

# BIO STOCK



## COMPANY ANALYSIS

ENORAMA PHARMA  
MAY, 2017

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# ENORAMA PHARMA

## ANALYTICAL SUMMARY

Swedish drug delivery company Enorama Pharma is closing in on a market approval for its consumer-friendly nicotine chewing gum. Armed with a novel method of production and a private label strategy, the company intends to challenge the market dominance of GlaxoSmithKline and Johnson & Johnson. With the essential agreements in place and recently gaining positive results in a bioequivalence pilot study, the company is now actively preparing for the final hurdles prior to market launch. Until then, Enorama aims to build a value proposition towards strategic partners in the market of smoke cessation products based on a unique taste profile and a different method of production.

Enorama is challenging a market with well-established players who are offering a range of flavored products based on large scale production processes. However, Enorama is planning to commercialize its product through a business model based on outsourced production and marketing, which arguably will lower the risks by not having to invest in manufacturing factories and recruiting a salesforce team. Moreover, instead of launching a product under its own brand Enorama will implement a private label strategy where it benefits from the partner's brand and marketing channels. By partnering with the right brand owner, Enorama could achieve a higher market share than it would as an unknown competitor against the market leaders. This would obviously come at the cost of a smaller piece of the (bigger) pie, but could certainly result in a very positive business scenario for Enorama.

BioStock believes that Enorama's go-to market strategy could prove profitable for its shareholders by quick financial returns after a market approval through its non-disclosed business partner. However, it remains to be seen if Enorama's choice of focusing on quality and flavor is the right way to achieve strong strategic partnerships. Traditionally, managers at potential partners examine private label opportunities on a cost basis as they will need to invest much resources in inventory, packaging, marketing and sales. Another challenge is that whenever Enorama's private label contract comes up for renewal, there

will inevitably be a long and arduous negotiation as competitors will attempt to steal its business. To prevent this, Enorama may have to develop its intellectual property portfolio to increase the barriers of substitution. However, Enorama's current partnership may prove these concerns to be invalid and BioStock is looking forward to learn more about this deal.

Following an ongoing 6-month stability study and a final bioequivalence study, the company expects to see a market launch as early as 2018 in Europe, with the US and Asia as follow-up markets. With development underway for Enorama's nicotine gum, the company announced late last year its intention to potentially leverage the drug delivery platform, with an as-of-now undetermined active substance, to produce a medical chewing gum for allergic rhinitis as the first expansion of the company's drug delivery platform. With a clear path forward for the nicotine gum and the potential of new indications, it will be intriguing to see what the ambitious management of Enorama will achieve during 2017 and if the company can see a similar path as the \$44 million acquisition deal of brand-developer Niconovum AB.

Important catalysts for investors to watch:

- Completion of 6-month stability study. Expected in Q3 of 2017
- Completion of regulatory bioequivalence. Expected in Q3 of 2017.
- Submission for European market approval. Expected in Q4 of 2017.
- European product launch. Expected in 2018.

## ABOUT THE COMPANY

### Background

The Malmö-based drug delivery company Enorama Pharma was founded and spearheaded in 2006 by experienced entrepreneur Mats Rönngard to develop novel consumer-friendly medicated chewing gums for the nicotine dependency market. It wasn't however until 2012 when the company actively began the product development of the what would eventually become the Enorama Pharma drug delivery platform of cold compressed chewing gums. During the development process, the company realized the potential of utilizing the drug delivery platform with other active pharmaceutical ingredients in new indications and markets. With development underway for Enorama Pharma's nicotine gum, the company recently announced the intention to potentially leverage the drug delivery platform, with an as-of-now undetermined active substance, to produce a medical chewing gum for allergic rhinitis. The company has also highlighted its potential to further expand into the markets of pain relief and cold medicine. After substantial progress of the primary product, the company commenced trading as a public company on Nasdaq First North Stockholm last year..

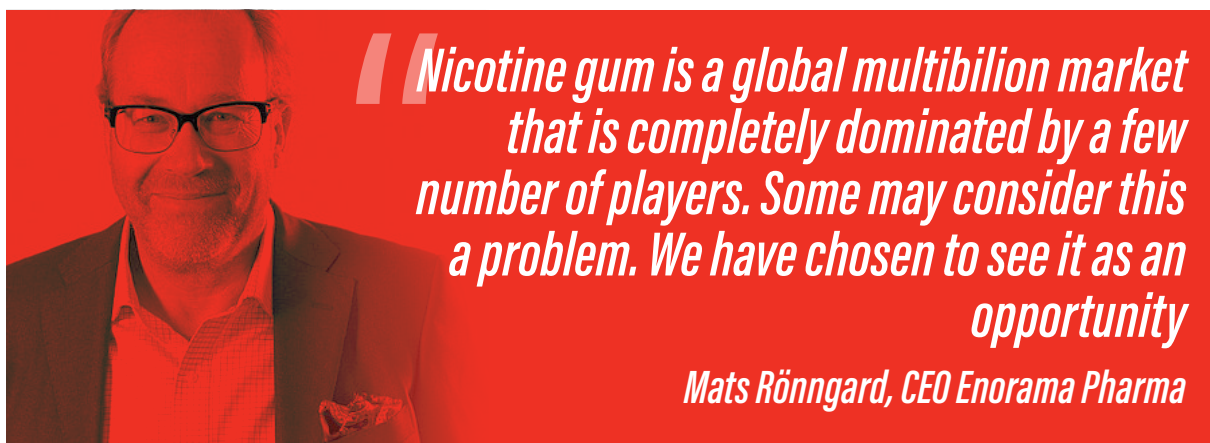
### Enorama Pharma

Enorama Pharma is a Swedish pharmaceutical company that focuses on consumer-friendly medicated chewing gums. The company intends to leverage the new drug delivery platform of compressed gums with generic active pharmaceutical ingredients (API) as to provide new

