



VECTA LTD.

***Strategic Partnership Opportunity for
VECAM™, the Next Generation in PPI Therapy***

NON-CONFIDENTIAL INFORMATION MEMORANDUM

JUNE 2009

**Contact Dr. Michael Naveh, CEO.
9 Atir Yedda Street, Kfar-Saba 44643, Israel
P: +972-9-768-0304 F: +972-1539-768-0304
navem@Vecta.co.il**

TABLE OF CONTENTS

Executive Summary	3
The Opportunity	6
PreClinical Studies	10
Clinical Studies	11
Clinical and Regulatory Strategy:	14
Intellectual Property:	14
Management	15
Scientific Advisory Board	16
Summary	17
References	18

EXECUTIVE SUMMARY

Vecta Ltd. (Vecta) is a privately-held, gastroenterology-focused, specialty pharmaceutical company located in Kfar Saba, Israel. Founded in 2001, Vecta is using safe and novel physiological approaches to create products for the multibillion-dollar gastrointestinal (GI) diseases market.

A particular focus of the company is on diseases that are usually treated by proton pump inhibitors (PPIs) the patents for which have now begun to expire. The PPI market in the US alone exceeds \$13 billion yearly. Despite being the second most successful drug category in the world, treatment with PPIs shows significant unmet medical needs which remain to be solved. Vecta's lead product is VECAM™ which addresses unmet medical needs in the PPI space.

The mechanism of action of PPI's requires the activation of proton pumps in the parietal cells of the stomach, which are responsible for the production of gastric acid. In order to be effective, the PPI has to engage a large number of active pumps because the drug does not bind quiescent pumps. This is accomplished by following the administration of PPIs with a timely prescribed meal. For this reason, it is recommended that PPIs should be dosed 30 - 60 minutes before breakfast on an empty stomach, so the pumps are activated upon exposure to the PPI. Due to this prerequisite for effective PPI action, bedtime administration of PPIs for patients suffering from Gastro Esophageal Reflux Disease (GERD) is not possible because these patients are advised to refrain from food three hours before recumbence. This is particularly relevant in GERD patients who suffer from nighttime symptoms (which are more than 70% of all GERD patients), since current therapeutic regimens do not provide an adequate solution for this problem an effective, patient-friendly treatment for this problem remains an unmet medical need.

The technology:

Vecta has developed VECAM™, a patented approach to improve the action of PPIs and potentially extend the IP lifetime of these drugs, which are nearing the end of their patent life. This approach consists of a new, single daily dose oral medication containing a low molecular weight agent, Succinic Acid (SA) that activates proton pumps without a meal, combined with a PPI. The profound advantage of VECAM™ is that since it is a meal-independent drug, it can be administered at bedtime offering effective control of night time acid reflux symptoms without compromising the overall 24 hour effect of the PPI. Evidently, meal-independent bedtime administration is expected to improve patient compliance.

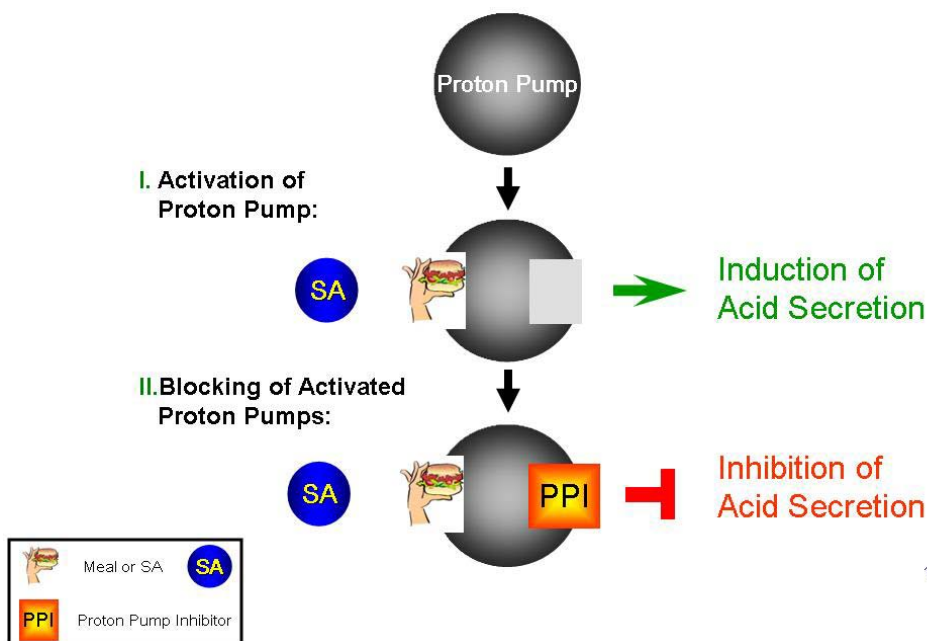
To identify agents that are capable of maximizing PPI activity, Vecta screened and selected several small molecular entities (SMEs) that, in the past, were shown to induce acid secretion in humans. Among the tested molecules, Vecta selected SA, which upon oral administration to humans exhibits a dose-dependent stimulatory effect similar to parenteral Pentagastrin, used to define maximal gastric acid output (MAO), the benchmark for proton pump activation. SA is designated by the FDA as GRAS and is used as a pharmaceutical excipient and nutraceutical. The SA dose used in VECAM is a fraction of the daily allowed dose, even though it is up to 5 times the amount used as a pharmaceutical excipient.

