Zacks Small-Cap Research

December 14, 2016

Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

Miramar Labs (MRLB-OTC)

MRLB: Game Changer For Hyperhidrosis? No Sweat!

Our 10-year DCF, which uses a 10% discount rate and 2.5% terminal growth rate values MRLB at approximately $10/share.
Average of 2016 and 2017 P/S comps (CYNO and ZLTQ) also implies fair value of MRLB is approximately $10/share.

Current Price (12/14/16)	$4.58
Valuation	**$10.00**

OUTLOOK

It is estimated that 4M Americans have primary axillary hyperhidrosis, or uncontrollable sweating of the underarms, which among all dermatological conditions is the one associated with the greatest negative effects to quality of life. MRLB's miraDry System is the only non-invasive device cleared by the FDA for permanent reduction of underarm sweat. Additionally, it is the only device cleared by the FDA for both permanent reduction of underarm hair of all colors as well as for the potential reduction of odor. Adoption of miraDry has been brisk and facilitated by compelling clinical data and related patient outcomes and satisfaction scores. This, along with a dearth of effective alternatives, significant compromises to life from hyperhidrosis, attractive economics for both patients and clinicians, and a revamped marketing strategy have been the main impetuses to revenue growth. Miramar is looking to build on the early success of miraDry and is strategically reinvesting proceeds from the recent equity raises in activities and programs aimed at realizing deeper and wider penetration of the primary axillary hyperhidrosis market as well as expanding the device's label to include additional indications. Revenue growth, combined with 90%+ consumable margins should move MRLB closer to profitability.

SUMMARY DATA

52-Week High	**$6.50**
52-Week Low	**$4.58**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**1,545**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$43**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**Small-Growth**
Industry	**Med Instruments**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in 000s of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	2,960 A	5,069 A	3,793 A	5,377 A	17200 A
2016	4,287 A	7,445 A	4,303 A	5,298 E	21333 E
2017					26055 E
2018					35363 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$11.77 A	-$9.17 A	-$9.57 A	-$6.92 A	-$37.33 A
2016	-$8.32 A	-$4.10 A	-$0.42 A	-$0.39 E	-$3.87 E
2017					-$1.19 E
2018					-$0.74 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

SNAPSHOT

Santa Clara, CA-based Miramar Labs, Inc. (MRLB) was created by The Foundry, a Silicon Valley-based medical device incubator with an impressive track record (see link…http://bit.ly/2cFVKTf) of finding compelling ideas and products and transforming them into successful companies.

Miramar went public via an alternative public offering in early June. Commensurate with, and subsequent to the reverse merger, Miramar raised approximately $9.9M ($8.9M net) via the sale of 1.98M common shares at $5/share in four separate private placements. The equity sales cleaned up the balance sheet and bolstered cash position, which stood at $6.1M as of the end of Q3. The cash is being used to help accelerate commercialization of miraDry, the company's flagship device for the elimination of primary axillary hyperhidrosis (i.e. excessive and uncontrollable idiopathic underarm sweat).

miraDry received FDA clearance in January 2011 and CE Mark in December 2013 for the treatment of primary axillary hyperhidrosis and for permanent reduction of axillary hair removal of all colors in June 2015. The device launched in 2012 and is marketed in the U.S. and Canada via a direct sales force and through third-party distributors in approximately 40 international territories including in Asia, Europe, the Middle East and South America.

The miraDry System, which consists of a console, handpiece and single use bioTip (i.e. consumable), incorporates proprietary microwave technology that non-invasively ablates sweat glands in the armpit. It is the only non-invasive device cleared by the FDA for the treatment of underarm sweat. Additionally, it is the only device cleared by the FDA for both permanent reduction of underarm hair of all colors (FDA clearance in June 2015) as well as for the potential reduction of odor (FDA clearance in October 2016). The technology is protected by 19 U.S. and 39 international patents. Another 11 U.S. and 43 international patent applications are currently outstanding.

