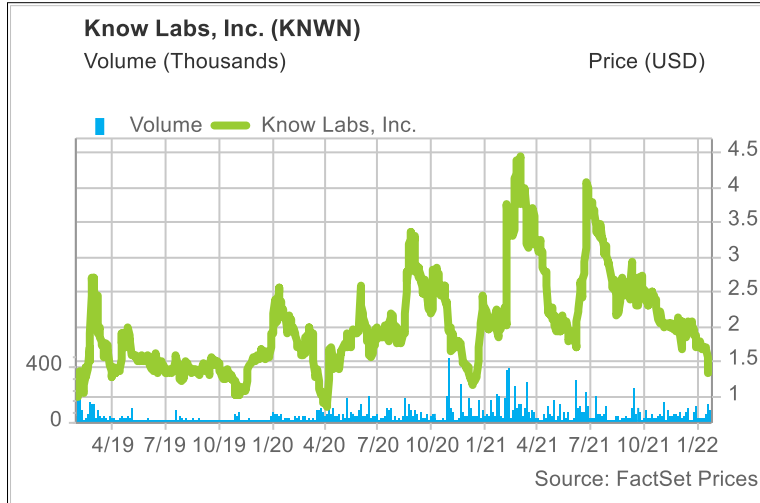
Exhibit 21. Income Statement

KNWN., Inc. Income Statement ($000)																	
YE Sept. 31	2021A	1Q22E	2Q22E	3Q22E	4Q22E	2022E	1Q23E	2Q23E	3Q23E	4Q23E	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		-	-	-	-	-	-	-	-	-	-	-	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													14%	10%	8%	7%	6%	5%
Gross Profit		-	-	-	-	-	-	-	-	-	-	-	94,224	210,906	307,749	416,383	675,670	783,537
Research & Development	3,970	667	695	695	723	2,779	720	750	750	780	3,000	6,000	12,000	12,240	12,485	12,734	12,989	13,249
General & Administrative	6,476	1,200	1,250	1,250	1,300	5,000	1,224	1,275	1,275	1,326	5,100	5,202	10,000	15,000	15,300	15,606	15,918	16,236
Marketing & Business Development	-	-	-	-	-	-	-	-	-	-	-	2,000	4,000	15,000	25,000	25,500	26,010	26,530
Total expenses	10,446	1,867	1,945	1,945	2,023	7,779	1,944	2,025	2,025	2,106	8,100	13,202	26,000	42,240	52,785	53,840	54,917	56,016
Operating Profit	(10,446)	(1,867)	(1,945)	(1,945)	(2,023)	(7,779)	(1,944)	(2,025)	(2,025)	(2,106)	(8,100)	(13,202)	68,224	168,666	254,964	362,542	620,753	727,522
Oper Margin																		
Interest Income (expense)	(14,914)					-					-	-	-	-	-	-	-	-
Other Income						-					-	-	-	-	-	-	-	-
Pre-tax income	(25,360)	(1,867)	(1,945)	(1,945)	(2,023)	(7,779)	(1,944)	(2,025)	(2,025)	(2,106)	(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%	0%	0%	0%	0%	10%	15%	20%	25%
GAAP Net Income	(25,360)	(1,867)	(1,945)	(1,945)	(2,023)	(7,779)	(1,944)	(2,025)	(2,025)	(2,106)	(8,100)	(13,202)	68,224	168,666	229,468	308,161	496,602	545,641
GAAP-EPS	(0.86)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	(0.13)	0.65	1.60	2.16	2.88	4.60	5.02
Non GAAP EPS (dil)	(0.86)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	(0.13)	0.65	1.60	2.16	2.88	4.60	5.02
Wgtd Avg Shrs (Bas) - '000s	29,371	40,000	40,080	60,160	60,280	50,130	60,401	70,522	70,663	70,804	68,097	71,159	71,730	72,305	72,886	73,471	74,060	74,654
Wgtd Avg Shrs (Dil) - '000s	29,371	93,000	93,186	113,372	113,599	103,289	93,186	103,372	103,579	103,786	100,981	104,202	104,933	105,670	106,411	107,158	107,910	108,668

Source: Dawson James estimates, company reports

Companies mentioned in this report:

Important Disclosures:

Price Chart:

Know Labs, Inc. (KNWN)
Volume (Thousands)   Price (USD)

■ Volume ━━ Know Labs, Inc.

Source: FactSet Prices

Price target and rating changes over the past three years:
Initiated – Buy – February 8, 2022 – Price Target $7.0

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1) **Buy**: The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months.
2) **Neutral**: The analyst believes the price of the stock is fairly valued for the next 12-18 months.
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The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of…   8-Feb-22

Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	31	76%	6	19%
Market Perform (Neutral)	10	24%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	41	100%	6	15%

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