Zacks Small-Cap Research

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RestorGenex Corp. (RESX - OTC)

RESX: An In-Depth Look At RES-440…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	03/16/2015
Current Price (05/13/15)	$2.45
Target Price	**$6.50**

UPDATE

On May 11, 2015, RestorGenex Corp. reported financial results for the first quarter of 2015. The company had a net loss of $3.5 million, or $0.19 per share. At the end of the quarter the company had approximately $19.2 million in cash and cash equivalents, which will be utilized to complete the necessary pre-IND work in the upcoming year.

In March 2015, we initiated coverage of RestorGenex Corp. with a Buy rating and a $6.50 price target.
In the last update, we discussed RestorGenex's lead compound, RES-529, a first-in-class inhibitor of the PI3K/AKT/mTOR signaling pathway. In this report, we will focus on RES-440, a first-in-class anti-androgenic compound for the treatment of acne.

SUMMARY DATA

52-Week High	**$5.49**
52-Week Low	**$2.35**
One-Year Return (%)	**-51.00**
Beta	**0.64**
Average Daily Volume (sh)	**2,740**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$46**
Short Interest Ratio (days)	**0.14**
Institutional Ownership (%)	**24**
Insider Ownership (%)	**20**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 E	0 E	0 E	0 E
2016					0 E
2017					0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.23 A	-$0.35 A	-$0.18 A	-$0.26 A	-$1.00 A
2015	-$0.19 A	-$0.27 E	-$0.27 E	-$0.28 E	-$1.01 E
2016					-$0.70 E
2017					-$0.65 E

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WHAT'S NEW

Financial Update

On May 11, 2015, RestorGenex Corp. (RESX) announced financial results for the first quarter of 2015. The company did not report any revenues. Net loss for the quarter was $3.5 million, or $0.19 per share, and was comprised of $1.55 million in R&D expenses, $1.96 million of G&A expenses, and $0.006 million of depreciation and amortization.

The company had approximately $19.2 million in cash and cash equivalents at the end of the first quarter of 2015. Total burn for the first quarter was approximately $2.7 million and the company did not raise any money during this time period. There are approximately 18.6 million shares currently outstanding, along with approximately 3.6 million stock options and approximately 4.5 million warrants. The majority of the warrants have an exercise price of $4.80 (range $2.00-$4.80) and could potentially provide an additional $20 million if all of them are exercised.

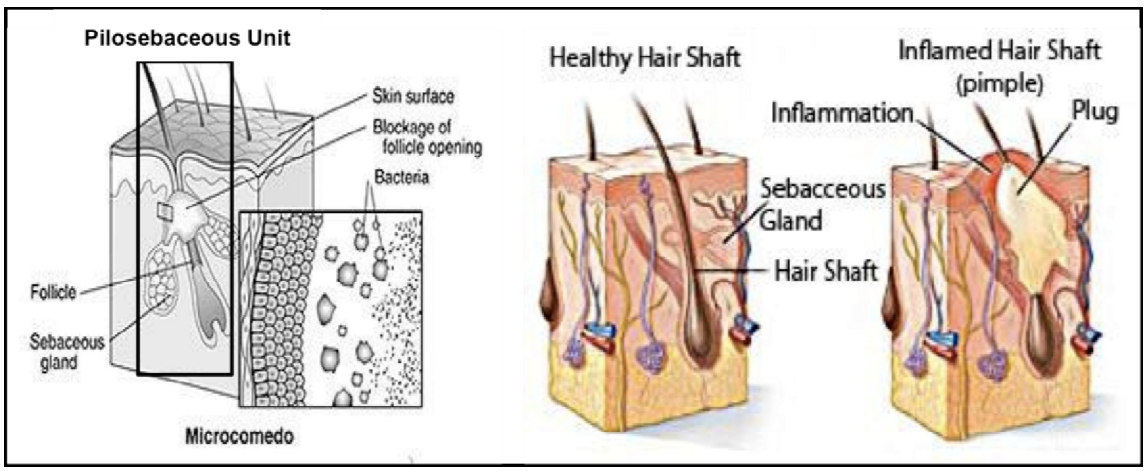
RES-440: A First in Class "Soft" Anti-Androgen

It has only been two months since we initiated coverage on RestorGenex, a specialty pharmaceutical company developing treatments for ophthalmology, oncology, and dermatology. The company has two proprietary compounds under development, RES-529 and RES-440. In our last update (April 7, 2015) we discussed RES-529, which the company is developing for the treatment of wet age-related macular degeneration (AMD) and glioblastoma mutiforme (GBM). For the purpose of this article, we will discuss only RES-440, a first-in-class anti-androgenic compound for the treatment of acne.