According to the International Hyperhidrosis Society, approximately 220M people worldwide, or more than 3% of the global population, suffer from hyperhidrosis. In the U.S. it is estimated that 2.8%, or approximately 7.8M Americans, have hyperhidrosis and 4M have axillary hyperhidrosis, which is often described as being intolerable and significantly negatively affecting the lives of those that suffer from it. In fact, studies indicate that among all dermatological diseases and conditions, hyperhidrosis is the one that has the greatest negative effect on quality of life.

miraDry's safety and effectiveness have been validated in clinical studies which demonstrated 89% of patients treated with the device experienced significant reduction in sweat. Additional validation of the benefits of miraDry treatment is supported by; the International Hyperhidrosis Society recommending it as a safe and effective treatment, patient satisfaction of 90%+ and the fact that more than 80k total treatments have been performed to-date.

Other FDA-cleared treatments for primary axillary hyperhidrosis include prescription-strength antiperspirants, botulinum toxin (Botox), laser ablation and surgery - all of which have certain drawbacks relative to miraDry.

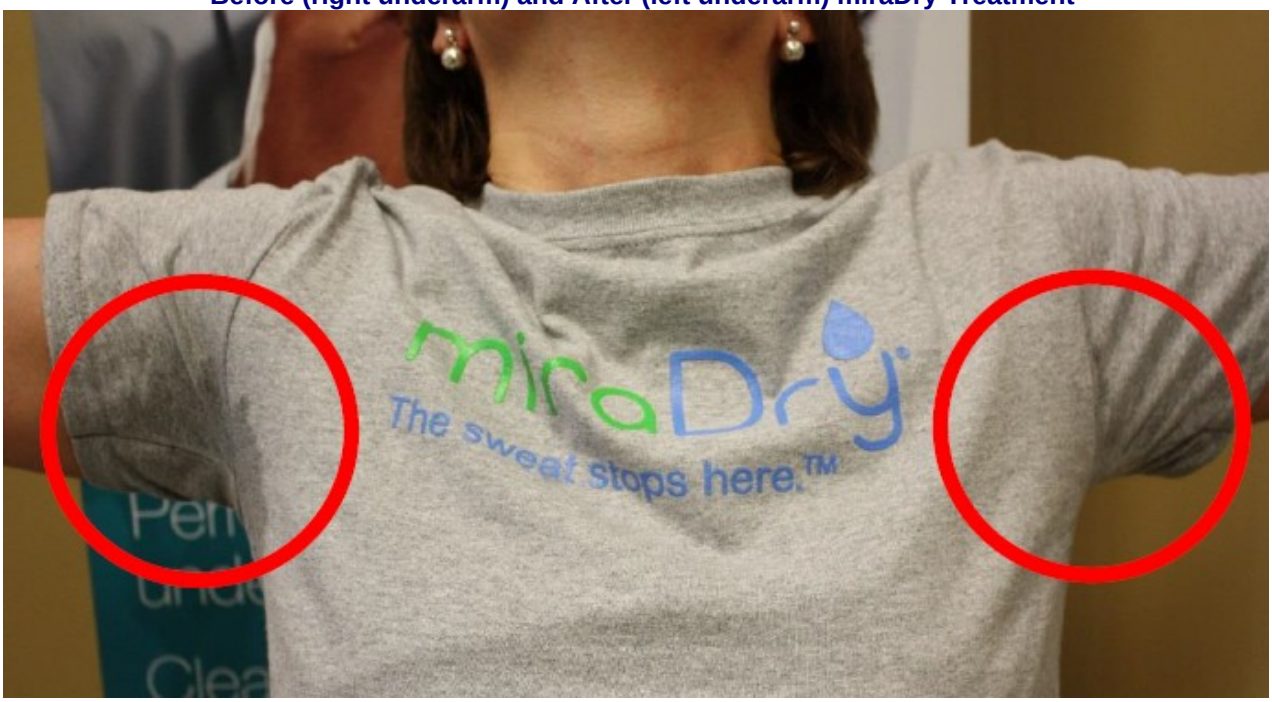
- Antiperspirants: usually considered a first-line therapy but often fail to effectively control sweating, aluminum content can cause skin irritation and oftentimes must be reapplied
- Botox: while effective, it is a temporary solution with symptoms typically returning within four to twelve months. Cost, at approximately $1k per treatment (i.e. every 4 – 12 months), can also be prohibitive
- Laser ablation: includes Cynosure's PrecisionTX system which is more invasive than miraDry treatment, may not be as effective as miraDry (there is scant clinical data of PrecisionTx for hyperhidrosis), is highly technique-dependent and appears to be (based on publicly available pricing) more expensive than miraDry
- Curettage: involves insertion of a metal instrument to scrape sweat glands from underside of skin. Drawbacks include high cost, invasiveness and inconsistent effectiveness
- Surgery: endoscopic thoracic sympathectomy (ETS) is highly invasive and involves a surgeon interrupting the nerves responsible for activating the sweat glands in the underarm areas. Due to the relatively high risks, permanent nature and high cost of the procedure, ETS is often considered a last resort after all other options have failed