Vecta has demonstrated in preclinical models, that SA in combination with a PPI, results in a notable enhancement of the PPI effect compared to the PPI alone. Proof of concept has been obtained for Omeprazole and Pantoprazole, but the effect is similar for all PPIs.

Vecta has shown in proof of concept clinical trials (Phase I) that SA induces significant and dose dependent increases in gastric acid production in humans. Based upon these findings and supported by the extensive known safety profile of SA, Vecta has advanced the VECAM™ drug product, with Omeprazole, into Phase I/IIa clinical trials in healthy human volunteers in the US.

Furthermore, following the successful completion of these clinical trials, Vecta has received encouragement from the US FDA in a Pre-IND meeting, to advance the product rapidly to Phase III trials under 505(b)(2) New Drug Application, targeting the unmet clinical need for the control of nighttime Heartburn (HB) symptoms and other disorders associated with GERD.

Sequence of VECAM Activity



Vecta has conducted in 2007 and 2008 a series of clinical Phase I/II studies. In these trials Omeprazole and SA were used, and provided clear evidence of improved pH control during the day and especially at night in all patients compared to Omeprazole alone.

Vecta completed a clinical PD trial in Q1 2009 PD under a US FDA IND which has confirmed that VECAM™ bedtime administration without food is effective for control of gastric pH (pH>4) during nighttime and the following daytime.

Vecta believes that the continued clinical development and commercialization of VECAM™ should be accomplished through an alliance with a leading pharmaceutical partner with a proven track record of marketing through primary care physicians. Management believes that the commercial opportunity for VECAM™ is in excess of \$1 billion yearly in the US alone and that the cost and risk associated with its development are minimal.

The following factors strongly support the size and attractiveness of this opportunity for current PPI companies or GI players as well as for others interested in entering the PPI market:

Regulatory landscape:

- 505(b)(2) NDA regulatory path and advancement to pivotal phase III.
- A unique indication for the treatment of nighttime and daytime heartburn and other symptoms associated with GERD as well as healing of esophagitis.
- **Clinical use:**
- Completed Phase I/IIa study with strong evidence of:
 - VECAM™ treatment results in gastric pH>4 values throughout the critical nighttime hours, without compromising its daytime effect.
 - VECAM™ can be effectively administered in a meal independent manner at bedtime.
 - VECAM™ treatment results in unprecedented gastric pH values higher than 4 during night and daytime, providing the robust acid suppressive activity.
 - VECAM™ exhibits an early effect from the first treatment.
 - VECAM™ was shown to be safe.
- The clinical implications are:
 - VECAM™ is ideal to treat nighttime HB which affects more than 70% of GERD patients.
 - Meal independence combined with effective bedtime administration increases overall efficacy and patient satisfaction / compliance.
 - Rapid onset and early achievement of steady state make VECAM™ suitable for on-demand use and relevant for first time PPI users (first time PPI users contribute 20% of all yearly PPI prescriptions).
 - Achievement of unprecedented high pH values for extended periods of time may provide an advantage to treat symptomatic GERD patients.

Intellectual Property use:

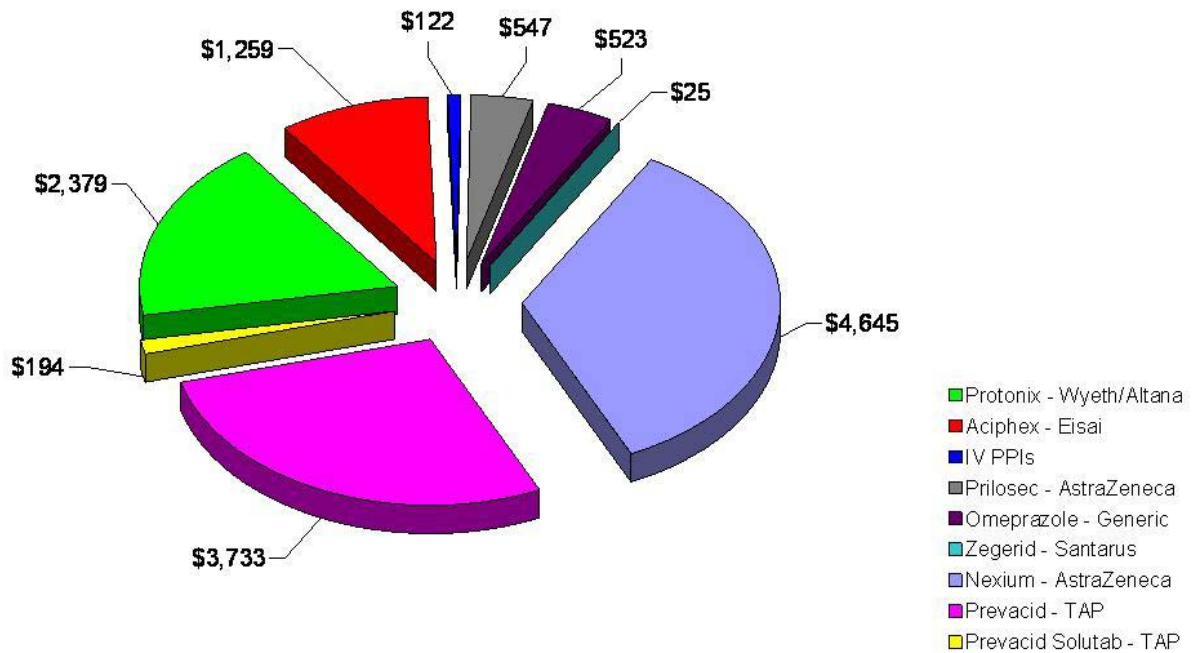
- Proprietary entry opportunity for new players.
- Opportunity to create a novel market position for existing PPIs, providing IP protection for any PPI in combination with SA with a unique label.
- Opportunity to influence IP life cycle management of existing PPIs at the end of their IP protection.

