Harbinger Research
Independent Investment Analysis

Coverage Initiation Report

Novel Medical Devices
Type I Diabetes Management

June 2, 2025

Brian R. Connell, CFA
Senior Research Analyst

American Diversified Holdings Corp. (ADHC – OTC Pink)

Breakthrough Diabetes Device Promises Better Health Outcomes and Fewer "Dead in Bed" cases for Millions of Type 1 Diabetes Sufferers Around the World

Strong Speculative Buy

Recent Price: **US$0.0022**

Market Data (closing prices, May 30, 2025)

Market Capitalization (mln)	3.22
Fully-Diluted Market Cap (mln)	8.01*
Fully Diluted Shares (mln)	3642
Avg. Volume (30-day, mln.)	23.69
Institutional Ownership	0%
Insider Ownership	64.1%
Exchange	OTC Pink

**Fully diluted, as of March 31, 2025*

Balance Sheet Data (as of Jan. 31, 2025, in $000s)

Shareholders' Equity (000s)	(22,747)
Price/Book Value	N/A
Cash (000s)	2.3
Net Working Capital (000s)	(409)
Long-Term Debt (000s)	0
Total Debt to Equity Capital	N/A

Company Overview

American Diversified Holdings Corp. is developing a breakthrough device for sufferers of nocturnal diabetic hypoglycemia. Its GlucoGuard device promises to address this problem by being the first of its kind that will automatically sense and treat low blood glucose in sleeping individuals without waking them up. The Company has a strategic partnership with industry giant Dexcom that powers the data portion for their device.

ADHC trades on the OTC Pink market.

Company / Investor Contact Information

John A. Cacchioli, Esq.
Chief Executive Officer
O: (212) 537-5900
JC@American-Diversified.com
GlucoGuardSleep.com
American-Diversified.com

Investor Hotline: (858) 325-7098
ADHCinvestor@yahoo.com
American Diversified Holdings Corp.
122 15th Street. Suite 2568
Del Mar, CA 92014

Summary and Investment Opportunity

- **1.6 million Americans suffer from Type 1 diabetes, reducing their life by 7 years**

On average, people with Type 1 diabetes have a life expectancy that is seven years lower than that of the general U.S. population. Furthermore, they experience elevated levels of health problems such as extreme daytime sleepiness, general lethargy, cardiovascular problems leading to vision loss, kidney damage, peripheral nephropathy, and a host of other problems. Most of these problems are caused by unrecognized low blood sugar levels.

- **ADHC's GlucoGuard device promises a better life for diabetics globally**

The Company's GlucoGuard device is designed to prevent low blood sugar levels (hypoglycemia) in sleeping individuals without waking them. This device potentially constitutes a revolution in nocturnal diabetes care, as competing devices rely on calls or alarm systems to wake the hypoglycemic patient so they can ingest glucose. These patients sometimes miss these alarms, for various reasons, sometimes resulting in "death in bed."

- **The Company is seeking "Breakthrough Device Designation" from the FDA**

The Company's ultimate goal is to receive FDA marketing clearance so that it can begin selling its product and helping Type 1 diabetes sufferers in the U.S. and abroad. However, its first challenge is to have the FDA recognize its device as "De Novo," signifying that is in fact based on a new technology and should be given Breakthrough Device Status. It has already received a positive reaction from the FDA, which has asked it to provide a prototype for evaluation. Given the Company's data partnership with Dexcom and prototyping contract with Arete Biosciences, we believe this could occur in the very near future. However, the Company believes that it will take two years and $3M to $5M in additional capital before it is likely to earn FDA marketing clearance for GlucoGuard.

- **Conclusion and Valuation Analysis**

The Company has the potential to cultivate a business worth tens or hundreds of millions of dollars in the coming years, if several things go its way. It has an exciting and truly novel product vision that has the potential to help millions of people in the U.S. and around the world. This future is of course not without risks. Therefore, we are initiating coverage of ADHC with a rating of Strong Speculative Buy and an initial 12-month price target of $0.012. We recommend that all investors seeking exceptional return potential consider the investment merits of American Diversified Holdings Corp. and its GlucoGuard device.

P&L (000s)	FY'25A	FY'26A	FY'27A	FY'28E	FY'29E	FY'30E	FY'31E	FY'32E
Revenues	**0**	**0**	**0**	**7,500**	**22,500**	**63,750**	**146,250**	**298,125**
Rev CAGR	*N/A*	*N/A*	*N/A*	*N/A*	*100%*	*125%*	*100%*	*75%*
Gr. Margin	*N/A*	*N/A*	*N/A*	*60.0%*	*62.5%*	*65.0%*	*67.5%*	*70.0%*
Op. Income	(200)	(1,650)	(2,950)	2,625	10,350	33,150	84,824	183,347
Op. Margin	*N/A*	*N/A*	*N/A*	*35%*	*46%*	*52%*	*58%*	*61.5%*
Net Income	**(200)**	**(1,650)**	**(2,950)**	**2,625**	**8,177**	**26,189**	**67,012**	**144,844**
Net Margin	*N/A*	*N/A*	*N/A*	35.0%	36.3%	41.1%	45.8%	48.6%
Dil. EPS*	**(0.01)**	**(0.04)**	**(0.07)**	**0.06**	**0.20**	**0.62**	**1.59**	**3.43**
Dil. Shares*	36,422	39,348	41,104	41,490	41,785	41,985	42,137	42,238

** In millions, based on all classes of stock converted to common stock*

Please see analyst certification and disclosures on page 13 of this report.

Industry Background and Analysis

Introduction

The diabetes management industry is a rapidly growing sector within the broader medical device market, propelled by the rising global incidence rate of diabetes, technological innovation, and an increasing emphasis on patient-centric care. American Diversified Holdings Corporation (ADHC) is positioned in this dynamic industry through its development of GlucoGuard, an innovative device designed to address nocturnal hypoglycemia in Type 1 diabetes patients using continuous glucose monitoring (CGM) integration and automated glucose delivery. This section explores the industry context, focusing on the global diabetes epidemic, the CGM market, the unmet need for nocturnal hypoglycemia management, the role of artificial intelligence (AI), competitive dynamics, regulatory challenges, and future opportunities.