…Acne…

Acne vulgaris (or simply acne) is a common skin condition that causes pimples. It can present as non-inflammatory lesions, inflammatory lesions, or a combination of the two. Acne typically affects the face, but can also be found on the chest and back (Dawson *et al*., 2013). It occurs as a result of blockages in the follicles. Excess deposition of keratin, a structural protein that makes up the outer layer of skin, and oily sebum, a substance secreted by the sebaceous gland that helps to keep skin and hair from drying out, results in the formation of a plug, otherwise known as a microcomedo (Benner *et al*., 2013). A microcomedo may go on to form an open comedo ("blackhead") or a closed comedo ("whitehead").

Comedones are associated with the pilosebaceous unit, which includes a hair follicle and a sebaceous gland. These units are found mostly on face, neck, shoulders, chest and upper back (Williams *et al*., 2012). An increase in androgen production causes more sebum to be produced, thus increasing the probability of a plug forming in a hair follicle. After a plug forms, the mostly commensal bacterium *Propionibacterium acnes* can cause inflammation within and around the follicle, leading to inflammatory lesions that causes redness and may lead to scarring or hyperpigmentation.



***Source*: RestorGenex Corp.**

…Current treatment options for acne…

While not a life-threatening condition, severe acne can often impart a substantial psychological burden and negatively impacting a person's quality of life (Barnes *et al*., 2012). Consequently, there is a strong patient-driven demand for effective acne therapies, including prescribed medications and over-the-counter products. As a result, there are a large number of treatments available in a variety of formulations.

Classification of acne according to the severity of lesions into mild (comedones limited to the face), moderate (high number of pustules on the face and mild acne on the body), or severe (nodules and cysts on the face and body) is the first step in treatment, as this will guide the proper therapy. These therapies include topical antibiotics, retinoids, and benzoyl peroxide in monotherapy or in combination products. Systemic medications also include antibiotics and retinoids, as well as hormonal agents, and are only used in patients with moderate to severe acne. For a detailed overview of current treatment recommendation, we refer interested readers to the American Academy of Dermatology treatment guidelines for acne vulgaris.

Topical Therapy

Retinoids have a well-documented history of treating acne effectively. They act by reducing blockages within the follicle and are comedolytic and anti-inflammatory. In addition, they reduce the numbers of microcomedones, comedones, and inflammatory lesions (Gollnick *et al*., 2003). The most commonly prescribed retinoids are adapalene (Differin®), tazarotene (Tazorac®), and tretinoin (Avita®). Several randomized controlled trials have been performed that demonstrated their efficacy and tolerability. In general, all retinoids are effective in reducing the number of comedones and inflammatory lesions by 40-70% (Costa *et al*., 2013).

Antibiotics are mainly used for their role against *P. acnes*, however they may also have anti-inflammatory properties. Unlike retinoids, topical antibiotics are not comedolytic, and their use may lead to antibiotic resistance. Commonly prescribed antibiotics are clindamycin and erythromycin. Topical antibiotics are always used in combination with another treatment, such as a retinoid or benzoyl peroxide.

Benzoyl peroxide is a bactericidal agent and is proven to treat acne. It comes in a variety of prescription and over the counter formulation including soaps, washes, lotions, creams, and gels. Due to its ability to fight antibiotic resistance, these products are typically utilized in conjunction with a topical antibiotic.

Salicylic acid has been used for a number of years to treat acne although there are few clinical trials examining its effectiveness. Its comedolytic properties are less potent than retinoids, thus it is usually prescribed to those individuals who develop skin irritation as a result of topical retinoid treatment.

A number of combination products have also been developed that target multiple pathogenic factors. These include Ziana®, a combination of the antibiotic clindamycin and the retinoid tretinoin, and Epiduo®, a combination of the retinoid adapalene and benzoyl peroxide. These products have been shown to be more effective when compared with using each agent alone (Seidler *et al*., 2011). In addition, combination products have the advantage of simplifying the treatment regimen and reducing the dosing frequency (Alexis, 2008).

Oral Therapy

Oral antibiotics are a common treatment for moderate to severe acne. The tetracycline group of antibiotics is typically prescribed, with doxycycline and minocycline considered to be more effective than tetracycline. Side effects from systemic use of antibiotics include vaginal candidiasis; doxycycline can be associated with photosensitivity; and minocycline has been linked to pigment deposition of the skin, mucus membranes, and teeth.

