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Coverage Initiation

Industry: Medical Devices

PETVIVO HOLDINGS, INC.

Set to Emerge as Leader in Key Pet Therapeutics Segment

Analyst: Rob Goldman

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PETVIVO HOLDINGS, INC. (OTC – PETV - \$0.65)

Rating: Speculative Buy

Price Target: \$3.00

COMPANY SUMMARY

PetVivo is an emerging biomedical device company focused on the licensing and commercialization of innovative medical devices for pets and pet therapeutics. PetVivo is leveraging investments made in the human medical device industry to commercialize therapeutics for pets in a capital and time efficient way. A key component of this strategy is the accelerated timeline to revenues for veterinary medical devices, which enter the market much earlier than the more stringently regulated pharmaceuticals.

KEY STATISTICS

Price as of 8/8/16	\$0.65
52 Week High – Low	\$5.25 - \$0.35
Est. Curr. Shares Out.	9.0M
Market Capitalization	\$4.3M
Average Volume	5,086
Primary Exchange	OTCPK

CORPORATE INFORMATION

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Suite 186
Eden Prairie MN 55344

Phone: 612.296.7305

Website: www.PetVivo.comEmail: info@petvivo.com

INVESTMENT HIGHLIGHTS

PetVivo Holdings is well-positioned to emerge as the standard of care for the treatment of osteoarthritis in dogs and horses, an estimated \$3.2 billion combined annual market. There is no current treatment for this unmet medical need, only treatment of the ailment's symptoms.

Slated for full-scale commercialization in the coming months, the PetVivo platform directly improves activity, reduces pain, and is characterized by a strong safety profile. Given the efficacy of its treatment, affordable cost, and the emergence of new, profitable revenue streams for veterinarians PetVivo offers a compelling, therapy for beloved pets, vets, and owners alike.

PetVivo has a deep IP portfolio and enviable leadership team. With \$15 million invested in R&D including \$7 million from NIH, PetVivo has a 17 product-deep human and pet therapy. This includes a dermal filler for wrinkles that targets the cosmetic market. A successful Pivotal FDA Human Trial has been completed but an FDA Premarket Approval (PMA) submission will be deferred until 2017.

In our view, PetVivo is worth \$3.00 today. At 1x 2017 sales, the stock trades at a substantial discount to its peer group, which trades at a nearly 7x P/S multiple. Our \$3.00 price target is based upon a 6x sales multiple on 2017E revenue and affirmed by a Net Present Value (NPV) calculation derived from our preliminary 2019 revenue forecast of \$30M. Thus, we rate these shares Speculative Buy.



COMPANY OVERVIEW

Minnesota-based **PetVivo Holdings, Inc. (OTC – PETV – \$0.65 - Speculative Buy)** is a biomedical device company primed to emerge as the new standard of care for the treatment of osteoarthritis (OA) in canines with *Kush™*, its proprietary and proven therapy for canines and equines. OA is a condition with degenerating cartilage that creates joint stiffness from mechanical stress, resulting in pain and inflammation.

There is no cure for lameness caused by OA and current therapies treat the symptoms and not the cause. Moreover, they typically do not carry a favorable risk profile. Conversely, the PetVivo approach directly improves activity, reduces pain, and is characterized by a strong safety profile.

In a recent report, the American Pet Products Association (APPA) estimates that the current annual pet therapeutics market is roughly \$16 billion, driven by the love affair we have with our pets, especially dogs and cats. After all, we increasingly treat them as family members rather than just domesticated animals and we actively endeavor to keep them healthy and extend their lives as much as we can. Given the efficacy of its treatment, affordable cost, and the emergence of new, profitable revenue streams for veterinarians, PetVivo estimates that the size of the canine OA treatment markets in the U.S. and EU alone are \$2.6 billion annually.

The Company's core technology traces its roots to the November 2014 acquisition of Gel-Del Technologies, Inc. The technology was originally developed by the Company's President Dr. David Masters at the Mayo Clinic and then licensed on a royalty free technology transfer. The core technology produces thermoplastic protein-based biomaterials that mimic the body's tissue to allow integration, tissue repair and regeneration for long-term implantation.