The Global Diabetes Epidemic and Market Size

Diabetes represents a significant global health challenge, with its prevalence steadily increasing. The International Diabetes Federation estimates that 537 million adults were living with diabetes (globally) in 2021, a figure projected to rise to 643 million by 2030[1]. In the United States, over 37 million individuals are diagnosed with diabetes, of which 5-10% (approximately 1.8 to 3.7 million) have Type 1 diabetes, an autoimmune condition requiring intensive glucose management.

The economic impact of diabetes is profound, driving a robust market for management solutions. The U.S. diabetes market was valued at $28 billion in 2023, encompassing costs for diagnostics, treatments, and complication management. Globally, the diabetes devices market – covering blood glucose monitoring and insulin delivery systems – was valued at $30.31 billion in 2023 and is expected to grow at a compound annual growth rate (CAGR) of 7.45% through 2030. Additionally, the digital diabetes management market, which includes connected devices and software, reached $13.4 billion in 2024, with a projected CAGR of 8.7% to 2030. These figures underscore the significant demand for advanced diabetes care solutions, setting the stage for ADHC's entry with GlucoGuard

The Continuous Glucose Monitoring (CGM) Market

Continuous Glucose Monitoring (CGM) has emerged as a cornerstone of modern diabetes management, offering real-time glucose readings that enhance glycemic control and reduce complication risks. The global CGM market is expanding rapidly, projected to reach $13.13 billion by 2025 and $24.07 billion by 2030, reflecting a CAGR of 12.89%[2]. This growth is driven by technological advancements, including improved sensor accuracy, extended wear times, and integration with insulin delivery systems, alongside a shift away from traditional self-monitoring blood glucose (SMBG) methods.

Historically dominant, the SMBG market – valued at over $7.8 billion in 2010 – is declining, expected to constitute just 5.15% of the diabetes device market by 2035. Leading companies such as Dexcom, Abbott, and Medtronic dominate this segment, with innovations like Dexcom's G7 (compact and accurate) and Abbott's FreeStyle Libre (cost-effective) reinforcing their market positions. For ADHC, the CGM market is critical, as GlucoGuard integrates with the Dexcom CGM system to deliver its automated nocturnal glucose solution.

Nocturnal Hypoglycemia: A Critical Unmet Need

Nocturnal hypoglycemia – low blood sugar during sleep – poses a severe risk for Type 1 diabetes patients, potentially leading to seizures, coma, or even death (known as "Dead in Bed" syndrome). Approximately 6-10% of Type 1 patients experience severe hypoglycemic events annually, contributing to a life expectancy reduction

[1] International Diabetes Federation, IDF Diabetes Atlas. https://diabetesatlas.org/

[2] Mordor Intelligence, Continuous Glucose Monitoring Market. https://www.mordorintelligence.com/industry-reports/continuous-glucose-monitoring-market

of seven to ten years compared to non-diabetics. While CGM devices provide alarms to alert users of low glucose levels, these are often inadequate for patients who sleep through alerts and/or lack immediate support.

This constitutes a pressing unmet need for an automated, intervention-free solution. GlucoGuard addresses this by using CGM data to detect hypoglycemia and deliver glucose intraorally, bypassing the need for patient action. Unlike existing solutions focused on insulin adjustment, GlucoGuard's direct glucose delivery offers a novel approach, positioning it as a potential game-changer in this market.

The Role of Artificial Intelligence in AI in Diabetes Management

Artificial Intelligence (AI) is reshaping diabetes care by leveraging data analytics for predictive insights and automated interventions. AI systems analyze CGM data to forecast glucose trends, enabling proactive management of hypoglycemic and hyperglycemic events. This aligns with the industry's move toward integrated, patient-minimizing solutions, such as closed-loop insulin systems.

For GlucoGuard, AI is integral, processing CGM inputs to predict nocturnal hypoglycemia and trigger glucose delivery. This capability not only enhances efficacy but also aligns with broader industry advancements, including AI-driven personalization and digital health platforms.

Competitive Landscape and Market Dynamics

The diabetes device market is highly competitive, with Dexcom, Abbott, and Medtronic leading the CGM segment. These firms are advancing closed-loop systems that combine CGM with insulin pumps to create artificial pancreas solutions that manage both high and low glucose levels through insulin modulation. However, these systems do not directly administer glucose, relying instead on insulin cessation to mitigate hypoglycemia.

The Company's focus on automated glucose delivery distinguishes it from these competitors, offering a complementary rather than substitutive solution. Potential competition may arise from glucagon delivery systems under development, though these target severe hypoglycemia and lack GlucoGuard's nocturnal automation focus. ADHC's success will hinge on differentiating its GlucoGuard offering, and on leveraging partnerships, such as its collaboration with Dexcom, to enhance market penetration.

Regulatory Environment and Challenges

The regulatory landscape for medical devices is rigorous, with the U.S. Food and Drug Administration (FDA) setting high standards for safety and efficacy. The Company's submission under the FDA's Breakthrough Devices Program, which is designed to accelerate approval for innovative, life-saving technologies, reflects GlucoGuard's potential to address an important unmet need. The FDA has recognized its novelty and has requested additional data, including prototype validation and safety evidence for unattended glucose delivery. The Company is aggressively working to fulfill all FDA requests and requirements in the near future.

Outlook and Opportunities

The diabetes management industry is poised for sustained growth, fueled by rising diabetes incidence and technological innovation. Trends such as non-invasive glucose monitoring, AI integration, and digital health ecosystems signal a future of smarter, more accessible care. For ADHC, GlucoGuard's alignment with these trends – offering automation, AI-driven precision, and mobile app integration – presents significant opportunities.

With an estimated 190,000 to 380,000 U.S. Type 1 diabetes patients as potential customers (5% to 10% of the Type 1 population), GlucoGuard could generate $360 million to $720 million annually at a $2,000 per-patient cost. Success will depend on securing FDA approval, proving clinical efficacy through ongoing studies, and establishing market traction amidst competition. Strategic partnerships, particularly with CGM leader Dexcom, could amplify its reach, although in our opinion ADHC must also address affordability and reimbursement to maximize the likelihood of broad adoption.