offerings with improved administration and potentially more rapid effects. The gums are produced through a process of cold compression, which limits the time and cost requirements usually associated with traditional gum production. The company's business strategy is structured as to minimize market-related risks and limit the need for further financial investments. In order to achieve this, the company will outsource localized marketing, development and production activities while the company will be responsible for quality assurance of the product and production. The in-house competences of Enorama Pharma will also manage R&D, logistics, marketing data and the interactions with key accounts. Enorama Pharma has decided to pursue a private-label strategy, meaning that the company will indirectly sell its products through the use of distributors and retailers to its intended end-consumers and the product will then be marketed under the respective partner's brand identities.

### Strategic direction

Enorama Pharma operates in a business-to-business context where key activities such as R&D, clinical studies, regulatory affairs, sales and marketing etc. are outsourced to global partners - leaving the company's organization lean and agile. Commercializing the technology platform through license- and supply agreements with major pharmaceutical companies, pharmacies, tobacco and FMCG companies who market and distribute the products under their own brand and new therapeutic applications will be developed together with different partners and



the partnering companies or pharmaceutical retailers will then sell the final products. This means that Enorama Pharma can keep costs for production and marketing low and instead offer products to partners at a competitive price.

The short-term objective is to launch a state-of-the-art nicotine gum with superior consumer properties compared to competition. The long term objective is to develop several different applications for the Enorama Pharma medicinal gum within various therapy areas, such as allergy, pain management, erectile dysfunction and others. Development will be made in collaboration with different partners using the compressed gum technology platform.

Enorama Pharma intends to market the nicotine gum and other products produced from the technology platform through a private-label (PL) strategy. In essence, this strategy constitutes a synergistic partnership where Enorama Pharma will manufacture and produce a product or service under another company's brand identity and marketing channels. The end-customers will be exposed to the product through distributors and retailers while Enorama Pharma will provide aforementioned retailers with the physical product. Some well-known Swedish examples of private-labels are "ICA Basic" from the well-known retailer and "Apofri" from the pharmacy, Apoteket, where this is used to market generic pharmaceutical products.

In 2011, the value share of PLs in Europe, which at the time was the most mature PL market in the world, averaged 30% across the region (compared to 18.5% in the United States). Retailers are increasingly making an effort to expand on their PL offering mainly because the high retail margins. This strategy would allow Enorama Pharma to reach with relative ease, a large number of consumers

and build upon the already established brand identity of others. However, the trade-off would be a reduction in potential revenue, as according to a survey by the Institute of Grocery Distribution, 85% of the retailers rated "improved margins" as the primary reason for investing in PL. Prior studies reported an average gross retailer PL margins of up to 30% and higher.

### Strategic partnerships

Due to the outsourcing- and private-label nature of the Enorama Pharma's business strategy, managing partnering and collaborations is of great importance for the company. The company already has several important agreements in place:

- Enorama Pharma has an agreement with a non-disclosed medium-sized manufacturer. The company currently has around 450 employees that will manage R&D and the mass production of Enorama Pharma's products.
- Enorama Pharma has signed an agreement with a Northern European pharmaceutical company with a commercial focus on generic medications. The company has a number of major and minor sales channels in several markets.
- A contractual agreement is also in place with the supplier of the active pharmaceutical substance, nicotine.

## *Private-label for nicotine gum?*

There is currently one dominant company in the intersection of producing nicotine gums for private-label; Actavis Generics (formerly known as Watson Pharmaceuticals and Actavis). A leading healthcare supplier that develops, manufactures and distributes OTC (over the counter) products to partners under their brand identities. The company has a portfolio of NRT products, including a range of nicotine chewing gums in different tastes and formulations. Actavis Generics also appears through its subsidiary Nicobrand to target a global market. In addition to the above mentioned private-label actor, Novartis, GSK and McNeil / Johnson & Johnson all manufacture products under different private-labels brands. Examples of private-label nicotine gums are NicAssist which is sold by Boots and NicAid by Tesco.



## TECHNOLOGY & ASSET PORTFOLIO

### Cold Compressed Chewing Gums

While the company's main focus is to develop a consumer-friendly nicotine chewing gum, the development process has generated a drug delivery platform. This ability to produce cold compressed medical gums provides a range of potential new applications. Medicated chewing gums as a drug delivery form are intended to function as an extended-release dosage form that can provide continuous release of the contained medicine. Big Pharma could potentially approach Enorama Pharma to leverage the cold compressed drug delivery platform in combination with their own substances to produce new and novel products with unique delivery characteristics. Enorama Pharma's cold compression technology also enables the company to develop products with heat-sensitive active substances..

### Lead Product – Nicotine Gum

Enorama Pharma aims to create a chewing gum that is as refreshing as a confectionery gum with the same medical effect as other nicotine gum products. The company has emphasized a competitive position based on consumer experience. Typically, this translates to a product with packaging, appearance, color, shape and taste that will be more appealing than competing offerings. The process of cold compressions facilitates a product with a distinct sensation of crunchiness that the company argue will distinguish it from competitors. .