PetVivo boasts a strong and deep patent portfolio with 8 patents granted in the U.S. alone. Its flagship product, *Kush™ Canine*, is actually a joint injection although categorized as a medical device with a demonstrated history of human safety and efficacy as well as efficacy and safety in canines. Once a small funding for product manufacturing is complete, the treatment will be ready for full-scale commercialization in a matter of months.

It should be noted that following the broad market introduction the Company's canine OA treatment, PetVivo plans to introduce a similar product to treat OA in horses, which represents a \$600 million annual market. With \$15 million invested in R&D including \$7 million from the National Institutes of Health (NIH), PetVivo actually has a deep human product pipeline to match its pet/veterinary efforts. The Company's



lead human product is a dermal filler for wrinkles that targets the cosmetic market. A successful Pivotal FDA Human Trial has been completed but an FDA Premarket Approval (PMA) submission will be deferred until 2017, following the Kush™ commercialization launch.

With a number of competitive advantages in the space, a deep product pipeline and IP portfolio, combined with a clever financial model, we believe that the Company can enjoy hockey-stick type sales growth in the next 2-3 years. At current levels, PetVivo trades at a substantial discount to its peer group on a price/sales basis. In fact, the stock barely trades at a 1x price/sales multiple on our estimated 2017 sales, as compared with a P/S metric of nearly 7x for the peer group. Our \$3.00 price target is based upon a 6x sales multiple on 2017E revenue and affirmed by a Net Present Value (NPV) calculation derived from our projected 2019 revenue of \$30M. We rate these shares Speculative Buy.

INDUSTRY OVERVIEW

According to the American Pet Products Association (APPA), U.S. pet owners will spend around \$63 billion on their pets in 2016, up from \$36 billion just ten years ago. The APPA project \$16 billion, or 26% of all expenditures, will be spent on veterinary care, which happens to be one of the segment's primary growth drivers. Clearly, our love affair with Fido has taken on a life of its own, as we are willing to spend more and more on our pets to extend their lives and quality of life.

At present more than two-thirds of all U.S. households have at least one pet. In fact, today there are an estimated 86 million cats, 78 million dogs and more than 8 million horses owned by U.S. households. Given that there is no current treatment for OA in for canines and equines, and the Company's core technology could be re-positioned for this wide-open market that addresses an unmet medical need, PetVivo has focused its efforts in this treatment category.

OA and the OA Treatment Market

It is estimated that 20 million dogs in the U.S. and EU are diagnosed with osteoarthritis each year, along with 1 million horses diagnosed with "lameness." According to PetMeds.com, osteoarthritis, also known as degenerative joint disease (DJD), is defined as the progressive and permanent long-term deterioration of the cartilage surrounding the joints. Arthritis is the medical term for inflammation of the joints, while osteoarthritis is the term referring to a form of chronic joint inflammation caused by deterioration of joint cartilage. Older dogs are at the highest risk.



http://www.petmd.com/dog/conditions/musculoskeletal/c_multi_arthritis_osteoarthritis?page=show

A physical examination will usually demonstrate degenerating cartilage creating joint stiffness from mechanical stress resulting in inflammation and pain. Affected dogs may also show signs of irritability and reclusiveness which may accelerate a pet owner's desire for swift treatment. Unfortunately, there is no current treatment for OA, only palliative pain therapy or joint replacement, which treat symptoms and not the cause. Furthermore, as illustrated in Table I below, they also carry their own sets of issues. Conversely, PetVivo's flagship product offers significant competitive advantages over these therapies.