THE OPPORTUNITY

The control of acid secretion is a cornerstone in the therapy of upper gastrointestinal disorders. PPIs (Proton Pump Inhibitors) are the most potent inhibitors of gastric acid secretion in clinical use to date and have grown to become the second largest class of pharmaceuticals in the world, behind cholesterol lowering agents.

PPI Sales, U.S 12 month pharma market share

Total of \$13,427 Million 12 months ending May 2006



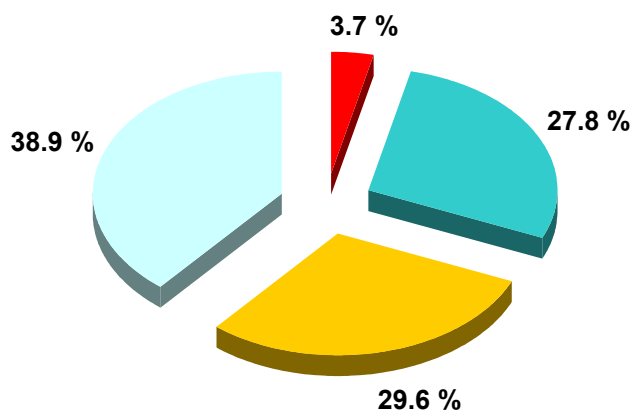
Optimal PPI efficacy is dependent on administration before a meal (preferably on an empty stomach, 30-60 minutes prior to food intake). This event sequence: first treat and then eat, is essential for success of any PPI treatment and is related to the PPI mechanism of action. The effectiveness of these agents is critically dependent on the number of available active proton pumps while the PPIs are present in the blood (the window of opportunity is 60 to 90 minutes) and relies on careful timing of food intake and its content following the administration of a PPI. [1][2]

Depending on the constituents of the meal, meal stimulation may activate up to 75% of the proton pumps. The percentage of pump activation defines the number of pumps available for binding by the PPI [3] and ultimately the PPI effect. In a fasting patient, only approximately 20% of the proton pumps are activated, an activity which is mediated by the hormone PACAP [4][5][6].

Coordination with proton pump activation is attempted by administering PPIs between 30 to 60 minutes prior to mealtime. However, compliance with this regimen is far from perfect, frequently leading to suboptimal control of acid secretion in specific patient

populations and clinical situations. A recent review has demonstrated that only 33% of primary care physicians in the US prescribe the medications before meals [7] and as little as 4% of patients actually dose their medications optimally [8][9].

Poor control of GERD with poor patient compliance



■ > 60' before meals ■ As needed ■ At bedtime ■ After meals

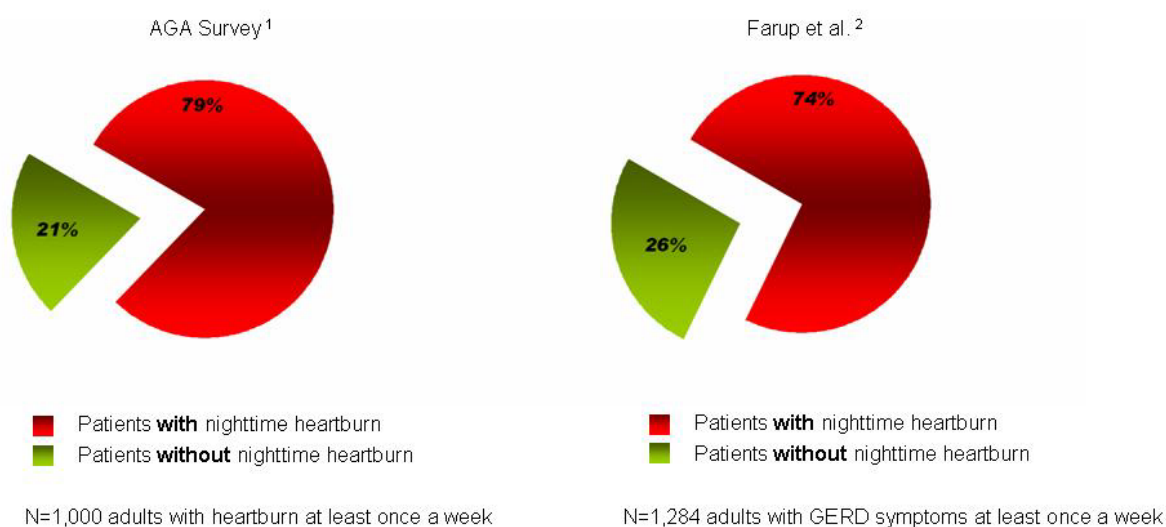
An additional drawback of PPI therapy is the need to achieve the blockade of a significant number of proton pumps in order to obtain the desired elevation of gastric pH. Due to the kinetics of pump activation / blockade, steady state is reached with conventional PPI therapy only after five to seven days of consecutive therapy [3]. VECAM™ achieves this steady state more rapidly by activating a maximal number of pumps as of the first day of administration. This allows for a greater number of pumps to be inactivated by the PPI as compared to activation of pumps with food, timing of which is suboptimal and where the number of activated pumps is related to the highly variable content of a “meal”. The suboptimal activation will allow for residual pumps to take over and secrete acid while new pumps are synthesized to replace the inactivated ones. Only after 5-7 days of consecutive PPI treatment is a balance achieved between pump synthesis, activation and blockade with current PPI therapy. VECAM™ consistently activates a large proportion of these pumps so this balance is achieved at a faster rate.