Conclusion, Industry Background and Analysis

In summary, ADHC operates in a thriving industry with a clear growth trajectory, driven by the urgent need for advanced diabetes solutions such as the Company's. GlucoGuard's innovative approach to nocturnal hypoglycemia positions it to meet a critical unmet need, but its path forward requires overcoming regulatory hurdles and establishing a foothold in a competitive market. With the right execution, ADHC could capitalize on this opportunity to become a key player in diabetes care.

Company Analysis

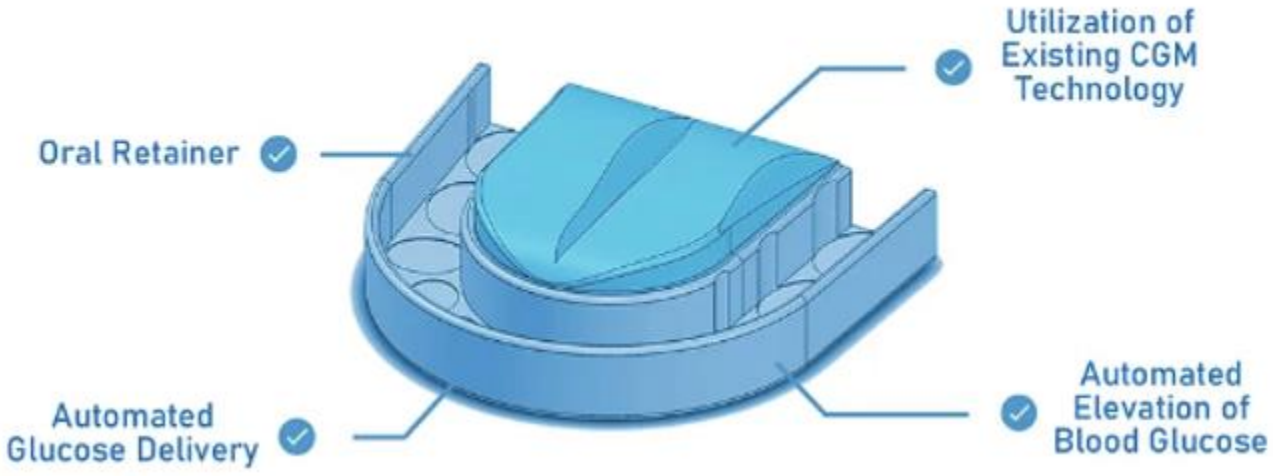
Company Overview

American Diversified Holdings Corporation is a medical device company dedicated to advancing diabetes management through innovative technology. Its flagship product, GlucoGuard, is a nocturnal glucose monitoring and delivery system aimed at preventing hypoglycemia during sleep. The company partners with a leading U.S. research university, a prominent biomedical engineering firm, and a major continuous glucose monitoring (CGM) company to develop its cutting-edge solutions

Based in Del Mar, California, American Diversified Holdings Corporation trades on the OTC Pink market under the symbol ADHC.

The Product

GlucoGuard is a patent-pending medical device developed by American Diversified Holdings Corporation (ADHC) through its operating division GlucoGuard. It is designed to address the critical issue of nocturnal hypoglycemia in Type 1 diabetic patients, a condition that can lead to severe health risks, including the potentially fatal "Death in Bed" syndrome. The device integrates with continuous glucose monitoring (CGM) systems, such as Dexcom's, to provide real-time monitoring of blood glucose levels during sleep. When hypoglycemic glucose levels are detected, GlucoGuard automatically administers glucose intraorally into the buccal cavity (mouth), ensuring that patients do not need to wake up to manage their nocturnal blood sugar levels.



Key Features

- Automated Glucose Delivery: The mouthpiece delivers glucose directly into the buccal cavity when needed, preventing dangerous drops in blood sugar levels during sleep.
- AI-Driven Predictive Algorithms: Sophisticated artificial intelligence predicts hypoglycemic episodes with 95% accuracy, enabling proactive management.
- Seamless CGM Integration: Partners with Dexcom for real-time glucose data integration.

- User-Friendly Design: Simple to use; patients only need to turn it on, place it in their mouth, and sleep.

Development Status

As of May 27, 2025, GlucoGuard has achieved significant milestones in its development:

- Completed Level 2 App integration through Dexcom's Developer Program.
- Developed a functional front-end and back-end app capable of running on an emulator.
- Created a trained predictive algorithm for detecting hypoglycemia with 95% accuracy.
- Secured Registered Developer access to the Dexcom API for initial integration with CGM data.
- Ongoing development of AI features to predict and mitigate negative blood glucose events.

The device is developed in collaboration with a leading U.S. research university (University of California Irvine's MADO program through CALIT2), a prominent biomedical engineering firm (Arete Biosciences), and a major CGM company (Dexcom). The Company anticipates a 2-year timeline from prototype completion to full marketing clearance, with an estimated funding requirement of $3M to $5M to reach IDE submission, pivotal trial completion, and full marketing clearance. The planned pivotal study involves 20-30 Type 1 diabetic patients, and the device is positioned for FDA Breakthrough Device designation due to its unique approach with no comparable Class II biodevices.

Intellectual Property, Current Status and Future Plans

ADHC has established a strategic intellectual property (IP) framework to protect its flagship product, GlucoGuard, ensuring a competitive edge in the diabetes management market. The core technology behind GlucoGuard is covered by a nonprovisional patent application titled "Automated Oral Compound Administration System and Method," filed on May 6, 2021, under application number 17313790, with Zachary Smith as the lead inventor alongside co-inventors Cade Montplaisir, Mauro Robles, Ty Promreuk, and Michael Grapp. This application claims priority from a provisional patent filed on May 12, 2020 (U.S. Provisional Application No. 63/023,514), providing an early priority date for the invention.