Despite lack of insurance reimbursement for most hyperhidrosis therapies, adoption of miraDry has been brisk and facilitated by highly compelling clinical data and related patient outcomes and satisfaction scores. This, along with a dearth of effective alternatives, significant compromises to quality of life that is associated with hyperhidrosis, attractive economics for both patients and clinicians, and a revamped marketing strategy have been the main impetuses behind the 36% revenue growth through the first nine months of 2016.

Miramar is looking to build on the early success of miraDry and is strategically reinvesting proceeds from the recent equity raises in activities and programs aimed at realizing deeper and wider penetration of the primary axillary hyperhidrosis market as well as expanding the device's label to include additional indications. The recent FDA clearance for the reduction of underarm odor could position it as a direct replacement for the relatively enormous deodorant/antiperspirant market. An indication for treatment of palmoplantar (hand and foot sweat) hyperhidrosis could be next and would further broaden the market for miraDry. Investments are expected to be made in additional clinical studies, incremental expansion of the direct sales force in North America, entry into more international markets and new consumer-focused marketing programs.

And while we expect these investments will mean operating losses may continue over the near-term, anticipated sustained rapid adoption of miraDry along with a razor/razor-blade business model which affords 90%+ gross margins of the single-use consumables should result in improvement in profitability.

Before (right underarm) and After (left underarm) miraDry Treatment[1]



[1] Miramar Labs August 2016 investor presentation. Female patient four weeks after left underarm was treated with miraDry. Photo taken following 30 minutes of exercise

BACKGROUND

miraDry System

The miraDry System consists of a console, handpiece and single-use bioTip. The **console** is portable (measuring approx. 47"H x 20"W x 32"D, weighs 112lbs) and can be used in a typical physician's office. The console generates heat through microwave energy which is applied to the skin to rapidly and non-invasively ablate sweat and odor glands and hair follicles located in the underarms. The console also contains a chiller unit which provides continuous hydro-ceramic cooling to protect the skin from damage. The system is controlled via a built-in user interface with touchscreen software that also provides step-by-step instructions and status updates. Additional software collects data, such as utilization metrics, which can help clinicians analyze usage trends and to assist the company with marketing, purchasing, inventory and other strategic decisions.

Console **Handpiece** **bioTip**



SOURCE: miramarlabs.com

The **handpiece**, which delivers the microwave energy to the targeted tissue, also contains a cooling plate which maintains constant contact and cooling of the skin (via circulating water), has audible and visual indicators of the heating and cooling cycles during treatment.