### Modern and Cost Efficient Production

Medicated chewing gums are, despite their resemblance to normal chewing gums, difficult to manufacture. The traditional industrial production is done through the heating and baking of gum-dough, a huge process, which includes several machines and operations. The manufacturing of chewing gums typically comes with extensive initial costs and with the limited ability to change the shape, color and taste of the product during the development and mass production phase. Additionally, accurately distributing the medical substances in the gum dough have proven to be troublesome by conventional methods. Enorama Pharma has after years of work developed a novel chewing gum by a manufacturing process of cold compression. Rather than a traditional dough-based method of manufacturing chewing gum, the method resemble the traditional manufacturing process normally used in the production of pharmaceutical tablets. Pre-mixed powders are pressed together under high pressure to produce a highly customizable product, a process that is highly adaptable and cost efficient.

### Development Status

Enorama Pharma announced in December of 2016 that a pilot study had been completed and demonstrated that the company's nicotine gum was bioequivalent to the market leading brand Nicorette. The study compared Enorama Pharma's 4 mg nicotine gum with mint flavor against Nicorette's 4 mg mint product, and the test showed that the two products were medically equivalent. The pilot study was conducted with a recognized CRO in preparation for the actual bioequivalence required for regulatory approval.

In addition, the company has conducted a central location test, a sensory analysis, in collaboration with the Danish Technological Institute to evaluate the consumer experience of the Enorama Pharma's nicotine gum. The data gathered from the professional testers indicated that the product had a high initial taste intensity with a degree of sweetness and freshness that could be experienced during the whole chewing process. In comparison to competing products (with mint and fruit taste profiles), the testers determined that Enorama Pharma's pilot product had a softer profile, higher degree of taste (sweetness and freshness) and that the taste of nicotine was more apparent.

The next step for the company is to conduct a bioequivalence study and 6-month stability study on the company's regulatory registration batch of the gum. The company expects to file for European market approval late this year with an anticipated market launch expected in 2018.

Important catalysts for investors to watch:

- Completion of 6-month stability. Expected in Q3 of 2017
- Completion of regulatory bioequivalence study. Expected in Q3 of 2017.
- Regulatory submission for European market approval. Expected in Q4 of 2017.
- European product launch. Expected in 2018

*Market Launch expected in 2018.*

## Potential first extension: Allergic rhinitis

Last year in September, Enorama Pharma announced that the company had begun the technical evaluation developing a medicated chewing gum for allergic rhinitis. This condition is an inflammation of the mucous membrane inside the nose, which occurs when the immune system overreacts to allergens in the air. The goal of rhinitis treatment and medication is to prevent or reduce the symptoms caused by the inflammation of affected tissues. Antihistamines and steroids are the most common approaches of managing these symptoms. Provided that most of the patents covering these drugs have expired, Enorama Pharma intends to select a generic substance to combine with the drug delivery platform and offer a novel product for the OTC allergy market.

The company intends to make a decision regarding the development of a prototype by the summer of 2017.

## IP PORTFOLIO

While Enorama Pharma currently holds no patents covering its inventions, the company recently announced that it is actively evaluating the opportunity to generate patentable innovations.

## Advantages of medicated chewing gums as a drug delivery technology

Potential increased rate of effectiveness compared to other oral delivery systems

Ease of termination of drug release – Simply remove the gum

Reduced risk of overdosing if swallowed whole (requires mechanical movement for release)

No water to drink required

High acceptance of teenagers and children

Good for rapid delivery

Good stability against light, oxygen and moisture

Reduced risk of intolerance to gastric mucosa

Protection of the susceptible drugs contained from chemical or enzymatic attack in gastrointestinal tract

Both systemic and local drug delivery.



# 3.8 million SEK

*cash and cash equivalents reported in December of 2016*

# 0.97 million SEK

*estimated burn-rate per month, in 2016*

# 11.67 million SEK

*costs during 2016*

## Financial summary

Enorama Pharma AB, like many of its industry peers, is financed by its shareholders. No income was reported in the latest interim report (Jan-December 2016) and should not be expected in the short-term by investors. Per the consolidated statement of comprehensive income, costs during 2016 amounted to 11.67 MSEK. Enorama Pharma notes that close to 3.9 MSEK relates to the activation of product development for the nicotine gum. It is likely that the costs during 2017 will be more, since production is ramping up to produce regulatory batches in the preparation of a market launch. The company had costs of 11.67 MSEK, during 2016, resulting in a monthly burn-rate of 0.97 MSEK. With current assets of 3.8 MSEK, reported on Dec 31, 2016, it is clear that Enorama Pharma will need to fill its war chest soon.

The company has stated that it expects that the current capital will last at least until June of 2017. An issue is scheduled for completion at the end of the month of August or September during 2017. However the company will require a bridge financing for the period from June until time of new issue. The company expects to complete the bridge financing by the end of April/May.

## Summary of Income statement (Year End Report January - December 2016)

[kSEK]	Oct-Dec, 2016	Oct-Dec, 2015	Jan-Dec, 2016	Jan-Dec, 2015
Operating income	86	1 994	4002	1994
Purchase of development services	-98		-3266	
Other external expenses	-1084	-1257	-6616	-2553
Personnel costs	-763		-1784	
Other operating expenses	-5		-9	0
<b>Total operating expenses</b>	<b>-1950</b>	<b>-1257</b>	<b>-11675</b>	<b>-2553</b>
Earnings before interest and taxes	-1864	737	-7673	-559
Interest expenses and similar income items	-49	-39	-163	-97
<b>YEAR RESULTS</b>	<b>-1913</b>	<b>698</b>	<b>-7836</b>	<b>-656</b>