Treatment	Kush	NSAID	Galliprant	Joint Injection	Joint Replacement
Pros	Joint Protection; Activity Increase; Pain Reduction; Safety Profile	Temporary Relief; Delivery Form	Temporary Relief	Temporary Relief; Safety Profile	Joint Replacement
Cons	New Treatment	Treats Symptoms, Gastric/Kidney Risks	Treats Pain Only	Declining Efficacy; Vet-Only Treatment	Invasive Procedure; Cost
Treatment Frequency	Annual Injection	1x-2x Daily	Once Daily	Monthly Injection	Surgery & Rehab
Estimated Cost	\$400 - \$600/joint	\$0.90 - \$2.40	TBD	\$150 - \$250/joint	\$2000 - \$4000/joint
Est. Annual Cost	Same as Above	\$400 - \$700	TBD	\$1800 - \$3000	Same as Above
Sources: Company websites, Marble Arch Research					

NSAIDs (Nonsteroidal anti-inflammatory drugs), are currently the most common treatment for OA in canines as they are relatively inexpensive and can be administered by pet owners. However, these drugs do not carry the most favorable safety profile. After prolonged use NSAIDs have been found to cause gastrointestinal issues and could raise renal risk as well in canines (as well as humans.) Most



important, NSAIDS do not treat the cartilage degeneration issue to halt or slow the progression of the osteoarthritis condition.

Other treatments include joint injection and joint replacement. Both of these can be very costly and are vet-only treatments and procedures with that demonstrate varying degrees of efficacy.

In April of this year, **Aratana Therapeutics (NASDAQ – PETX - NR)** received FDA approval for its new treatment for canine OA pain and inflammation only, called Galliprant. According to their website, Galliprant is a novel, first in-class type of NSAID that has a unique mechanism of action and appears to still have mild gastrointestinal side effects but have a better safety profile and perhaps greater (albeit temporary) efficacy than other available NSAIDs on the market today. This once a day anti-inflammatory will be available for sale by veterinarians in the fall of 2016.

Judging by the huge market cap (\$302M) afforded this competing company despite no sales to date, Aratana and Wall Street see huge opportunities in this \$2.6 billion therapeutic opportunity in the U.S. and EU. Aratana estimates that the number of pets diagnosed with arthritis has significantly increased over the past five years, including:

- 13% of all geriatric dogs (22% of geriatric large and giant breed dogs)
- As many as 20% dogs with arthritis remain undiagnosed

The market for equines, while much smaller, offers an extremely attractive opportunity. After all, there is no current reparative treatment for equine joint lameness. Moreover, OA lameness worsens with time from ongoing loss of protective cushion and lubricity (i.e., loss of slippery padding). The estimated annual market for the 1 million potential horses diagnosed with lameness is \$600 million.

PetVivo Solves the Vet's Dilemma

The veterinary business is ever-evolving, and many veterinarians are struggling in consequence. Historically, drug sales represent up to 30% of total revenues at a typical veterinary practice. Revenues and margins at veterinary practices are being eroded because online, big box and traditional pharmacies recently started filling veterinary prescriptions. Plus, OTC products carry lower margins and availability is now ubiquitous. As a result, beyond traditional examinations, vaccinations, and surgery, vets are actively seeking new revenue streams, along with a differentiating, profitable service to offer its patients.

Enter PetVivo.



THE PETVIVO MODEL

PetVivo Holdings, Inc. is an emerging biomedical device company focused on the licensing and commercialization of innovative medical devices for pets, or pet therapeutics. PetVivo believes that it can leverage the investments in the human biomaterials and medical device industries to commercialize therapeutics to pets in a capital and time efficient way. PetVivo's strategy is to in-license proprietary products from human medical device companies specifically for use in pets.

A key component of this strategy is the accelerated timeline to revenues for veterinary medical devices, which enter the market much earlier than the more stringently regulated pharmaceuticals. PetVivo has secured exclusive rights to its first product, an osteoarthritis medical device, which has been shown to be both safe and efficacious. PetVivo believes the administration of its initial therapeutic devices exceeds the benefits of those found in current remedies. Therefore, the commercialization of PetVivo's initial therapeutic devices will provide veterinarians and pet owners safe, effective, and long-lasting treatments to improve the pet's quality of life.

Kush: A Disruptive and Effective OA Therapy



Figure 1: *Kush*[™] Canine Injection

The Company's lead animal product is VD-01 "*Kush*[™] Canine" for osteoarthritis indication in canines. The Company is planning to aggressively launch *Kush*[™] Canine in 4Q16/1Q17. *Kush*[™] Canine is a veterinarian-administered joint injection for the treatment of osteoarthritis in dogs. The device is made from natural components that are lubricious and cushioning to perform like cartilage for the treatment of pain and inflammation associated with osteoarthritis. Management believes that *Kush*[™] Canine is a superior treatment that safely improves joint function.