The patent application details a comprehensive system for intraoral compound delivery, specifically targeting conditions like hypoglycemia through integration with CGM systems such as Dexcom’s G6 or G7. Key claims include a removable oral retainer housing a compound, a pump mechanism (e.g., piezoelectric or electroactive polymer), a release valve (e.g., duckbill valve), and a controller for wireless communication with remote monitoring devices. Additional claims cover the method of dispensing compounds like glucose based on real-time analyte levels, ensuring precise and automated delivery to maintain patient stability during sleep.

ADHC’s IP strategy extends beyond this patent, with plans to file additional applications for enhancements in AI algorithms and mobile app integration. The Company also employs confidentiality agreements, such as those in its partnership with Arete Biosciences, to safeguard proprietary information during development

However, the current approval status of the nonprovisional patent remains unclear, as no public record confirms its grant by June 2025. This uncertainty, coupled with the competitive patent landscape dominated by CGM giants like Dexcom, underscores the importance of securing broad IP protection to maintain GlucoGuard’s first-mover advantage in this niche and lucrative market.

Target Market Size and Analysis

The total addressable market for GlucoGuard is substantial, driven by the significant prevalence of diabetes and the specific needs of Type 1 diabetic patients at risk for nocturnal hypoglycemia. The following sections detail the U.S. and global TAM estimates, based on company-provided data and corroborated by recent statistical sources.

United States

The U.S. diabetes market is significant, with an estimated 38.4 million people living with diabetes as of 2024, representing 11.6% of the U.S. population (CDC National Diabetes Statistics Report 2024). Of these, approximately 5-10% are Type 1 diabetics, equating to 1.9 million to 3.8 million individuals, as per company estimates. Approximately 10% of these Type 1 diabetics, or 180,000 to 360,000 patients, are potential candidates for the GlucoGuard device, particularly those prone to experience nocturnal hypoglycemia. At an estimated yearly cost of $2,000 per patient for the device and glucose refills, the Company's potential annual revenue in the U.S. is between $360 million to $720 million

Global

Globally, the diabetes population is estimated at 589 million adults (20-79 years) in 2025, according to the IDF Diabetes Atlas (IDF Diabetes Atlas 2025). The company estimates a slightly lower figure of 587 million, which is consistent with recent data. Of these, 5-10% are Type 1 diabetics, resulting in approximately 29.35 million to 58.7 million individuals worldwide. Assuming 10% of these Type 1 diabetics are potential candidates for GlucoGuard, the market includes 2.935 million to 5.87 million patients.

Sales and Marketing

The Company has two options in terms of building the business once the Company's product has received FDA approval and marketing clearance. The first would be to sell the Company to a major player in the industry, such as Dexcom (DXCM – NasdaqGS), at a valuation that is highly favorable to shareholders. In our opinion this is a likely outcome for the Company and its current and future investors, assuming that the Company achieves FDA marketing clearance.

However, it would also be reasonable for the Company to pursue traditional sales and marketing of the then-approved GlucoGuard device, assuming it would have access to sufficient capital do so by this point in its development. This option would entail an initial focus on the U.S. market, with other international markets soon to follow.

Market Entry

Securing FDA Breakthrough Device designation and subsequent marketing authorization is a cornerstone of market entry. The FDA's recognition of GlucoGuard as a novel technology with no direct competitors enhances its market credibility and ability to potentially penetrate the U.S. market relatively quickly.

Upon receiving FDA marketing clearance, the Company would likely begin by collaborating with select diabetes clinics and hospitals to conduct pilot programs, gathering real-world data on GlucoGuard's efficacy and user experience. These programs should both build early sales traction and provide testimonials for broader marketing efforts in the near future.

Once these pilot programs develop traction, the Company would then be in a position to begin sales and marketing in earnest. If things go according to the Company's timeline and they have not already been acquired, then we believe this will begin in approximately 30 months from this writing at the end of 2027 or the beginning of 2028. While it is impossible to know what sales and marketing strategies the Company will choose at this time, we can make an educated guess based on industry norms.

Sales Channels

- Direct Sales: Establish a specialized sales force to engage key opinion leaders (KOLs) in endocrinology and diabetes management. These professionals can influence prescribing decisions and drive adoption in clinical settings.

- Distributor Partnerships: Partner with established medical device distributors with existing networks in hospitals, clinics, and pharmacies. These partnerships can expand GlucoGuard's reach, particularly in rural or underserved areas.

- Online Sales: Develop an e-commerce platform on the GlucoGuard website (GlucoGuardSleep.com) for direct-to-consumer sales, offering patients a convenient purchasing option and access to educational resources.

Marketing Strategies

- Educational Campaigns: Launch targeted campaigns to raise awareness about the risks of nocturnal hypoglycemia and GlucoGuard's unique solution. These campaigns would target healthcare providers through medical journals and conferences, such as the American Diabetes Association's Scientific Sessions, and patients through diabetes advocacy groups.

- Digital Marketing: Utilize social media platforms, diabetes forums, and online communities to engage patients and caregivers. Content will highlight GlucoGuard's ease of use, AI-driven 95% accuracy in predicting hypoglycemic episodes, and integration with Dexcom CGM systems

- Content Marketing: Produce whitepapers, case studies, and videos demonstrating GlucoGuard's effectiveness and user-friendliness. These materials will be shared with healthcare providers and patients to build trust and credibility.

- Influencer Partnerships: Collaborate with diabetes influencers, patient advocates, and healthcare professionals to endorse GlucoGuard, leveraging their platforms to reach a wider audience.

- Trade Shows and Conferences: Participate in major diabetes and medical device conferences to showcase GlucoGuard, network with potential partners, and engage with the medical community.

Strategic Partnerships

The Company has established strategic partnerships to advance the development, regulatory approval, and market positioning of GlucoGuard. These collaborations leverage expertise in continuous glucose monitoring (CGM), software development, and bioengineering, positioning ADHC to deliver a groundbreaking solution in the diabetes management market.

Dexcom

ADHC has secured access to Dexcom's Developer Program, enabling integration of Dexcom's CGM data into GlucoGuard. This allows GlucoGuard to utilize real-time glucose readings to predict and manage hypoglycemic events during sleep.