## Summary of balance sheet (Year End Report January - December 2016)

[kSEK]	2016-12-31	2015-12-31
Incomplete share issue	0	2415
<b>Total fixed assets</b>	<b>9653</b>	<b>5662</b>
Other receivables	83	230
Prepaid expenses and accrued income	63	20
Cash and cash equivalents	3827	841
<b>Total current assets</b>	<b>3973</b>	<b>1091</b>
<b>TOTAL ASSETS</b>	<b>13626</b>	<b>9168</b>

### EQUITY AND LIABILITIES

[kSEK]	2016-12-31	2015-12-31
Total equity	9080	5949
Long-term debt	3400	550
Short-term debt	1146	2094
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>13626</b>	<b>8593</b>

## BOARD OF DIRECTORS

### ANDERS ERMÉN CHAIRMAN

Chairman since 2012 and specialized in accounting, business development and management. Board member in A1M Pharma AB, Xintela AB, Baulos Capital Belgium SA



### MATS RÖNNGÅRD CEO & BOARD MEMBER

Co-founder and board member since 2008. Experienced entrepreneur. Director of the board in It's Green AB. Board member in Excellent Invest Sweden AB. .



### TOMAS ERIKSSON BOARD MEMBER

Board member since 2012. Co-founder and CEO of A1M Pharma AB. CEO of Preelumina Diagnostics AB. Board member in Merozyne Therapeutics AB,



### MATS PERSSON BOARD MEMBER

Board member since 2016. CEO of Hamlet Pharma. More than 20 years' experience of drug development and clinical research from AstraZeneca.



## OPERATIONAL TEAM

### ANNETTE AGERSKOV DEPUTY MANAGING DIRECTOR

Previous senior positions in Fertin Pharma A/S. Extensive international experience from working with nicotine substitutes and chewing gum.



### MATS RÖNNGÅRD CEO & BOARD MEMBER

- See Above -



## MANAGEMENT AND OWNERS

### Management team

Enorama Pharma has an experienced management team with a large network and relevant competence to support the company's development and further expansion plans. The company is led by CEO and board member Mats Rönngard, an experience entrepreneur with over 30 years of experience in supporting internationally listed companies, mainly in the pharmaceutical and fast moving consumer goods sectors in with marketing and sales. Mats is accompanied by Annette Agerskov as vice president who has extensive international experience from working with nicotine substitutes and chewing gum as a delivery form. For most of her career, she has held senior positions in Fertin Pharma A/S, which is one of the world's largest manufacturers of nicotine gums. There she held responsibilities in the areas of R&D, supply chain management, sales and business development. Agerskov's many years in the industry for nicotine substitutes has generated a wide international network of contacts to both suppliers and industry actors.

Enorama Pharma is supported by a board of industry experienced members and chairman, Anders Ermén. Ermén is an experienced economist with operations in accounting, business development and management. He is board member in A1M Pharma, Preelumina and Xintela and Head of Investment Relations in the investment company Baulos Capital Belgium. Another board member is Mats Persson who also is the CEO of Hamlet Pharma, a drug company developing protein-lipid complexes for the treatment of cancer. He also holds a Ph.D. in biochemistry and has more than 20 years of experience in clinical research and development at AstraZeneca. Next board member, Tomas Eriksson, is the co-founder and CEO of A1M Pharma, a drug company focusing on pre-eclampsia and renal damages. Tomas Eriksson has extensive experience from senior positions in industry of medical technology and diagnostics as Area Manager in Gambro AB, Sales Manager in Nordic Bioscience (Denmark) and Sales & Marketing Director of Magle Life Science AB

### Shareholders

Enorama Pharma AB is listed on Nasdaq Stockholm and trades under the ticker ERMA. The share capital is 708 586 SEK, divided between 4 534 955 shares (share value around 0,16 SEK). Approximately 479 shareholders own Enorama Pharma shares as of 31/5 of 2016. The major shareholder in Enorama Pharma AB is Swede Unipharma AB (59,30%). Second largest investor is Baulos Capital Belgium SA (12%). Additional shareholders are Laika Consulting AB (2%), Novatelligence (1,70%), TL Display AB (1,70%), Martin Lind (1,10%), Pong AB (1,10%). (3,58%).

## MARKET OPPORTUNITY



### TOBACCO AND SMOKE CESSATION

The World Health Organization (WHO) estimates that there are around 1 billion smokers in the world and approximately six million smokers perish each year from smoke-related diseases. While the majority of the incidents are linked to active smoking, 600 000 can be contributed to effects of passive smoking. There is also a great socioeconomic difference in the prevalence of smoking. Only one in five smokers reside in high-income countries, resulting in the majority of the world's smokers located in developing countries and newly developed countries. On a positive note, the CDC estimated that 15% of the adult population in the US, under 2015, smoked cigarettes on a regular basis, which is a steady decrease from 20,9% in 2005. The prevalence of smoking in the European region has been reported to be around 26% and while it is higher than the US, it has similarly steadily decreased in the last decade. In contrast, the prevalence of smoking has increased in some Asian countries such as Taiwan. Authorities across the globe are increasingly banning smoking in public, in addition to promoting financial incentives and introducing plain cigarette packaging as measures to reduce smoking. The proven health risks of passive smoking are likely to continue to drive this development.

In pace with the increasing public awareness of the unhealthy effects of smoking, there has emerged a growing market of smoke cessation products that assist consumers to limit or even cease their smoking habits. These products can include everything from prescription medications, e-cigarettes to Nicotine Replacement Therapy (NRT) products. According to a study recently published by the CDC, it was found that 55,4% of the adult smoking population in the US had made at least one

attempt to quit in the last year and at least 29% of the individuals used some type of medication, such as nicotine replacement products, as part of their attempts to quit. The European commission reported that 19% of smokers in the European region had performed an attempt to quit smoking in 2014, with 12% utilizing nicotine replacement therapy.