Hormonal agents have shown some effectiveness in treating acne. Estrogen-containing oral contraceptives have been studied and shown to be effective in treating acne in clinical trials. Spironolactone is an anti-androgen that works by blocking androgen receptors at high concentration, although it may cause hyperkalemia and irregular menstrual periods. Flutamide is a nonsteroidal anti-androgen approved for the management of prostatic hypertrophy and hirsutism, however while effective its use is limited due to the potential for hepatic failure when used systemically.

Isotretinoin, a derivative of vitamin A, has been shown to be the most effective acne treatment, promoting a cure in 85% of cases (Costa *et al*., 2013). However, the drug is associated with a number of severe side effects involving the musculoskeletal, mucocutaneous, and ophthalmic systems. In addition, the drug has been reported to increase

the risk for irritable bowel disease, depression, and suicide. Lastly, the compound is a known teratogen, thus females taking the drug must be on a strict pregnancy prevention program. Due to this, the FDA requires all patients taking isotretinoin to sign up with an online tracking database, called iPledge, before receiving their prescription.

…Acne market…

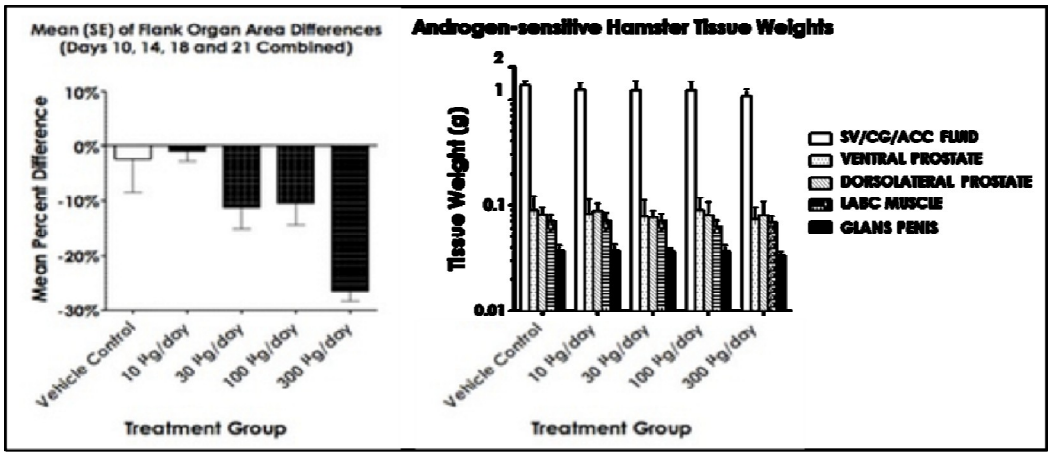
The acne market is divided into over-the-counter (OTC) products and prescription medications. In 2012, according to IMS Health, the top five prescription acne drugs combined for over $1 billion in sales in the U.S. According to IBISWorld Industry Research, the OTC market for acne medications was approximately $2.3 billion in 2012 and was expected to grow to $2.7 billion in 2017. The market is dominated by Johnson & Johnson (Neutrogena, Clean & Clear, Aveeno) and Guthy-Renker (Proactiv), with those companies commanding 29% and 25% of the OTC acne market, respectively.

…RES-440 is a topical anti-androgen with no systemic side effects…

RestorGenex is developing RES-440, which is a carboxylic acid ester of hydroxyflutamide, and is engineered to be the first topical anti-androgen that is rapidly deactivated by hydrolytic enzymes near the site of application to a single inactive metabolite. The company refers to this as a “soft” anti-androgen. The approach has the advantage of sparing internal, androgen sensitive tissues, thus potentially resulting in fewer side effects. The expected major metabolite of RES-440 has no detectable androgen-receptor affinity or ability to interfere with the androgenic effects of endogenous androgens.

The Syrian Golden Hamster model has long been validated as a model for topical anti-androgens as the animals have flank glands that are highly sensitive to androgen stimulation. The sebaceous gland flank organ spots are visible as a dark raised spot on each flank. Application of anti-androgenic compounds will cause the glands to diminish in size. The advantage of this model is that one gland can be treated with the test compound and the other compound with a control.

Topical doses of RES-440 from 10 to 300 µg/day were administered to male Golden Syrian Hamsters. In addition to monitoring the untreated flank organ size for systemic effects, androgen-sensitive tissues collected at the end of the experiment were weighed and compared to vehicle-treated intact animals and castrated controls. The results of the Golden Syrian Hamster study with RES-440 are shown below.