Dexcom is a global leader in CGM technology, with products like the Dexcom G7 that are renowned for accuracy and user-friendliness. The Company's partnership with Dexcom enhances GlucoGuard's technical capabilities and market credibility, leveraging Dexcom's established reputation and infrastructure.

University of California, Irvine

Through UC Irvine's Mobile Application Design and Development (MADO) program under the California Institute for Telecommunications and Information Technology (CALIT2), ADHC is developing GlucoGuard's mobile app and AI-driven predictive algorithms. UC Irvine's expertise in telecommunications and information technology supports the creation of a sophisticated mobile application that interfaces with GlucoGuard and Dexcom's CGM systems. The AI algorithms, trained to predict hypoglycemic episodes with 95% accuracy, are a core component of GlucoGuard's value proposition.

Arete Biosciences, Inc.

Arete Biosciences, a San Diego-based bioengineering firm, is responsible for designing and prototyping the GlucoGuard device over the next few weeks. When completed, this will be a significant milestone in the Company's development. Arete's expertise in early-stage medical technology development is critical for translating GlucoGuard's conceptual design into a functional prototype. Arete's team reviewed foundational documentation, including intellectual property and design schematics, and with the help of Dr. Stephen Weber devised a development protocol to support FDA approval.

Conclusion, Strategic Partnerships

These partnerships provide ADHC with technical expertise, regulatory support, and market access, enhancing GlucoGuard's potential for success. Future collaborations, such as potential licensing deals with other CGM providers or healthcare institutions, may further strengthen ADHC's market position.

The Team

Apart from its collaborations with researchers, engineers, and medical professionals, the Company employs a full-time CEO and a highly seasoned Medical Advisory Board Chairman.

John Cacchioli, ***President & Chief Executive Officer, and Director***

Mr. Cacchioli has been a licensed attorney in the State of New York since 2009, with significant transactional experience in a wide range of corporate and commercial matters. His legal expertise contributes to his leadership role at ADHC, where he oversees strategic initiatives and corporate governance.

Under his leadership, ADHC has pursued the development of GlucoGuard, a patent-pending nocturnal glucose monitoring and delivery system. Mr. Cacchioli's role involves coordinating with various partners and stakeholders to advance the development and commercialization of GlucoGuard. To this end, John leads the Company's strategic direction, securing funding and partnerships with Dexcom, UC Irvine, and Arete Biosciences.

Dr. Stephen Weber, MD, FACS, ***Chairman, Medical Advisory Board***

is a distinguished orthopedic surgeon and medical advisor with over 25 years of clinical and regulatory experience. He currently serves as Assistant Professor at the Johns Hopkins School of Medicine and leads the Medical Advisory Board at American Diversified Holdings Corporation (ADHC), where he oversees the development of GlucoGuard, an AI-driven device designed to prevent nocturnal hypoglycemia in diabetic patients.

Dr. Weber earned both his undergraduate and medical degrees from the University of Michigan, where he was recognized as an Alpha Omega Alpha scholar. From 1986 to 2016, Dr. Weber maintained a private orthopedic practice in Sacramento, California, focusing on clinical research and sports medicine.

Dr. Weber has contributed extensively to medical literature, authoring numerous papers, clinical articles, and book chapters. He holds editorial roles in several peer-reviewed journals, including the Journal of Shoulder and Elbow Surgery, Sports Medicine and Arthroscopy, and Techniques in Shoulder and Elbow Surgery. In recognition of his contributions, he received a Lifetime Achievement Award from the American Academy of Orthopedic Surgeons in 2015 and the Smith & Nephew/James C. Esch Award for Outstanding Clinical Research in 2016.

Dr. Weber's regulatory expertise stems from his tenure as a Medical Officer and Clinical Reviewer at the U.S. Food and Drug Administration (FDA), where he evaluated orthopedic devices. He continues to offer his insights as an independent regulatory consultant, assisting in the evaluation and clearance of orthopedic and other devices for both the FDA and the European Union.

Zachary Smith, ***Founder, Advisory Board Member***

Zachary is the founder of GlucoGuard and a key member of American Diversified Holdings Corporation's (ADHC's) advisory board, driving the development of the innovative GlucoGuard device. He holds both a

bachelor's degree and master's degree in biomedical engineering from Arizona State University, equipping him with deep expertise in medical device design and development. As the lead inventor named in the nonprovisional patent application for the "Automated Oral Compound Administration System and Method" (filed May 6, 2021), Zachary has been instrumental in conceptualizing and engineering GlucoGuard's unique intraoral delivery system, integrating continuous glucose monitoring (CGM) and AI-driven dosing technology. His technical leadership and vision position ADHC to address a large and important market.

Competition and Competitive Risks

GlucoGuard operates in a competitive diabetes management market, but its unique approach – automated intraoral glucose delivery for nocturnal hypoglycemia – sets it apart. While there are no direct competitors offering a comparable solution of which we are aware, several established players provide indirect competition through alternative hypoglycemia management technologies, posing potential risks to ADHC's market entry. What follows is a breakdown the key players in each alternative technology and the risk it represents to the Company.

Continuous Glucose Monitoring (CGM) Systems

- **Key Players and Products**: Dexcom (G7, G6), Abbott (FreeStyle Libre), and Medtronic (Guardian Connect) dominate the CGM market, valued at $13.13 billion in 2025[3]. These devices provide real-time glucose data and alerts for low glucose levels, enabling manual interventions.
- **Competitive Risk**: **Moderate.** Patients using CGM systems may not perceive a need for GlucoGuard if their current devices effectively manage hypoglycemia through alerts, especially if paired with caregiver support.

Insulin Pumps with Hypoglycemia Prevention Features

- **Key Players and Products**: Medtronic (MiniMed 780G), Tandem Diabetes Care (t:slim X2 with Control-IQ), and Insulet (Omnipod 5) offer insulin pumps with low glucose suspend or predictive algorithms that pause insulin delivery to prevent hypoglycemia.
- **Competitive Risk**: **Moderate.** These systems provide automated hypoglycemia management, potentially reducing demand for a separate device like GlucoGuard, particularly among patients already invested in closed-loop systems.