The market for smoke cessation products has been reported to be around \$3 billion annually.

### Nicotine replacement therapy

The underlying rationale of using NRT for treating nicotine dependence is based on the theory of harm reduction. NRT is essentially non-toxic forms of nicotine delivery systems used to provide nicotine to maintain stimulation of nicotine receptors, thereby eliminating withdrawal symptoms and the sensations of craving for nicotine during a smoking cessation attempt. Nicotine gum, the first NRT, was first made available in Europe in the early 1980s and in the US in 1984. However today, there is a range of existing NRT products; including nicotine transdermal patch systems, nicotine nasal spray, and nicotine delivery through the oral mucosa including gum, lozenge, sublingual tablet, and vapor inhalers.

A study found that over 6.3 million individuals in the US purchased NRT products over the counter and concluded that around 882 000 (14%) could sustain quitting after 6 months. While the primary usage of NRT products remains to be a method of quitting, particularly during the first 3 months, the product category sees recreational use from current smokers. A study from England reported that around 11.8% of smokers used NRT products concurrently with regular tobacco smoking.

Tobacco-induced diseases are considered the



single most preventable cause of death according to the WHO. The smoke from tobacco contains at least 40 proven carcinogens and the CDC estimates that smoking contributes to the death of 480 000 individuals annually, amounting to one of every five deaths reported in the US. The consumption of tobacco commonly lead to diseases affecting the heart and lungs, with hands and feet usually affected as first signs of smoking related health issues. Since smoking is a major risk factor for heart attacks and cancer of the lung, mouth and pancreatic cancer, health organizations and regulatory agencies are increasingly providing a range of incentives to decrease the prevalence of smoking and to increase the awareness of de-nicotine products. Additionally, government agencies are introducing smoke-free zones and several incentive plans to support this development and the WHO has listed NTR products on the List of Essential Medicines, as one of the most effective and safe medicines needed in a health care system.

### Competing remedies

Despite a wide spectrum of available NRT products, the market is essentially dominated by a small number of large players. The brands of Nicorette and Nicotinell, have established a large share of the European and the global market. In several European countries, including Sweden, the two leading brands hold 60-80% of the market, according to Enorama Pharma's own sources.

Nicorette is the brand name for several NRT products, originally developed in the late seventies as nicotine gum by the Swedish company Leo AB. The product is today manufactured by McNeil Consumer Healthcare company, a subsidiary of Johnson & Johnson and co-marketed by GlaxoSmithKline in US and Johnson & Johnson globally. At the time of product launch, the product was the first NRT product on the market and remains to be the market leader. Nicotinell is the umbrella brand for Novartis's range of NRT products marketed everywhere, but Northern Europe where it is marketed by GlaxoSmithKline. Overall, nicotine gums have remained relatively unchanged since their introduction, with exceptions for the introduction of new flavors.

## Competing Brands

Brand	Company	Taste profiles (gum)
Nicorette	McNeil/Johnson & Johnson/GSK	White Ice Mint, Fruit Chili,
		Cinnamon Surge, Fresh mint, Mint, Origina
Nicotinell	Novartis/GSK	Spearmint, Tropical Fruit, Peppermint, Mint, Liquorice
NiQuitin/Nicabate	Perrigo	Fresh Mint

### Electronic cigarettes

Electronic cigarettes are handheld electronic devices which vaporizes a flavored liquid, often referred to as e-liquid, which may or may not contain nicotine. The e-liquid is then vaped or smoked similarly to a normal cigarette but without the toxic tobacco smoke. E-cigarettes have been marketed as both a smoking cessation tool and an alternative to conventional cigarettes. Since the market introduction in 2004, by the Chinese pharmacist Hon Lik, the market for e-cigarettes have grown from one manufacturer in China to an estimated US\$7 billion global business with over 466 brands. An estimated 2.8 million adults in Great Britain used electronic cigarettes in 2016, which is a substantial increase from only 700 000 in 2012. The CDC estimates that 12.6% of US adults had tried an e-cigarette at least one in 2014. While the market growth has been exceptional, the product has been surrounded by a great deal of controversy. Mainly this concerns marketing practices, undetermined long term effects on public health and intertwined legislation practices. New directives were recently adopted by the European Commission to limit e-cigarette related liquids and vaporizers, ingredients, and to child-proof liquid containers. In parallel, the FDA introduced new regulations for E-cigarettes in 2016, which will hit the e-cigarette market particularly hard due to the requirements of a retroactive premarket approval process for all e-cigarette products, from e-liquids to vaporizers. Just like Icarus flew too close to the sun, it would seem that due to restrictive regulations and waning sales of e-cigarettes, the product category already has had its day in the sun.

*Dominant actors McNeil & GSK*



## BENCHMARKED DEALS

### NRT Deals

Acquisitions and deals within the NRT space are relatively sparse. However, a deal of interest for Enorama Pharma occurred in 2009 when the American tobacco company Reynolds America acquired the publicly traded Swedish-based NRT company Niconovum AB. The tobacco giant purchased all outstanding shares of the company in a 310 MSEK deal (corresponding to approximately \$44 million). Niconovum marketed NRT products under the brand name Zonnic in Sweden and Denmark and its nicotine gum, mouth spray and pouches all used its proprietary technology for nicotine delivery. Nivocum AB had during at the time of acquisition annual profit of around 16 MSEK and had only just started sales its secondary market of Denmark. As with Enorama Pharma, the company outsourced most of its operations including production. However, in contrast to Enorama Pharma, Niconovum AB ran a business model based on marketing its own brand and establishing a strong intellectual property position based on patents.