Current therapy, for the inhibition of acid secretion is incomplete and the residual acid secretion capacity allows for the frequent occurrence of nocturnal acid breakthrough defined as nocturnal reduction of gastric pH below 4 for more than 1 hour despite BID PPI therapy [10].

Special focus on GERD: Although secretion of acid at night is physiological, in GERD patients it may be of clinical importance. However, PPI administration prior to a meal is a problem with GERD patients at night, since it is recommended that GERD patients refrain from eating 2-3 hours before recumbence; a full stomach, especially following a meal rich in fat, will aggravate nighttime esophageal acid reflux. Thus, for GERD patients, a bedtime food-mediated activation of the parietal cells is not practical.

Of importance, in recent studies, more than 70% of GERD patients reported nighttime symptoms:

Nighttime heartburn: Prevalence among people with heartburn



1- Shaker R, et al. *Am J Gastroenterol.* 2003;98:1487-1493

2- Farup C, et al. *Arch Intern Med.* 2001;161:45-52

It is widely accepted in the field that around 50% of GERD patients with nighttime symptoms, do not achieve adequate relief with PPI treatment. Other forms of treatment such as antacids and H₂RA's (e.g. ranitidine) have proven generally inadequate to the task of filling this void. Johnson and Johnson's Propulsid (cisapride), a 5HT₄ agonist, achieved more than \$1 billion in annual sales after being approved in 1993 for the treatment of nighttime GERD before being withdrawn from the market in 2000 due to concerns over severe cardiac side effects. There hasn't been a drug approved for this indication since that time period.

In an April, 2006 review article in *Nature*, Ashburn and Gupta opined the following: "Assuming that 20% of GERD patients taking PPIs do not find adequate relief, nine (30-day) prescriptions per year, pricing on par with today's branded PPIs and a 50% penetration rate, the market for a safe, effective, durable and well-tolerated agent

targeting the unmet medical need in the GERD market could exceed \$1 billion in the US alone.” [13]

The PPI market is rapidly becoming generic where major companies, such as Wyeth, which have enjoyed high prices and sales, are beginning to abandon aggressive marketing since reimbursement payees continue to exert pressure for the use of generics. Since all of the leading PPI's essentially have similar indications, the emergence of a branded product with a differentiated indication provides a significant opportunity to capture market share without the necessity of matching the high level of promotional noise in the historical market. VECAM™ will clinically demonstrate the superior ability to treat nighttime HB symptoms with bedtime administration without food. The FDA has accepted that such a claim is achievable with a Phase III trial. No existing PPI has such claim.

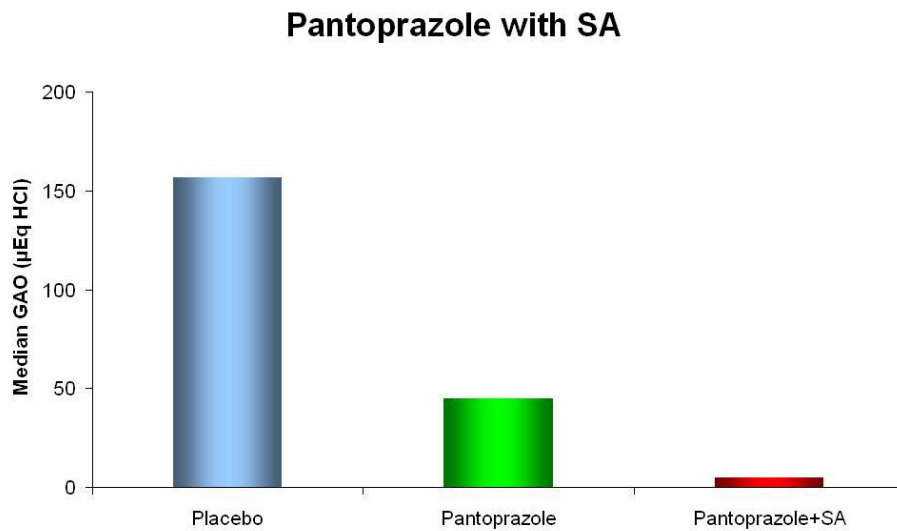
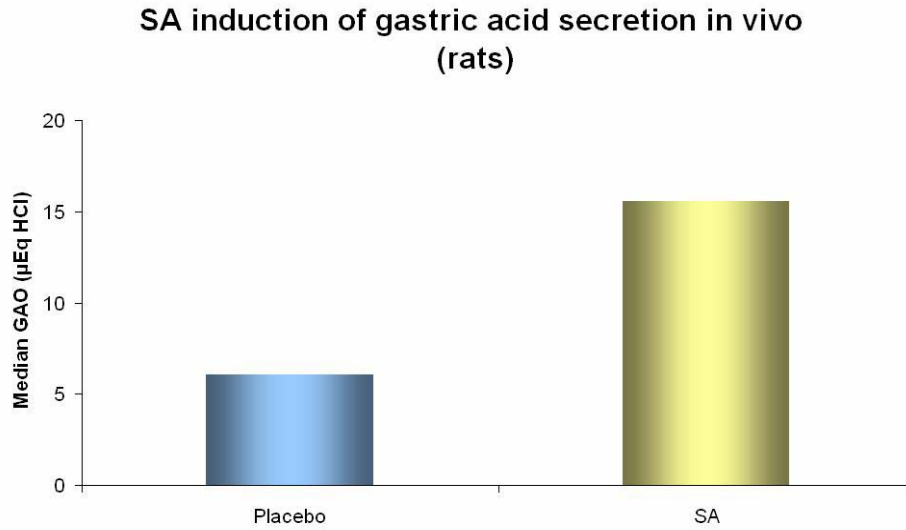
Surveys (see above) [11,13] indicate that more than 70% of GERD patients suffer from nighttime GERD symptoms, so it is reasonable to assume that VECAM™ has the potential to capture a significant share of the market. Since total US prescriptions for PPI's exceed 100 million annually, it would not be unreasonable to expect that VECAM™ could capture 5-8 million prescriptions following an aggressive launch by a motivated partner. Revenues in the US under such assumptions could reach \$1 billion.