Source: **RestorGenex Corp.**

The above left figure shows the result of treating the hind flank glands with the indicated amount of RES-440 once-daily for 21 days. The data show that the gland treated with 300 µg per day was almost 30% smaller than the flank treated with vehicle control. In addition, there did not appear to be any affect on various androgen sensitive tissues, as shown by the above right figure. Taken together, these data indicate that RES-440 has potent anti-androgenic activity that is locally contained and does not result in systemic effects.

…RES-440 development plan…

RES-440 has a number of advantages over currently available acne therapeutics including a short half-life, an inactive metabolite (to avoid systemic side effects), a melting point very near body temperature making it possible to penetrate into the pilosebaceous unit, and its stable at skin pH.

RestorGenex is planning to complete preclinical and toxicology studies to enable an Investigational New Drug (IND) application to be filed in 2016. The company will then initiate Phase 1/2 clinical trials to study the safety and efficacy of RES-440. Differin® was approved with a single 12-week study involving 653 patients, thus RestorGenex could potentially be ready to perform a Phase 3 study in 2017 and file the U.S. NDA in 2018. If all goes well, RES-440 could be ready for commercial launch in 2019.

Conclusion

RestorGenex currently has a market cap of approximately $46 million. The company currently has approximately $19 million in cash and cash equivalents as of March 31, 2014. We see this as plenty of capital to get the requisite IND enabling studies completed in 2015 as well as initiate the Phase 1/2 clinical trials, which we estimate will begin in the first half of 2016. For example, cash burn in the first quarter 2015 was only $2.7 million.

The company is targeting three multi-billion dollar indications, wet AMD, GBM, and acne. As evidenced by the recent launch of Regeneron's Eylea®, a successful wet AMD treatment can generate revenues in excess of $1 billion shortly after approval. With the limited treatment options for GBM, a successful therapeutic could also potentially generate over $1 billion in peak revenues, as Temodar® did before losing patent protection. Lastly, a differentiated acne therapeutic, RES-400, is a potential $450 million opportunity. While an investment in an early stage biotechnology company is very high risk, with multiple high revenue opportunities an investment in RestorGenex has an enormous potential return.

…Valuation Methodology…

For both indications for RES-529, we estimate that RestorGenex would initiate a Phase 2b study in 2017, with a Phase 3 trial commencing in 2018, and an NDA filing in 2020 with approval of RES-529 in 2021. For RES-440, RestorGenex could initiate a Phase 3 study in 2017, an NDA filing in 2018, and obtain approval in 2019. For each indication we apply a 22% discount rate and give a probability of success of 15% for wet AMD and 10% each for GBM and acne. For RES-529, we estimate peak revenues of $1.5 billion for wet AMD and $650 million for GBM. At this point we are modeling for RestorGenex to market RES-529 in the U.S. and to partner for selling in the rest of the world, with a 15% royalty rate on sales.

For RES-440, we are estimating peak revenues of $450 million, and just as with RES-529 we model for RestorGenex to market the compound in the U.S. and partner for sales in the rest of the world.

Adding up our "sum-of-parts" analysis gives an estimated net present value for each indication of $125 million for wet AMD, $25 million for GBM, and $30 million for acne. Adding in the company's current cash total and an estimate $25 million in capital requirements gives a net present value for the company of approximately $175. Dividing this total by the fully diluted share count of 26.75 million shares leads to a fair value of approximately $6.50 per share. Thus, at the current stock price of only $2.45 per share, we believe an investment in RestorGenex is warranted and could prove to be highly lucrative.