*Other relevant deals within the OTC NRT market include;*

Fertin Pharma, a leading B2B manufacturer of medicated chewing gums, was recently acquired by EQT Mid-Market that is part of the Swedish private equity group EQT Partners. While no financial value of the deal was disclosed, unofficial sources state that Fertin Pharma was valued to around \$290 million when

the deal was executed.

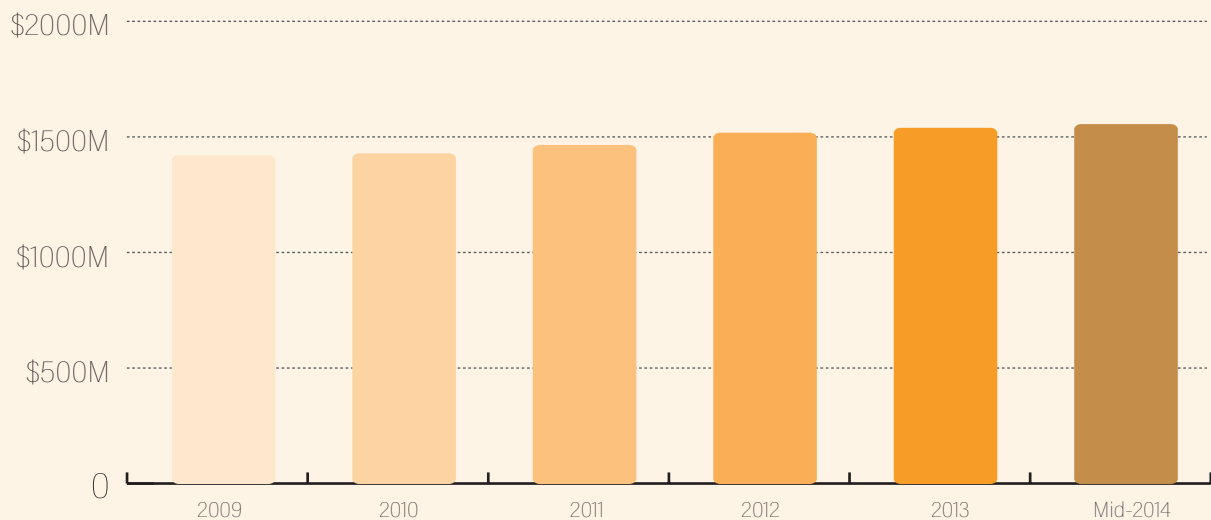
In a broad OTC deal, Perrigo Company acquired several OTC brands from GlaxoSmithKline in 2015. This included the NiQuitin NRT business, primarily in the European Economic Area and Brazil, and Novartis's legacy Australian NRT business, including the Nicotinell brand. Perrigo paid €200 million in cash for the portfolio acquisition. While the deal is a pure brand deal, the agreement demonstrates the value of the OTC market in particular in regards to nicotine products.

Another NRT brand deal occurred when the Indian pharmaceutical company Dr. Reddy's Laboratories entered into an asset purchase agreement with Novartis Consumer Health to acquire the title and rights of the Habitrol brand family of NRT products and to market the product in the U.S. in late 2014. According to an annual report, the deal amounted to around \$80 million. A smaller deal was completed when the polymer specialist Revolymer agreed to divest its nicotine gum business to the Danish specialty pharmaceutical company, Alkalon A/S, in exchange for a 15% equity holding in the combined new business. This deal was valued at £0.9 million.

## Deal Summaries

Deal Type	Partner 1	Partner 2	Deal Value
Acquisition	Reynolds America	Niconovum AB	\$44 million
Acquisition	EQT Mid-Market	Fertin Pharma	Undisclosed
Brand acquisition	Perrigo Company	GlaxoSmithKline	€200 million
Brand acquisition	Dr. Reddy's Laboratories	Novartis Consumer Health	\$80 million
Disinvestment	Alkalon A/S	Revolymmer	£0.9 million

## Global OTC market for smoking control products (2009 - Mid 2014)



### The global OTC tobacco and smoke cessation market

While the prevalence of smoking is steadily decreasing around the world, smoking control products remain a significant focus for OTC investments as governments worldwide are increasingly regulating smoking via bans, increased taxations and more widespread knowledge of the health dangers connected to smoking. According to market reports, the global OTC market for smoking control products has steadily increased during the time span of 2009 to mid-2014.

### Market estimation: Europe for NRT products used in quitting attempts

Enorama Pharma's initial target market for its nicotine gum is the OTC market in Europe through a private-label strategy. With an estimated overall prevalence of smoking of around 26% in the European region, this would amount to a prevalence of 130 million individuals in the EU28 region that are currently smoking. The European Commission found that around 19% of the European smoking population had attempted to quit the habit of smoking once during the past year, which is significantly lower than similar data from the US and a slight decrease from 2012. It is estimated that around 12% of the attempting quitters are utilizing NRT products, thus the annual estimated number of people purchasing NRT products would amount to 3 million consumers.