Glucagon Delivery Systems

- **Key Players**: Companies like Eli Lilly are developing glucagon-based products, such as auto-injectors, for treating severe hypoglycemia. These are primarily for emergency use rather than preventive nocturnal management.
- **Competitive Risk**: **Low**. Future advancements in automated glucagon delivery could compete with GlucoGuard, though current solutions lack its focus on sleep-specific automation.

Artificial Pancreas Systems

- **Key Players**: Medtronic, Tandem, and Insulet are advancing closed-loop systems that combine CGM with insulin pumps to manage both hypoglycemia and hyperglycemia through insulin adjustments.
- **Competitive Risk**: **Moderate.** As artificial pancreas systems become more sophisticated, they could overshadow GlucoGuard's niche by offering comprehensive glucose management, though they do not deliver glucose directly.

Conclusion, Competitive Analysis

The Company's lack of direct competitors provides a first-mover advantage in the niche of automated glucose delivery for nocturnal hypoglycemia. However, indirect competition from established CGM and insulin pump providers, combined with potential technological and regulatory challenges, poses significant risks. ADHC can mitigate these risks by leveraging its partnerships, securing robust IP protection, and executing targeted marketing that highlights the unique value proposition offered by GlucoGuard.

[3] Mordor Intelligence

Other Risks

Introduction

American Diversified Holdings Corporation (ADHC) confronts a multifaceted array of risks as it advances GlucoGuard, its innovative medical device designed to manage nocturnal hypoglycemia in Type 1 diabetic patients. We have evaluated these risks across regulatory, operational, financial, competitive, and market adoption categories.

Regulatory Risk

The regulatory landscape poses a formidable challenge for ADHC. GlucoGuard's commercialization hinges on obtaining clearance from the U.S. Food and Drug Administration (FDA), with the company pursuing either a 510(k) or De Novo pathway alongside a Breakthrough Device designation. However, the FDA has demanded additional data, including prototype validation and safety evidence for the device's unattended intraoral glucose delivery system. This regulatory scrutiny, intensified by the device's novel integration of continuous glucose monitoring (CGM) and automated dosing, introduces uncertainty around approval timelines and outcomes. Despite leveraging expertise from Dr. Stephen Weber, a former FDA officer, ADHC must navigate a complex process where delays or outright rejection could derail its market entry.

Operational Risk

Operationally, ADHC faces significant hurdles in developing a reliable GlucoGuard prototype. The device requires seamless integration of CGM connectivity, AI-driven dosing algorithms, and a compact intraoral delivery mechanism, all tailored for safe and comfortable use during sleep. Technical challenges—such as inaccurate glucose delivery, Bluetooth connectivity issues, or patient discomfort—could disrupt progress. Partnerships with Arete Biosciences and UC Irvine bolster ADHC's capabilities, but the intricate nature of this first-of-its-kind technology heightens the risk of setbacks, potentially delaying development and inflating costs.

Financial / Fundraising Risk

Financially, ADHC operates under tight constraints. The company estimates a $3-$5 million funding requirement to reach critical milestones, including IDE submission, pivotal trials, and marketing clearance. With a limited cash runway, ADHC depends on non-dilutive financing from an undisclosed hedge fund, structured in milestone-based tranches. While this arrangement provides temporary support, any failure to meet milestones or unexpected expenses could trigger a cash crunch. The opacity surrounding the hedge fund's identity and terms further clouds the financial outlook, raising the possibility that ADHC might resort to dilutive capital raises if additional resources are required but not available on terms favorable to the Company.

Dilution Risk

The Company's capital structure amplifies financial risk through potential dilution. ADHC has 1.33 billion common shares outstanding, alongside 100,000 Series B and Series C Preferred Shares convertible into 1 billion and 1.18 billion common shares, respectively, yielding a fully diluted count of 3.51 billion shares and a current fully-diluted market capitalization of $7.73 million. Conversion of these shares, coupled with super-voting rights attached to Series B shares, could significantly dilute existing shareholders and complicate governance and fundraising. Although ADHC has canceled 144 million shares and secured non-dilutive funding to mitigate this risk, the overhang of preferred share conversions remains a concern that could pressure the stock price and future fundraising efforts.

Market Adoption Risk

Market adoption presents its own obstacles. Even if approved, GlucoGuard must overcome patient and provider hesitancy to adopt a novel device, particularly given familiarity with existing CGM and pump solutions. Tentatively priced at $2,000 annually, affordability hinges on insurance reimbursement, which is neither guaranteed nor swift to secure. Convincing endocrinologists and diabetes educators to embrace GlucoGuard will require robust clinical evidence, while patient education campaigns and trials – planned by ADHC – may not quickly translate to widespread use. Slow adoption could stifle revenue growth and limit the device's market impact.

Conclusion, Risks

The Company faces significant risks across regulatory, operational, financial, competitive, and market adoption domains. These risks, if not adeptly navigated, would likely impede GlucoGuard's commercialization and ADHC's growth. Investors should closely monitor the Company's progress in navigating these risks, as they will be pivotal in determining ADHC's long-term success.

Valuation Analysis

ADHC's GlucoGuard device has amazing potential, and if it is ultimately approved by the FDA and given marketing clearance, then we have no doubt that it will serve as the basis for a Company that generates tens or even hundreds of millions in annual sales, both in the U.S. and in select international markets. That may be for ADHC, or for the Company that acquires GlucoGuard from ADHC. Either result would likely be a huge win for investors buying shares at current levels.

However, the Company's fully-diluted market capitalization as of this writing is just over eight million dollars, which is quite lofty for a Company that has not yet received marketing clearance or even entry into the FDA's De Novo Breakthrough Device approval track. If and when they are approved, they will still need to raise an additional $3M to $5M in capital to further develop their prototype into a production-ready device, and conduct two clinical trials for the FDA.