The single-use (consumable) **bioTip** attaches to the handpiece and is the only component that is in direct contact with the patient. When applied to the skin it creates a vacuum, pulling the skin slightly inside the handpiece. This suction provides three functions; it ensures constant contact between the skin and the cooling feature of the handpiece, it maintains the relative position between the handpiece and the target treatment zone over the 30 – 40 seconds of the treatment cycle (several cycles are involved in one full treatment cycle) and it helps to protect the underlying tissue from heat by creating distance from the treated tissue.

The bioTip, which must be used for the miraDry system to function, acts as the 'razor-blade' in the pay-for-procedure business model. Each bioTip is shipped preprogrammed which ensures that it is used for only one procedure, only for a specified amount of time and only with an authentic miraDry system. This also ensures that Miramar receives revenue for each procedure performed.

miraDry is classified as a Class II device with special controls by the FDA. The system received initial **FDA clearance** in January 2011 (510(k) No. K103014) for the treatment of primary axillary hyperhidrosis. An upgraded version (i.e. current system) received FDA clearance for the same indication in October 2013 (510(k) No. K131162), for permanent reduction of axillary hair of all colors in June 2015 (510(k) No. K150419) and for the potential reduction of underarm odor in October 2016 (510(k) No. K160141). And in December 2013, the current system also received **CE Mark**. The technology is protected by **19 U.S. and 39 international patents**. Another 11 U.S. and 43 international patent applications are currently outstanding.

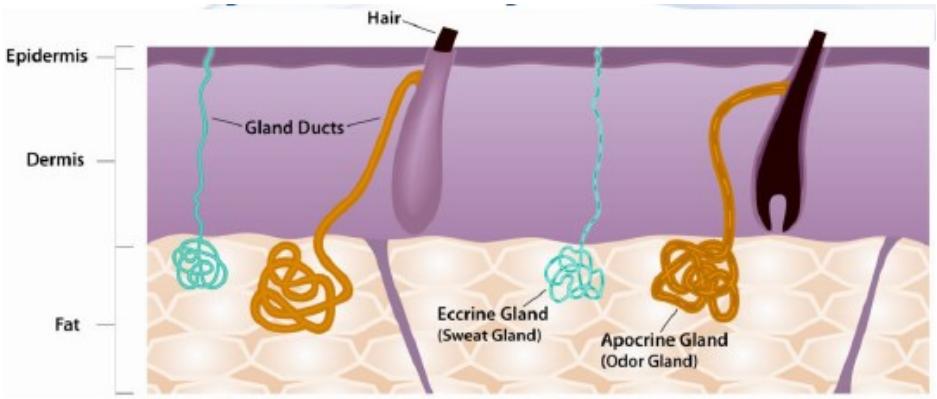
Sweat Glands

The human body has two primary types of sweat glands, eccrine glands and apocrine glands, both of which are mainly found in the hypodermis (i.e. subcutaneous fat tissue below the dermis) and the dermal/hypodermis interface (i.e. between dermis and subcutaneous fat). As we explain later, unlike other

energy-based modalities such as lasers which require an incision in order to reach sweat glands, microwaves are ideally suited to penetrate to depths where sweat glands are located, allowing the treatment to be performed non-invasively.

- **Eccrine glands** are found in almost all of the skin (including under the arms) and most densely on the palms of hands and soles of feet. Eccrine glands secrete a clear, aqueous and odorless substance, which is mostly made up of water and salt (the salt inhibits bacterial activity and related odor). They release sweat directly to the surface of the skin. Eccrine glands are mainly responsible for hyperhidrosis. The main functions of eccrine glands are for thermoregulation (i.e. cooling of the body), excretion of excess water and to protect the skin from certain bacteria
- **Apocrine glands** are found at only certain points of the human body including the underarms. They release sweat into the canal of hair follicles. Apocrine glands secrete an oily sweat, proteins from which are easily broken down by bacteria, making it odorous. Apocrine glands are typically activated during times of emotional stress