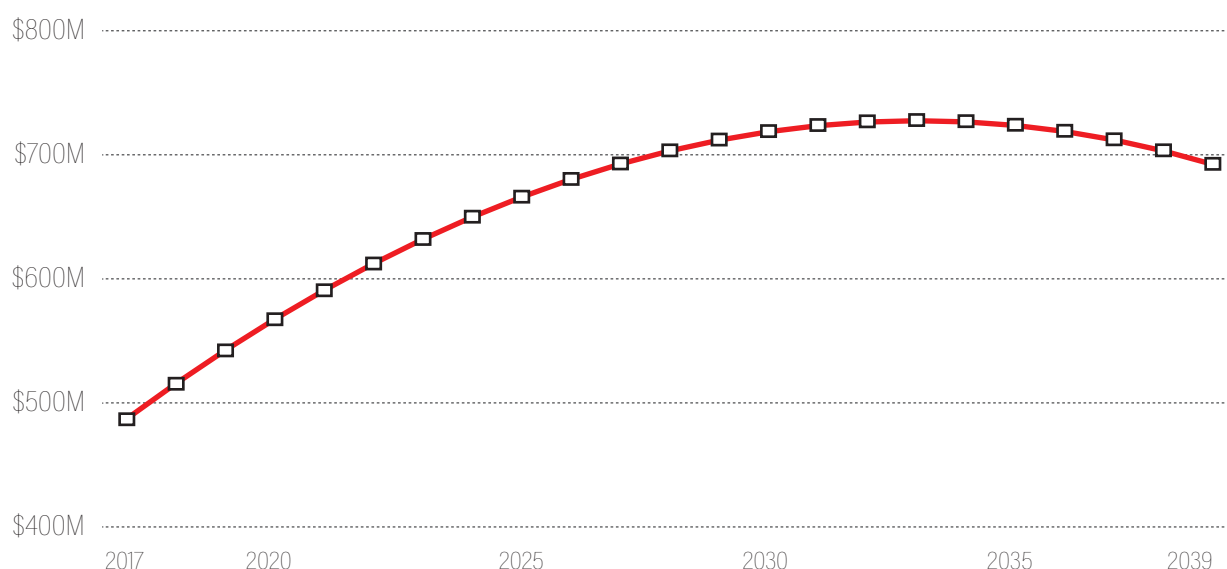
While it is difficult to determine the amount of products the average NRT quitter purchases, it was assumed for calculation purposes that the average user acquires products at the same level as the recommended dose. The recommended dose of NRT gums during the first 3 months amounts to around 21 packages at a cost of \$8 each. The total annual market for NRT products in the European region thus amounts to roughly \$490 million, during 2017 based on these estimations. Market analysts value the total sales of OTC smoking control products in the European region to \$625 million, which includes other products than NRT therapy. The same report indicated market growth at a CAGR of 4%, between 2009 to 2013, with a slight decrease between 2013 and 2014 (around -1%, partly because of the introduction of e-cigarettes), making the total annual market for NRT products reasonable.

It is reasonable to expect that the rate of quitting (or rather attempts to quit) will increase in the European region. An estimation is that the European annual rate of attempted quitting will reach at least 50% (compared to the American levels of 55.4%) in 20 years.

Taking into account population growth, an increase of individuals attempting to quit, and the decreased prevalence of smoking in the European region, the market for NRT products is expected to increase until the year 2034 followed by a slight decline while remaining a multimillion dollar industry for decades to come.

## MARKET POTENTIAL

### Market estimation: Europe for NRT products used in quitting attempts



#### Regional revenue scenarios

While annual revenue is a far stretch from annual profit, it is clear that the agreement between Enorama Pharma and its private-label partner and achievable market penetration will strongly influence the potential revenue. With the projected scenarios covering the whole European region and not only Sweden/Denmark as with the case of Nivonovum - only conservatory comparisons should be drawn between the two companies.

### Private label Scenarios - Europe

#### Low Private Label Cost (-35%, Price \$7)

Market Penetration	Annual Revenue (2023)
2.5%- 5%	\$8 987 725 - \$17 975 449

#### Medium Private Label Cost (-50%, Price \$7)

Market Penetration	Annual Revenue (2023)
2.5%- 5%	\$6 913 634 - \$13 827 269

#### High Private Label Cost (-65%, Price \$7)

Market Penetration	Annual Revenue (2023)
2.5%- 5%	\$4 839 544 - \$9 679 088

#### North America and Asia for NRT products used in quitting attempts

The US together with the European region are considered the two major markets in regards to OTC smoking control products and together they were valued at \$1289 million in 2014. Market reports state that almost half of the OTC smoking products are chewing gums. While not being the focus of this report, the market potential of a future expansion into the US for Enorama Pharma's gum products would appear substantial. With an increased prevalence of smoking in many Asian countries, there could also be a promising potential for Enorama Pharma there as well.

## CONCLUDING REMARKS

While in many regards, the road ahead for Enorama Pharma's nicotine gum can be described as the struggle between that of David and Goliath, the company is certainly going into battle with more than a sling. Led by a management with industry specific expertise and with a broad network, which has already generated several important agreements, the company is on a clear course to a market approval for its lead product. The overarching strategy of marketing through private-label, outsourcing the production and the willingness to expand upon the technology platform is clearly a sound and market-adapted model relevant for the static nicotine market. However, it remains to be seen if this is the best way to compete with the industry giants for the attention of the consumers. Nicorette and other dominant products have well established brands, sold through multiple marketing channels in each region. Enorama Pharma intends to achieve a competitive advantage based on unique taste profile and by applying a different production method. BioStock believes that this is a bold strategy provided that private-label partnering typically is evaluated based on cost-savings rather than unique product qualities. Betting on the desire of consumers rather than undercutting the price of the current dominant market players is thus unconventional.