The reparative *Kush*[™] Canine particles are lubricious, cushioning and long lasting. The spongy protein-based particles mimic the composition and protective function of cartilage (i.e., providing both a slippery cushion and healing scaffolding). Thus, the *Kush*[™] Canine particles protect the joint as an artificial cartilage.

The elegance and simplicity of the PetVivo approach is that the particles are injected into the synovial cavity or space, which is the space between bones that has synovial



fluid. The injection is a standard intra-articular technique requiring no special training, but must be performed in a vet's office. If needed, multiple joints can be treated simultaneously. Not only is there virtually no recovery period, but case studies demonstrate that *Kush™ Canine* increases walking/running/activity and eliminates the need for pain medications such as NSAIDs.

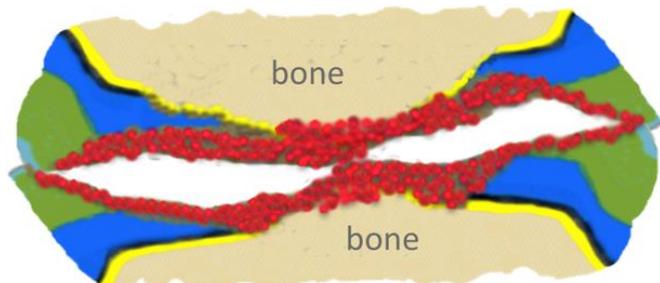


Figure 2: Inflamed Joint

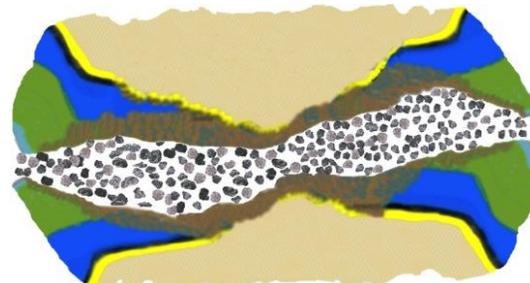


Figure 3: Kush™ Treated Joint

The Genesis

The Company's core technology traces its roots to the acquisition of Gel-Del Technologies, Inc. for 4.15 million shares of PetVivo. The technology was originally developed by the Company's President Dr. David Masters at the Mayo Clinic and then licensed on a royalty free technology transfer. The core technology produces thermoplastic protein-based biomaterials that mimic the body's tissue to allow integration, tissue repair and regeneration for long-term implantation.

Dr. Masters developed Gel-Del's proprietary biomaterials that simulate a body's cellular tissue and thus can be readily and effectively utilized to manufacture implantable therapeutic medical devices. The chief advantage of Gel-Del biomaterials is their enhanced biocompatibility with living tissues throughout the body.

Notably, Gel-Del Technologies successfully completed a pivotal clinical trial using this novel thermoplastic biomaterial as a dermal filler for human cosmetic applications. Gel-Del Technologies' core competencies are developing and manufacturing medical devices containing its proprietary thermoplastic protein-based biomaterials that mimic the body's tissue to allow integration, tissue repair, and regeneration for long-term implantation. These biomaterials are produced using a patented and scalable self-assembly production process. The inherent thermoplastic properties of these biomaterials are then utilized to manufacture or coat implantable devices.



It should be noted that no FDA PMA or 510(k) approval is required for medical devices to be used in veterinary medicine. The FDA defines a medical device as an apparatus or other item that does not achieve its intended purpose through chemical reaction in the body and is not dependent on being metabolized in the body. The PetVivo flagship platform (and the particles) is both classified as a medical device by the FDA since there are no chemical reactions with Kush™ particles and they are not metabolized in the body.

The platform boasts ten years of safety and efficacy in many species and there are strong precedents of comparable medical devices marketed under this above exemption in the veterinary market.