PRECLINICAL STUDIES

Vecta has conducted extensive preclinical assessments:

- Administration of SA only stimulated the production of gastric acid.
- SA in combination with several PPIs enhanced the PPI effect.

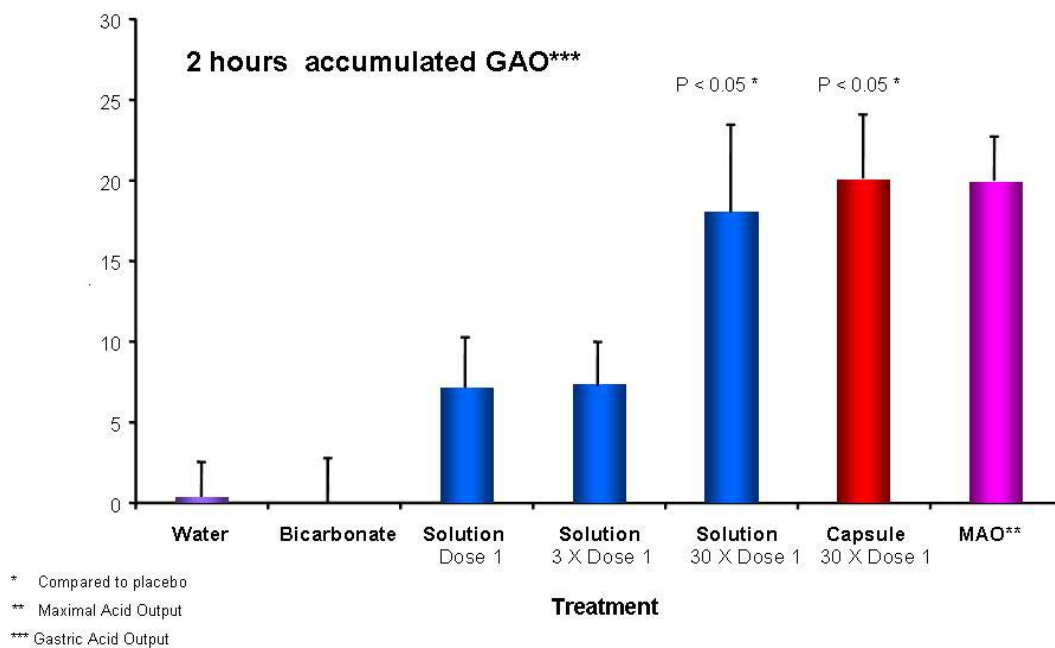
These findings are depicted below:



CLINICAL STUDIES

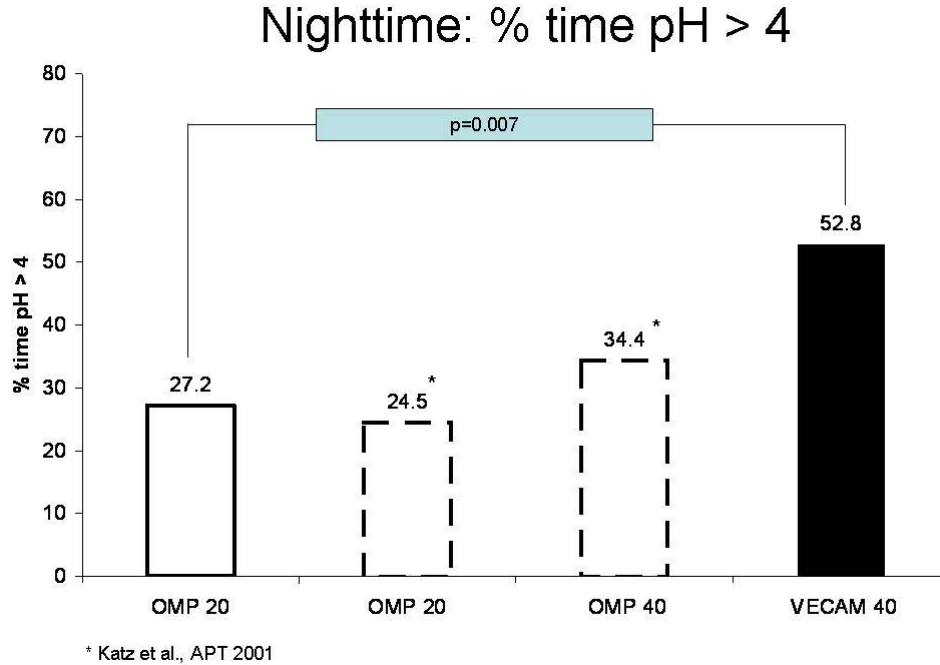
Early proof-of-concept trials conducted in the US showed the ability of SA to stimulate gastric acid output (GAO) in a timely and significant manner, as indicated by the following chart. Results clearly demonstrate that SA, both in solid- and liquid-form, achieves Maximal Acid Output (MAO) comparable to subcutaneous Pentagastrin.