Sweat Glands Located Deep Within The Skin

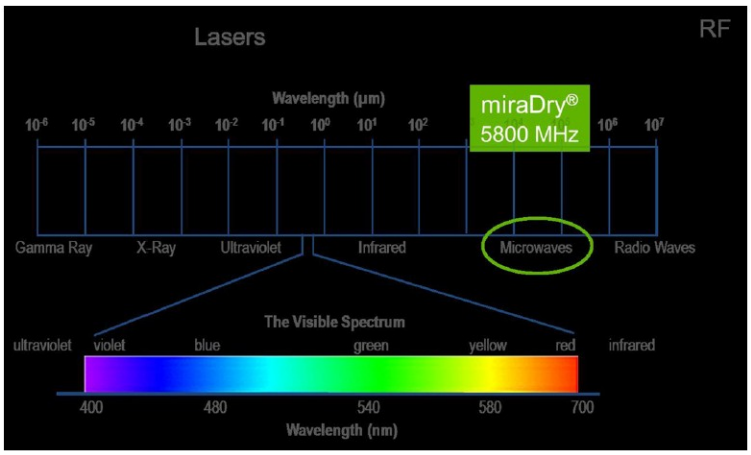


SOURCE: Miramar Labs

Microwaves ideally suited for sweat gland ablation…

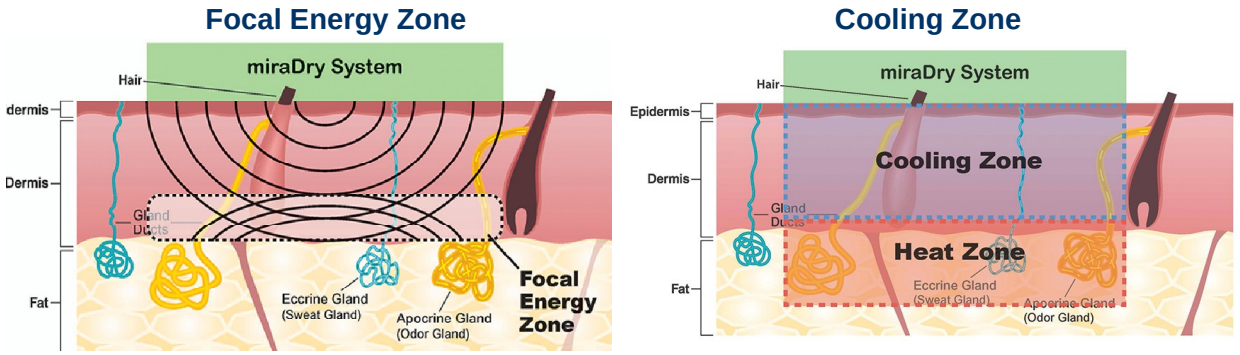
Microwave radiation causes dielectric heating which occurs when a high frequency electric field causes rapid rotation of dipole molecules. Friction from the molecules' rotation results in heat. Water has a high electric dipole moment, or high polarity, meaning that it is easily absorbed by microwaves and the molecules will continuously rotate (and create heat) when affected by an electromagnetic field such as from microwaves. Substances such as fat and sugars, which have much lower polarities than water, are less affected by microwaves.

Microwaves have wavelengths ranging between one millimeter and one meter (frequency of 300GHz - 300 MHz) which lies between infrared waves, with wavelength of 700nm to one meter (frequency of 430 THZ - 300 GHz, and radiowaves, with wavelength of one meter to 100km (frequency 300MHZ - 3Hz).



miraDry delivers microwaves at a frequency of approximately 5.8GHz (for context, microwave ovens deliver at ~2.4GHz), which was found to be optimal frequency associated with low amounts of microwave absorption at the surface of the skin and maximum absorption at the dermal-fat interface.