Looking Ahead

Unlike other companies of PetVivo's size and standing, the Company has a FDA validated manufacturing process for human clinical trial production with single line, scalable, consistent lot-to-lot production with a method that eliminates cleaning steps, reduces infrastructure and increases capacity. Moreover, this approach is all about a low capex infrastructure. The base particle materials manufactured internally then aseptically placed into syringes and packaged for distribution. Plus, the Company has already scaled manufacturing to produce batches of two Kilograms of base particles which equates to approximately 5,000 2mL syringes or roughly \$650,000 of sales based on distributor prices. PetVivo will retain manufacturing of base material in house to protect IP but will look to outsource syringe filling and packaging once an appropriate scale is reached.

One major sleeper characteristic of the product is the fact that it is room temperature stable beyond 24 months, which is a major advantage and plus for distributors and veterinarians alike.

A few months following a small funding to secure and ensure the above, full scale commercialization will occur.

Most veterinarians in the U.S. buy a majority of their equipment and supplies from one of six veterinary products distributors. On a combined three distributors (MWI, Patterson Veterinary, Butler Schein) deliver 75%, of the products sold to companion animal veterinarians in the U.S. The product distribution will leverage the existing supply chain and veterinary clinic and clinician relationships already established by these large distributors. This distribution channel will be supported with regional sales representatives who in turn will support our distributors and the veterinary clinics and hospitals. PetVivo will also target pet owners with product education and treatment awareness campaigns utilizing a variety of social media tools. The unique



nature and the anticipated benefits provided by our products are expected to generate significant consumer response.

Importantly, in-clinic, new, effective treatments can quickly grow veterinary practice revenues and accelerate product adoption. Kush can offer significantly higher margin opportunity at the same price point as existing OA medicines while providing better outcomes with less side effects for animals.

The PetVivo product launch schedule includes releases in 2016/2017. The *Kush™ Equine* device for the treatment of equine lameness related to or impacting synovial joints is currently scheduled for launch in 4Q16/1Q17. The *Kush™ Equine* product has similar features and benefits as to *Kush™ Canine* device. In addition to being a treatment for osteoarthritis, the joint cushioning and lubricity effects of our devices have shown an ability to treat equine lameness that is due to navicular disease (a problem associated with misalignment of joints and bones in the hoof and digits). Management anticipates launching our Kush Digital Cushion (DC) device for the treatment of navicular disease in 2017.

The Company's current pipeline includes 17 therapeutic devices for both veterinary and human clinical applications in various stages of development from safety tests to FDA submission. This includes HD-05, the dermal filler for wrinkles highlighted in tests above. A successful Pivotal FDA Human Trial has been completed but an FDA Premarket Approval (PMA) submission will be deferred until 2017, following the Kush™ commercialization launch.

In addition to commercializing its own products in strategic market sectors and in view of the Company's vast proprietary product pipeline, the Company anticipates establishing strategic out-licensing partnerships to provide secondary revenues.



EXECUTIVE MANAGEMENT

John Lai, Co-founder, CEO, Chairman

Mr. Lai has over 30 years of senior operations and financial experience and has served as CEO at Rovvr, Inc. & Genesis Capital Group, Inc., President at Viper Powersports, Inc. and CFO at Buyitnow.com. Mr. Lai has extensive experience in capital structure, financial analysis, business formation, mergers, acquisitions and driving production revenue growth.

David Masters, Ph.D., President, Chief Technical Officer, Director

Dr. Masters is an entrepreneur, biochemist, biomaterials expert and inventor with credentials from Rutgers, Harvard, U of MN and the Mayo Clinic. Dr. Masters has over 30 years of experience, including >50 publications, FDA clinical trial, 36 issued or pending patents and >\$7 million in NIH grant awards.

John Dolan, Co-founder, CFO, General Counsel, Director

Mr. Dolan has over 25 years of experience as a legal professional, patent attorney, corporate council and senior executive as an expert in the utilization of IP to capitalize and commercialize entities. He has served as a USPTO patent examiner in the organic chemistry and biotechnology area and as a partner at Fredrikson & Byron P.A.

Randall Meyer, Chief Operating Officer, Director

Mr. Meyer has over 25 years of leadership experience in medical device development and commercialization including expertise in successfully growing medical device companies from concept to profitability as a Chief Executive Officer, Chief Operating Officer and Director.