SA proof of concept: Dose dependent GAO

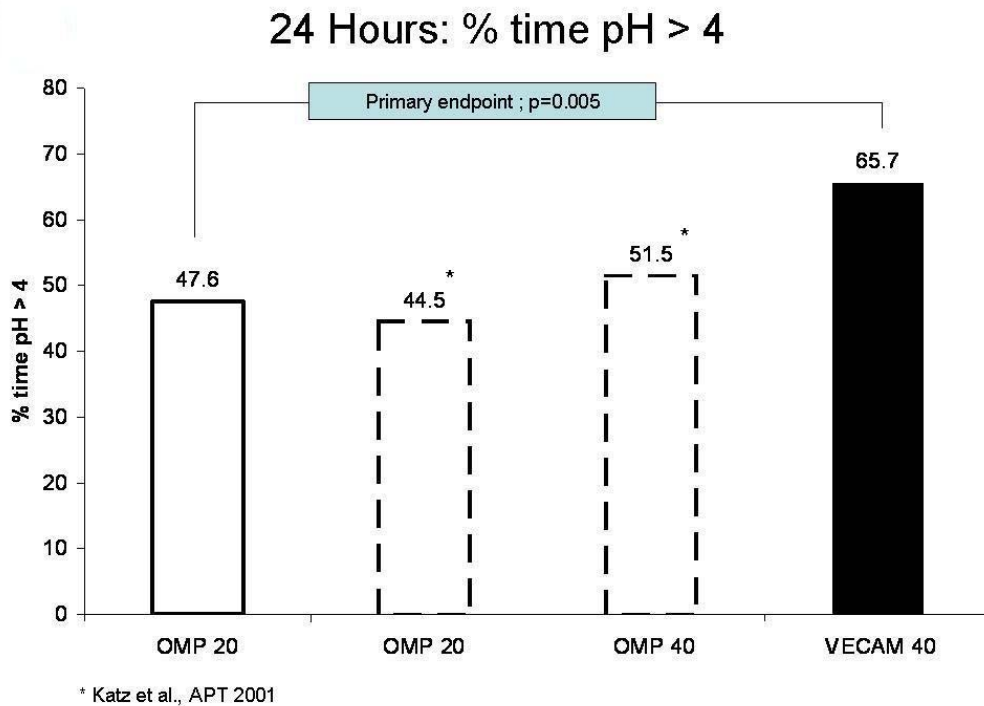


Under FDA endorsement, US Phase I/IIa trials with VECAM™ have been completed. In these trials, Vecta measured the effects of different doses of VECAM™ in successive regimens on healthy volunteers receiving the product for up to 6 consecutive days. The results of these trials demonstrated unequivocally the efficacy of VECAM™ and further supported its formulation concept.

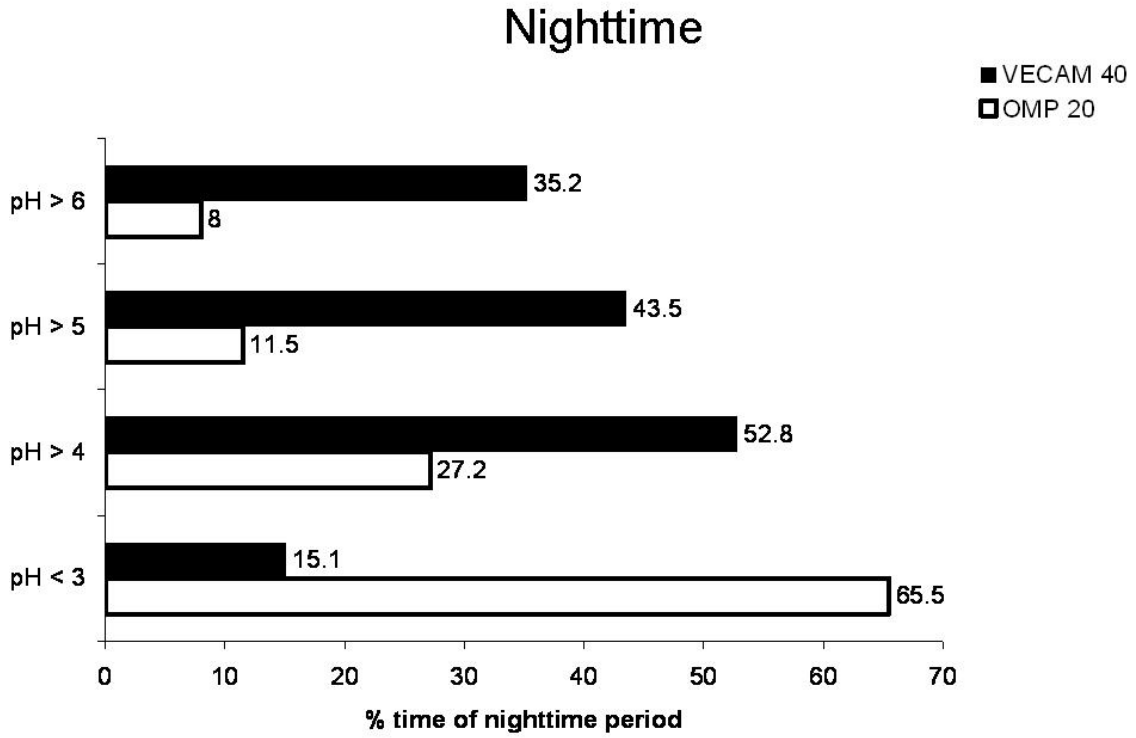
As shown below, VECAM 40 provides markedly higher sustained pH levels during nighttime hours compared to Omeprazole 20 (OMP) only (dashed lines show comparison with published data*):