The first of these trials, which was recommended to the Company by the FDA, is an Early Feasibility Study that is meant to confirm the safety of unattended intraoral glucose administration in sleeping patients, addressing concerns about potential risks like aspiration. It will also involve developing a prototype to verify the device's physical compatibility with adult oral anatomy, ensuring it can effectively house the glucose, dispensing mechanism, and electronics necessary to make the device work.

Once it clears this hurdle, to get full FDA approval, it will then need to conduct a trial with 20 to 30 Type 1 diabetic patients. This try is to prove that the GlucoGuard device can successfully detect a hypoglycemic state (below 70 mg/dl) using Dexcom CGM technology, transmit glucose levels to a proprietary mobile app, and then signal the GlucoGuard mouthpiece via Bluetooth to release 15 grams of glucose (equating to 13.9 ml) into the buccal cavity. The goal is to correct blood glucose levels to a normal range of around 90 mg/dl, and this study is a critical step in demonstrating the device's efficacy and safety for regulatory approval.

Conclusion, Valuation Analysis

To reiterate, we see the potential for amazing upside in the shares of ADHC both in the short term if the Company is accepted into the FDA's De Novo track for Breakthrough Device approval, and long term if the Company's human clinical trials are successful and it is given FDA marketing clearance. However, its current valuation and non-trivial future regulatory and fundraising challenges temper our excitement about ADHC to some degree.

We believe that an investment in this Company may be suitable for investors with a high risk tolerance who are looking for an extremely large potential return despite the risks we have identified. We are therefore setting our one-year price target at $0.012 and giving the Company a rating of Strong Speculative Buy. We believe this rating is appropriate due to the extreme upside possible in this industry, and the fact that the Company's device would be the first of its kind on the market with clear competitive advantages vs. other devices currently available.

Conclusion

In conclusion, American Diversified Holdings Corporation stands at a pivotal juncture with GlucoGuard, a device poised to revolutionize nocturnal hypoglycemia management for Type 1 diabetes patients. The Company's strategic partnerships with Dexcom, UC Irvine, and Arete Biosciences, coupled with its pursuit of FDA Breakthrough Device designation, position it to address a critical unmet need in a $28 billion U.S. diabetes market. Despite regulatory and financial hurdles, including a $3M to $5M funding requirement and a planned two-year

timeline to FDA marketing clearance, ADHC's innovative approach offers significant upside potential if it can navigate these challenges and achieve broad market adoption or cultivate an attractive buyout offer.

However, the path forward is not without risks, as outlined in this report, from FDA approval delays to competitive pressures and market adoption uncertainties. With a current fully-diluted total market capitalization of just over $8 million, ADHC presents a high-risk, high-reward opportunity for investors with high tolerance for risk. We see the potential for very substantial investor returns if GlucoGuard receives FDA approval and marketing clearance and captures even a fraction of its estimated $360M to $720M U.S. market potential. Therefore, we are initiating coverage with a Strong Speculative Buy rating and a one-year price target of $0.012.

American Diversified Holdings Corp. P&L Forecast Model

(In $000s, except for per share and customer-count items)

	H2 2025	2026	2027	2028	2029	2030	2031	2032
Total customers at year end				7,500	15,000	33,750	67,500	118,125
Market share of U.S. market, Type 1 diabetes patients				0.27%	0.54%	1.22%	2.43%	4.26%
Revenues								
GlucoGuard revenues at $2,000 annual price per patient				7,500	22,500	63,750	146,250	298,125
CAGR	*N/A*	*N/A*	*N/A*	*N/A*	*100.0%*	*125.0%*	*100.0%*	*75.0%*
Gross costs								
Product manufacturing				3,000	8,438	22,313	47,531	89,438
Gross margin				*60.0%*	*62.5%*	*65.0%*	*67.5%*	*70.0%*
Gross profit				4,500	14,063	41,438	98,719	208,688
Operating expenses								
Sales & marketing	50	150	250	3,000	6,750	15,938	29,250	52,172
As a % of revenues	*N/A*	*N/A*	*N/A*	*40.0%*	*30.0%*	*25.0%*	*20.0%*	*17.5%*
Research & development	100	1,400	2,500	1,125	3,150	8,288	17,550	32,794
As a % of revenues	*N/A*	*N/A*	*N/A*	*15.0%*	*14.0%*	*13.0%*	*12.0%*	*11.0%*
General & administrative	50	100	200	750	2,250	6,375	14,625	29,813
As a % of revenues	*N/A*	*N/A*	*N/A*	*10.0%*	*10.0%*	*10.0%*	*10.0%*	*10.0%*
Total operating expenses	200	1,650	2,950	4,875	12,150	30,600	61,425	114,778
Operating profit	(200)	(1,650)	(2,950)	2,625	10,350	33,150	84,825	183,347
Operating margin	*N/A*	*N/A*	*N/A*	*35.0%*	*46.0%*	*52.0%*	*58.0%*	*61.5%*
Taxes								
Effective state tax rate (CA)	**8.84%**	**8.84%**	**8.84%**	**8.84%**	**8.84%**	**8.84%**	**8.84%**	**8.84%**
California income tax	0	0	0	0	723	2,930	7,499	16,208
Effective federal tax rate	**21%**	**21%**	**21%**	**21%**	**21%**	**21%**	**21%**	**21%**
Federal income tax after CA state tax deduction	0	0	0	0	1,451	4,031	10,315	22,295
Total state and federal taxes	0	0	0	0	2,174	6,962	17,813	38,503
Net profit	(200)	(1,650)	(2,950)	2,625	8,177	26,189	67,012	144,844
Net margin				*35.0%*	*36.3%*	*41.1%*	*45.8%*	*48.6%*
Earnings per share, basic	(0.01)	(0.09)	(0.15)	0.13	0.41	1.30	3.29	7.08
Basic shares outstanding (In millions)	14,631	17,557	19,313	19,699	19,995	20,195	20,346	20,448
Additional dilution		*20.00%*	*10.00%*	*2.00%*	*1.50%*	*1.00%*	*0.75%*	*0.50%*
Earnings per share, fully diluted	(0.01)	(0.04)	(0.07)	0.06	0.20	0.62	1.59	3.43
Fully diluted shares outstanding (In millions)	36,422	39,348	41,104	41,490	41,785	41,985	42,137	42,238

Our Rating System

We rate enrolled companies based on the appreciation potential we believe their shares represent. The performance of those companies rated "Speculative Buy" or "Strong Speculative Buy" are often highly dependent on some future event, such as FDA drug approval or the development of a new key technology.