FINANCIALS

It should be noted that although the current listed shares outstanding figure is roughly 9 million shares, it does not reflect the 4.15 million shares as part of the share exchange/combination with Gel-Del. Once the next filing occurs, which will bring PetVivo current, the new shares out will be 13.15 million. It should be noted that the peer group in Table II below utilizes the 13.15 million share figure.

At this time, we are preliminary projecting that full-scale commercialization will occur around the turn of the year. However, with a small inventory of product in hand, investors could see anywhere from a few hundred thousand toward \$1 million in revenue in 2016. Clearly, the first full year of product commercialization, especially of *Kush Canine* will be on 2017. We estimate preliminary sales of \$8 million in 2017,



with sales rising to \$15 million in 2018 and \$30 million in 2019. We note that our forecasts assume essentially veterinary product sales only. Investors can expect industry-equivalent operating margins of 20-30% beginning sometime in 2018 (or sooner), as PetVivo enjoys a critical mass of sales.

RISK FACTORS

Although PetVivo is on the cusp of full-scale product commercialization, a number of hurdles exist, including business development, financial, and production. For example, while its capex requirements are relatively low, delays could occur, which would affect the timeline outlined above. Other risks include a slow sales build of key products or competition from current or new entrants into the field. Given the Company's current standing, battle-tested approach, major competitive advantages, and enviable leadership team, we do not believe that funding timing or sales growth are meaningful risks. In any event, these risk factors are commensurate with companies of PetVivo's size and standing.

Volatility and liquidity are typical concerns for newly listed microcap stocks that trade on the over the counter market with small public floats such as with PETV where fewer than 1,000,000 are in the public float. As a result, the stock is subject to sharp swings. Moreover, since this stock is newly traded, there is limited current available financial data at this time. But, as the year goes on, we expect the income statement to accurately reflect revenue generation and future potential. We should note that the shares outstanding could increase due to potential capital needs. However, since the proceeds of any future funding would likely be used in part to close on M&A, we believe that any dilutive effect from such a funding would be nullified by a related increase in overall market value.

CONCLUSION

PetVivo Holdings is well-positioned to emerge as the standard of care for the treatment of osteoarthritis in dogs and horses, an estimated \$3.2 billion combined annual market. There is no current treatment for this unmet medical need, only treatment of the ailment's symptoms.

Slated for full-scale commercialization in the coming months, the PetVivo platform directly improves activity, reduces pain, and is characterized by a strong safety profile. Given the efficacy of its treatment, affordable cost, and the emergence of new, profitable revenue streams for veterinarians PetVivo offers a compelling, therapy for beloved pets, vets, and owners alike.



MARBLE ARCH
RESEARCH, INC.

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Table II. PetVivo Holdings, Inc. Peer Group

Company Name	Symbol	Price (8/8/16)	Mkt Cap (mil)	FY16E Revs (mil)	FY17E Revs (mil)	16E - 17E Revs Growth	2016E Price/Revs	2017E Price/Revs	PETV @ 6.0x 2017E Revs
Abaxis	ABAX	\$48.93	\$1,100	\$239	\$267	11.7%	4.6	4.1	
Aratana Therapeutics	PETX	\$8.55	\$302	\$3	\$24	753.6%	107.9	12.6	
Idexx Labs	IDXX	\$108.62	\$10,210	\$1,770	\$1,910	7.9%	5.8	5.3	
Zoetis	ZTS	\$50.80	\$25,230	\$4,870	\$5,190	6.6%	5.2	4.9	
Average			\$9,211	\$1,720	\$1,848	195%	30.9	6.7	
PetVivo Holdings*	PETV	\$0.66	\$9	\$1	\$8	700.0%	8.5	1.06	

Sources: www.Yahoo!Finance.com, Company websites, Marble Arch Research



RECENT TRADING HISTORY FOR PETV

(Source: www.Stockta.com)





SENIOR ANALYST: ROBERT GOLDMAN

Rob Goldman joined Marble Arch Research in 2016. He founded and has operated Goldman Small Cap Research Inc. since 2009. Rob has over 20 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

ANALYST CERTIFICATION

I, Robert Goldman, hereby certify that the view 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.

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