Anders Ermén recently told BioStock in an interview that Enorama expects a positive cash-flow as early as in 2019. This optimistic outlook is certainly refreshing and the company's go-to market strategy has the potential to generate revenues much quicker than it would without a partner. The reason for this is that the partner is expected to make the necessary investments related to logistics, inventory, packaging, marketing and sales.

While this decreases investment risk, Enorama Pharma is highly dependent upon its business partner to commit enough resources to create a successful product. Choosing the right partner and negotiating a good deal are crucial success factors for Enorama Pharma for these reasons. Another challenge is that whenever Enorama Pharma's private-label contract comes up for renewal, there will inevitably be a long and arduous negotiation as competitors will attempt to steal its business. To prevent this, Enorama Pharma may have to develop its intellectual property portfolio to increase the barriers of substitution.

Based on the identified NRT deals, it is clear that strong brands drive high values. While a similar deal to Reynolds America's acquisition of Nicotivum AB is certainly possible, it may be more likely that a deal involving Enorama Pharma would be a vertical integration with its partner driven by economies of scale. In this regard, Enorama Pharma's focus on product uniqueness may increase the chance of this happening. However, to drive deal value it will still be necessary to protect unique assets by means of patents, trade-secrets or codified know-how.

It is encouraging to see Enorama Pharma's willingness to seize market opportunities by extending its delivery platform into new fields. This opens up new markets and opportunities for other business models (e.g. formulating another company's API). This signals a bigger company vision as it broadens its technical perspective and leverages the unique mechanism behind the medicated chewing gum drug delivery platform. The company could potentially address a wide range of indications longing for new delivery forms and BioStock is looking forward to learning more about these plans.

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## KEY REFERENCES

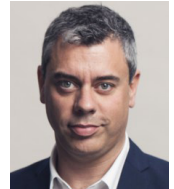
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- Monocl Strategy Services internal databases and reports;
- Imfeld, T. "Chewing gum—facts and fiction: a review of gum-chewing and oral health." *Critical reviews in oral biology & medicine* 10.3 (1999): 405-419.
- Asija, Rajesh, Shreya Patel, and Sangeeta Asija. "Oral dosages form: Medicine containing chewing gum: A review." *Journal of Drug Delivery and Therapeutics* 2.6 (2012).
- Heema, Naik, and Gupta Stuti. "Medicated chewing gums-updated review." *Int J Pharm Res Dev* 2 (2010): 66-76.
- Tobacco Fact Sheet, World Health Organisation (<http://www.who.int/mediacentre/factsheets/fs339/en/>)
- Current Cigarette Smoking Among Adults in the United States, CDC ([https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/adult\\_data/cig\\_smoking/](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/))
- Ng, Marie, et al. "Smoking prevalence and cigarette consumption in 187 countries, 1980-2012." *Jama* 311.2 (2014): 183-192.
- Babb, Stephen. "Quitting Smoking Among Adults—United States, 2000–2015." *MMWR. Morbidity and Mortality Weekly Report* 65 (2017).
- Eurobarometer, Special. "Attitudes of Europeans towards tobacco and electronic cigarettes." Retrieved from [http://ec.europa.eu/public\\_opinion/index\\_en.htm](http://ec.europa.eu/public_opinion/index_en.htm). doi 10 (2015): 670456.
- The Guardian, Article (<https://www.theguardian.com/business/2015/jan/16/vaping-dents-glaxosmithkline-sales-nicotine-patches-gum>)
- Henningfield, Jack E., et al. "Pharmacotherapy for nicotine dependence." *CA: A Cancer Journal for Clinicians* 55.5 (2005): 281-299.
- Novotny, Thomas E., et al. "Smoking cessation and nicotine-replacement therapies." (2000).
- Shahab, Lion, et al. "Prevalence of NRT use and associated nicotine intake in smokers, recent ex-smokers and longer-term ex-smokers." *PloS one* 9.11 (2014): e113045.
- World Health Organization. WHO report on the global tobacco epidemic, 2015: Raising taxes on tobacco. 2015.
- Cahill, Kate, Jamie Hartmann-Boyce, and Rafael Perera. "Incentives for smoking cessation." *The Cochrane Library* (2015).
- Use of electronic cigarettes (vapourisers) among adults in Great Britain, 2016 ([http://www.ash.org.uk/files/documents/ASH\\_891.pdf](http://www.ash.org.uk/files/documents/ASH_891.pdf))
- Schoenborn, Charlotte A., and Renee M. Gindi. "Electronic cigarette use among adults: United States, 2014." *NCHS data brief* 217 (2015): 1-8.
- Questions & Answers: New rules for tobacco products, European Parliament ([http://europa.eu/rapid/press-release\\_MEMO-14-134\\_en.htm](http://europa.eu/rapid/press-release_MEMO-14-134_en.htm))
- FDA's New Regulations for E-Cigarettes, Cigars, and All Other Tobacco Products (<https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm>)
- E-Cigarette Sales Rapidly Lose Steam, Wall Street Journal (<https://www.wsj.com/articles/e-cig-sales-rapidly-lose-steam-1447798921>)
- Reynolds American Inc. Completes Acquisition of Nicovum AB, Press release 2009
- Perrigo To Acquire Portfolio Of Leading OTC Brands From GSK, Press release 2015
- Perrigo Annual Report 2015
- Dr. Reddy's Laboratories closes the acquisition of Habitrol® Brand from Novartis, Press release 2014
- Dr. Reddy's Laboratories Annual Report 2014-2015
- Lifestyle OTCs – Nicholas Hall Report 2014
- Nicovum AB Annual report 2009

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