VECAM 40 provides markedly higher- and sustained pH levels during 24 hours following its bedtime administration compared to OMP 20 only, administered before breakfast.



VECAM 40 administered at bedtime provides for significant percentage of nighttime periods with a gastric pH up to 6.



All comparisons are statistically significant

In summary:

- VECAM™ treatment results in gastric pH>4 values throughout the critical nighttime hours, without compromising its daytime effect
- VECAM™ can be effectively administered in a meal-independent manner at bedtime
- VECAM™ treatment achieves unprecedented gastric pH values (up to 6), during night and daytime, providing robust acid suppressive activity
- VECAM™ exhibits an effect from the first dose

Taken together, the advantages of VECAM™ can be translated into the following clinical settings:

- 1) VECAM™ can be utilized to achieve the best results for control of nighttime HB
- 2) VECAM™, administered at bedtime will achieve optimal patient compliance
- 3) VECAM™ can be utilized as a therapy for symptomatic GERD patients (who may benefit from the high pH values)
- 4) Given its rapid onset of activity, VECAM™ may be used for "on-demand" treatment

CLINICAL AND REGULATORY STRATEGY:

- Vecta anticipates that VECAM™ will enter Phase III in 2010 and file for approval in 2011
- **Clinical development plan U.S FDA Advice letter (June 05, 2009):**
 - Agreement reached with the FDA on Phase II and III studies design
 - Agreement reached with the FDA on outcome measures to be utilized in PII and PIII studies
 - Final labeling claims will be based on future data submitted to the FDA

INTELLECTUAL PROPERTY:

Vecta has pending US and PCT patent applications covering the compositions and method of use for the treatment of pathologies that necessitate suppression of gastric acid secretion comprising PPI's and SA and / or SA derivatives. The initial filings were made in 2005 and additional expanded filings have followed in 2006 and 2007. The US application is currently under examination and the PCT is in the national phase in several other countries.

MANAGEMENT

Dr. Michael Naveh, CEO

Dr. Naveh is a graduate of the Zurich University in Switzerland. Prior to joining Vecta, he served for seven years as a General Manager of Israel's largest biological vaccines producing plant (BLT) of TEVA. In addition, Dr. Naveh was a member of R&D teams of TEVA and ABIC for several years and a fellow researcher at the Faculty of Life Science in University of Tel Aviv for thirteen years.

Professor Yehuda Chowers, MD, Founder, Medical Director and Director

Professor Chowers is a top-ranking gastroenterology specialist, with a proven track record in the field of medical research. His medical research experience includes a post doctorate (Mucosal Immunology) at the University of California, San Diego and more than 15 years of research experience in the fields of Molecular Biology, Infectious and Inflammatory diseases of the GI tract.

Professor Joseph R. Pisegna, M.D., Clinical Development, US

Professor Pisegna, an expert leader in Clinical Gastroenterology, recently joined Vecta to lead Clinical R&D in the US. Professor Pisegna is an Associate Professor, Division of Digestive Diseases, Department of Medicine, David Geffen School of Medicine at UCLA. As an expert in the management of gastric acid secretory disorders Professor Pisegna brings to the company experiences and expertise in both the design of scientific protocols, as well as sharing in our understanding of the marketplace in gastroenterology.

Dr. Dan J. Gelvan, Chairman and Director

Dr. Gelvan is Managing Director-Life Sciences, Aurum Ventures MKI Ltd. Dr. Gelvan is a seasoned life science executive who before joining Aurum Ventures managed GammaCan International, Inc. (OTCBB: GCAN), a development-stage pharmaceutical company. Prior to that, Dr. Gelvan founded and managed ZetiQ Technologies, a drug discovery company specializing in cell-based high-throughput screening for novel anti-cancer drugs. Dr. Gelvan founded ZetiQ after leaving a senior position in Clal (Israel) Ltd., one of Israel's largest holding conglomerates. Dr. Gelvan holds a Ph.D. in Business Economics from RUC in Denmark and he is an experienced lecturer of corporate finance and entrepreneurship. Dr. Gelvan is a member of Israel's National Committee for Biotechnology

SCIENTIFIC ADVISORY BOARD

Professor George Sachs

M.B., Ch.B., D.Sc. Professor, Medicine and Physiology, Wilshire Chair in Medicine, and Director of Membrane Biology Lab at UCLA. His discoveries in the field of gastroenterology and the microbiology of *H. pylori* have made him a leader in the GI-related disorders arena. His findings, published in some 300 scientific publications, led to the development of commonly used drugs including proton pump inhibitors and acid pump antagonists. Professor Sachs, formerly the Director of the Center for Ulcer Research and Education at UCLA, is a member of the NIH advisory board.