Microwave technology, similar to which is incorporated into miraDry, has been successfully used for years in other medical applications such as with tissue and tumor ablation. Microwaves have also been found to be ideally suited for ablation of sweat glands given the ability to reach their relatively deep location at the dermal-fat interface. And while microwaves are readily absorbed by tissue due to the high water content, they are not with fat due to its much lower polarity. This facilitates the creation of what Miramar calls the **'focal energy zone'**, which is the concentration of heat at the dermal-fat interface, or precisely where sweat glands reside. The ability to direct energy precisely where sweat glands reside and without being affected by skin thickness is a significant advantage of miraDry as compared to competing energy-based ablation technologies. miraDry also provides continuous hydro-ceramic cooling to protect the skin and other adjacent tissue located above the focal energy zone (in the **'cooling zone'**) from being damaged by heat.

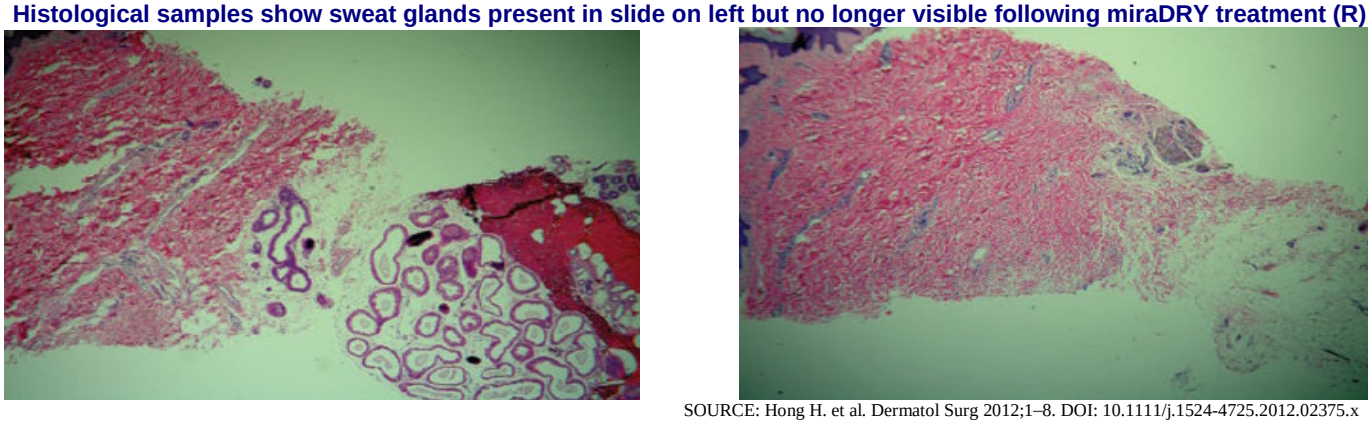


SOURCE: Miramar Labs

miraDry delivers energy at a constant rate. Settings on the device provide for the ability to deliver heat for shorter or longer periods of time. miraDry heats target tissue to above 60º C, which is when instantaneous cell death occurs.[2]

The heat triggers thermolysis, or the decomposition of chemical compounds, permanently destroying the sweat glands. Since sweat glands are only developed during the human embryonic stage, it is believed that they do not have the ability to regenerate after being destroyed.

Histological samples show sweat glands present in slide on left but no longer visible following miraDRY treatment (R)



SOURCE: Hong H. et al. Dermatol Surg 2012;1–8. DOI: 10.1111/j.1524-4725.2012.02375.x

miraDry Procedure…

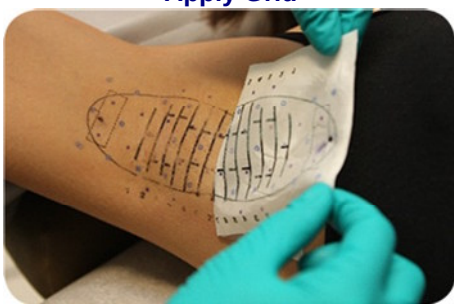
Unlike many axillary hyperhidrosis treatments including surgery and other heat-based therapies, miraDry is non-invasive. A typical miraDry procedure, which is performed in a physician's office, takes approximately one hour and the patient can immediately return to normal activities. While a single procedure is often