Explanation of Ratings Issued by Harbinger Research

STRONG BUY	We believe the enrolled company will appreciate more than 50% relative to the general market for U.S. equities during the next 12 to 24 months.
BUY	We believe the enrolled company will appreciate more than 30% relative to the general market for U.S. equities during the next 12 to 24 months.
STRONG SPECULATIVE BUY	We believe the enrolled company could appreciate more than 50% relative to the general market for U.S. equities during the next 12 to 24 months, if certain assumptions about the future prove to be correct.
SPECULATIVE BUY	We believe the enrolled company could appreciate more than 30% relative to the general market for U.S. equities during the next 12 to 24 months, if certain assumptions about the future prove to be correct.
NEUTRAL	We expect the enrolled company to trade between -10% and +10% relative to the general market for U.S. equities during the following 12 to 24 months.
SELL	We expect the enrolled company to underperform the general market for U.S. equities by more than 10% during the following 12 to 24 months.

Analyst Certification

I, Brian R. Connell, CFA, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report.

Disclaimer

This report was prepared for informational purposes only. Harbinger Research, LLC ("Harbinger") was paid $5,000 for the preparation and distribution of this research report by American Diversified Brands Corp. ("Company"). All information contained in this report was provided by the Company or from publicly available sources. To ensure complete independence and editorial control over its research, Harbinger has developed various compliance procedures and business practices including but not limited to the following: (1) Fees from covered companies are due and payable prior to the commencement of research; (2) Harbinger, as a contractual right, retains complete editorial control over the research; (3) Analysts are compensated on a per-company basis and not on the basis of his/her recommendations; (4) Analysts are not permitted to accept fees or other consideration from the companies they cover for Harbinger except for the payments they receive from Harbinger; (5) Harbinger will not conduct investment banking or other financial advisory, consulting or merchant banking services for the covered companies.

Harbinger did not make an independent investigation or inquiry as to the accuracy of any information provided by the Company, and is relying solely upon information provided by the companies for the accuracy and completeness of all such information. The information provided in the Report may become inaccurate upon the occurrence of material changes, which affect the Company and its business. Neither the Company nor Harbinger is under any obligation to update this report or ensure the ongoing accuracy of the information contained herein. This report does not constitute a recommendation or a solicitation to purchase or sell any security, nor does it constitute investment advice. This report does not take into account the investment objectives, financial situation or particular needs of any particular person. This report does not provide all information material to an investor's decision about whether or not to make any investment. Any discussion of risks in this presentation is not a disclosure of all risks or a complete discussion of the risks mentioned. Information about past performance of an investment is not necessarily a guide to, indicator of, or assurance of, future performance. Harbinger cannot and does not assess, verify or guarantee the adequacy, accuracy, or completeness of any information, the suitability or profitability of any particular investment, or the potential value of any investment or informational source. Harbinger and its clients, affiliates and employees, may, from time to time, have long or short positions in, buy or sell, and provide investment advice with respect to, the securities and derivatives (including options) thereof, of companies mentioned in this report and may increase or decrease those positions or change such investment advice at any time. Harbinger is not registered as a securities broker-dealer or an investment adviser either with the U.S. Securities and Exchange Commission or with any state securities regulatory authority.

ALL INFORMATION IN THIS REPORT IS PROVIDED "AS IS" WITHOUT WARRANTIES, EXPRESSED OR IMPLIED, OR REPRESENTATIONS OF ANY KIND. TO THE FULLEST EXTENT PERMISSIBLE UNDER APPLICABLE LAW, HARBINGER EQUITY RESEARCH, LLC WILL NOT BE LIABLE FOR THE QUALITY, ACCURACY, COMPLETENESS, RELIABILITY OR TIMELINESS OF THIS INFORMATION, OR FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE DAMAGES THAT MAY ARISE OUT OF THE USE OF THIS INFORMATION BY YOU OR ANYONE ELSE (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, LOSS OF OPPORTUNITIES, TRADING LOSSES, AND DAMAGES THAT MAY RESULT FROM ANY INACCURACY OR INCOMPLETENESS OF THIS INFORMATION). TO THE FULLEST EXTENT PERMITTED BY LAW, HARBINGER EQUITY RESEARCH, LLC WILL NOT BE LIABLE TO YOU OR ANYONE ELSE UNDER ANY TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY, PRODUCTS LIABILITY, OR OTHER THEORY WITH RESPECT TO THIS PRESENTATION OF INFORMATION.

Harbinger Research is an independent equity research firm with a focus on providing coverage to small-cap companies. Our mission is to help our clients achieve fairer market valuations, an expanded shareholder base, improved liquidity, and easier access to capital markets. We do this by providing insightful, in-depth research reports and by making sure those reports are widely distributed and made available to both institutional and individual investors. We strive to deliver superior research coverage, and the result is compelling – consistent coverage from industry-expert analysts that is well written and consists of insightful analysis, cogent arguments, and in-depth financial models. To learn more about Harbinger Research and view our research reports, we invite you to visit our website located at www.harbingerresearch.com.

Analyst Highlight

Brian R. Connell, CFA **Senior Research Analyst**

Mr. Connell has over 25 years' experience in the securities industry, as an equity analyst and portfolio manager, and as the Founder and CEO of StreetFusion (acquired by CCBN/StreetEvents), a software company serving the institutional investment community. On the sellside, Mr. Connell served as the technology analyst for Neovest, an Atlanta-based boutique, and as a Senior Analyst - Internet for Preferred Capital Markets, an investment bank based in San Francisco. Mr. Connell has also held the position of Executive Director of Marquis Capital Management, a technology-focused hedge fund.

Mr. Connell holds degrees in Economics and Psychology from Duke University and is a CFA Charterholder.