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PROJECTED FINANCIALS

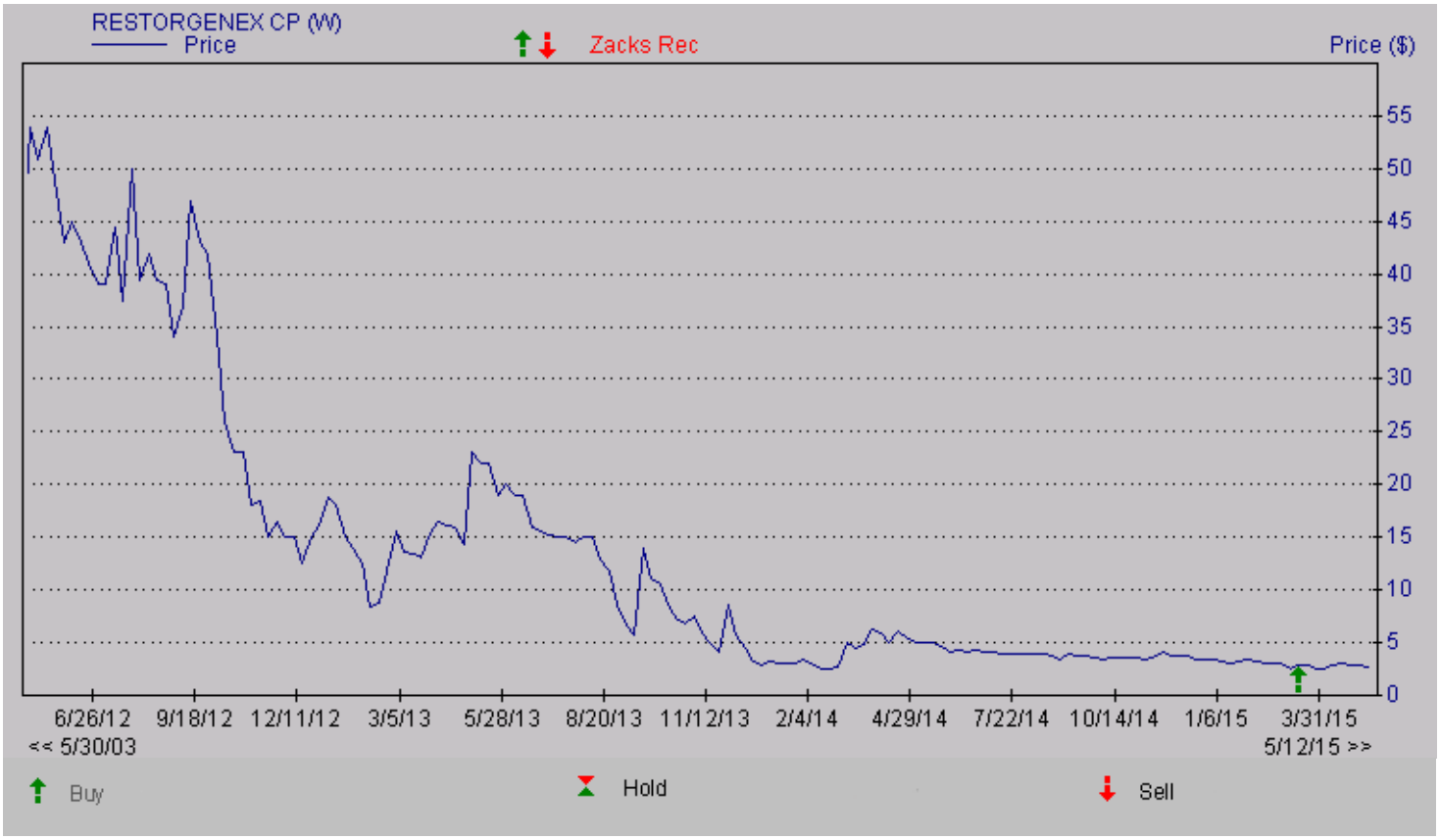
RestorGenex Corp.
Income Statement

RextorGenex Corp.	2014 A	Q1 A	Q2 E	Q3 E	Q4 E	2015 E	2016 E
RES-529 (Wet AMD)	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
RES-529 (Oncology)	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
RES-440 (Acne)	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-
Research & Development	$2.9	$1.6	$1.5	$1.5	$1.5	$6.1	$6.0
General & Administrative	$4.8	$2.0	$2.0	$2.1	$2.2	$8.3	$5.5
Other Expenses	$7.0	$0.0	$1.0	$1.0	$1.0	$3.0	$4.0
Operating Income	($14.6)	($3.5)	($4.5)	($4.6)	($4.7)	($17.3)	($15.50)
Operating Margin	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($2.6)	$0.0	($0.5)	($0.5)	($0.5)	($1.5)	($2.0)
Pre-Tax Income	($17.2)	($3.5)	($5.0)	($5.1)	($5.2)	($18.8)	($17.5)
Income Taxes Paid	($2.8)	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($14.4)**	**($3.5)**	**($5.0)**	**($5.1)**	**($5.2)**	**($18.8)**	**($17.5)**
Net Margin	-	-	-	-	-	-	-
Reported EPS	**($1.00)**	**($0.19)**	**($0.27)**	**($0.27)**	**($0.28)**	**($1.01)**	**($0.70)**
YOY Growth	-	-	-	-	-	-	-
Basic Shares Outstanding	14.3	18.6	18.6	18.7	18.7	18.7	25.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.5%, Hold/Neutral- 77.7%, Sell/Underperform – 5.1%. Data is as of midnight on the business day immediately prior to this publication.