Professor M. Michael Wolfe

M.D. Chief, Gastroenterology at the Boston Medical Center and the Boston University School of Medicine, where he is also a Professor of Medicine and a Research Professor of Physiology and Biophysics. Professor Wolfe has achieved significant recognition for his continued work in acid-related disorders (GERD and NSAID-associated gastro duodenal ulcers) and in the diagnosis and management of gastrinoma and other neuroendocrine tumors. He is a Fellow of the American College of Physicians and American College of Gastroenterology and a member of the Education Committee of the American Gastroenterological Association (AGA). He has served the AGA as Chair of the Constitution and Bylaws Committee, a member of the Research Committee, and Chair of the GERD Awareness Program. In addition to his numerous and significant contributions to the gastroenterological literature, he serves on the editorial boards of Digestive Diseases and Sciences and Alimentary Pharmacology and Therapeutics. Professor Wolfe is a member of the ZRG F10 Study Section of the National Institutes of Health and is Chair of the Advisory Board for Gastrointestinal Drugs of the U.S. Food and Drug Administration

Professor David Y. Graham

Chief Digestive Disease Division, Department of Medicine, Baylor College of Medicine, Houston, Texas. Professor Graham is a member of 10 societies and has received more than 25 honors in his career to date. He is a reviewer for more than 16 journals, and sits on the Editorial Boards of eight including being the editor of the journal *Helicobacter*. Research Interests: *Helicobacter pylori* infections, Mycobacterium paratuberculosis as a cause of Crohn's disease, Prevention of Norwalk virus infections, Mycobacteria as a cause of sarcoid. He is the author of more than 700 scientific articles and 100 chapters in books. He is listed as one of the most highly cited scientists in ISI's Highly Cited Researcher's database in Clinical Medicine.

SUMMARY

Vecta management believes that VECAM™ represents a unique and significant partnership opportunity for any pharmaceutical company with an existing or strategic interest in the GI marketplace. The opportunity may be particularly attractive to those companies, which are, or would like to be participants in the market segments dominated by PPI's. With generic competition within the PPI class, the unique label of VECAM™ and positioning, with demonstrable advantages in the GERD population, is expected to generate significant revenues.

VECAM™ is a unique approach to enhanced PPI activity because of:

- Unique nighttime GERD symptoms control
- The SA component optimizes PPI effects by obviating meal dependency and provides for bedtime administration
- Acid pumps are activated without relaxing the lower esophageal sphincter otherwise caused by a meal before recumbence
- Blockage of more pumps on first administration leads to an early steady state and a better clinical response
- Significant improvement of patient compliance since meal and its timing is a non-issue
- For potential partners in the PPI market -- IP life cycle management opportunity
- For potential partners in the GI pharmaceutical market having no PPI in their portfolio – proprietary market entry opportunity

REFERENCES

1. Sachs, G. Improving on PPI-based therapy of GORD. *Eur J Gastroenterol Hepatol* 13, S35-41 (2001).
2. Sachs, G., Shin, J. M., Briving, C., Wallmark, B. & Hersey, S. The pharmacology of the gastric acid pump: the H⁺,K⁺ ATPase. *Annu Rev Pharmacol Toxicol* 35, 277-305 (1995).
3. Sachs, G. et al. Review article: the control of gastric acid and *Helicobacter pylori* eradication. *Aliment Pharmacol Ther* 14, 1383-401 (2000).
4. Mungan, Z. et al. Effect of PACAP on gastric acid secretion in rats. *Peptides* 16, 1051-6 (1995).
5. Pisegna, J. R. et al. Role of PACAP1 receptor in regulation of ECL cells and gastric acid secretion by pituitary adenylate cyclase activating peptide. *Ann N Y Acad Sci* 921, 233-41 (2000).
6. Sandvik, A. K., Cui, G., Bakke, I., Munkvold, B. & Waldum, H. L. PACAP stimulates gastric acid secretion in the rat by inducing histamine release. *Am J Physiol Gastrointest Liver Physiol* 281, G997-G1003 (2001).
7. Barrison, A. F. et al. Patterns of proton pump inhibitor use in clinical practice. *Am J Med* 111, 469-73 (2001).
8. Gunaratnam NT, Jessup TP, Inadomi J, Lascewski DP. Sub-optimal proton pump inhibitor dosing is prevalent in patients with poorly controlled gastro-oesophageal reflux disease. *Aliment Pharmacol Ther*. 2006 May 15;23(10):1473-7.
9. Pezanoski, J., Camara, R. & Cowen, M. Correct and incorrect dosing of proton pump inhibitors and its impact on gerd symptoms. *Am J Gastroenterol* (2004).
10. Peghini, P. L., Katz, P. O. & Castell, D. O. Ranitidine controls nocturnal gastric acid breakthrough on omeprazole: a controlled study in normal subjects. *Gastroenterology* 115, 1335-9 (1998).
11. Shaker, R., Castell, D. O., Schoenfeld, P. S. & Spechler, S. J. Nighttime heartburn is an under-appreciated clinical problem that impacts sleep and daytime function: the results of a Gallup survey conducted on behalf of the American Gastroenterological Association. *Am J Gastroenterol* 98, 1487-93 (2003).
12. Martindale. The complete drug reference, 33rd edition edn. (2002).]
13. Ashburn, T. & Gupta, M.S.. The GERD Market. *Nature* 5, 277-278 April 2006