[2] Thomsen S. Pathologic analysis of photothermal and photomechanical effects of laser tissue interactions. Photochem Photobiol. 1991;53:825–35

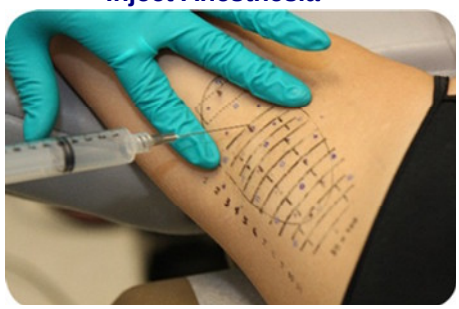
sufficient, some patients may desire a second treatment (typically performed three months after the first) for increased reduction.

1) Underarms are cleaned
2) Temporary grid 'tattoo' is applied to underarms to designate the area that is to be treated
3) A diluted form of lidocaine anesthesia is infused under the skin, typically through four or five insertion points, to numb the treatment area
4) Area is treated with miraDry handpiece and bioTip, which simultaneously applies cooling and heating during the first portion of the treatment cycle and then only cooling in the final phase. Handpiece uses suction to bring sweat glands closer to the heating element, make definitive contact between the cooling feature and the skin, fix the relative position between the handpiece and the target tissue and to help protect underlying structures through separation

Apply Grid



Inject Anesthesia



Treat



SOURCE: ww.bondimed.at

The miraDry procedure is not covered by insurance. While **cost** is physician practice-dependent, based on information in the public domain, including Miramar's most recent investor presentation, we believe a reasonable general estimate that a patient could expect to pay is in the range of $2k - $3k for one to two miraDry treatments, respectively. As we discuss later, given the lack of effective alternatives along with significant compromises to quality of life and economic costs that are associated with hyperhidrosis, we do not believe $2k - $3k is generally viewed as cost-prohibitive.

Clinical Data: Proven Effectiveness in Primary Hyperhidrosis and Hair Reduction…
miraDry's safety and effectiveness have been validated in randomized, sham-controlled clinical studies which demonstrated an 82% average reduction in sweat leading to 89% of patients reporting a significant reduction in sweat. Additional validation of the benefits of miraDry treatment is supported by; the International Hyperhidrosis Society recommending it as a safe and effective treatment, patient satisfaction of 90%+ and the fact that more than 80k total treatments have been performed to-date.

➢ The **pivotal study** which supported initial FDA clearance showed miraDry effectively and significantly reduced sweating of 89% and 69% of the 81 patients treated with the device through 3 months and 12 months, respectively.

This was a multi-center, randomized, sham-controlled trial with 120 individuals with primary axillary hyperhidrosis rated 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) and baseline sweat production of 50mg/5 minutes. HDSS is an industry-standard tool that provides a measure of the severity of a particular individual's condition. A score of 3 or 4 (on a scale of 1 to 4) indicates severe hyperhidrosis (see Appendix for HDSS scale). Subjects were randomized 2-to-1 to treatment (n=81) and sham (n=39) and underwent one to three treatment sessions. Both groups received anesthesia. Final follow-up for sham and treatment groups was 6 and 12 months, respectively. Primary endpoint was an individual HDSS score of 1 or 2 (i.e. mild or moderate hyperhidrosis) at 30-day follow-up. Secondary endpoints were HDSS scores of 1 or 2 at 6 month and 12 month follow-up.

Results showed that the miraDry treated group experienced statistically significant greater efficacy than the sham cohort at every time point and stable efficacy from 3 through 12 months. Efficacy for the treatment vs. sham groups was;

- 89% vs. 54% at the primary endpoint of 30 days ($p < 0.001$), 74% vs. 44% at 3 months ($p = 0.001$), 67% vs. 44% at 6 months ($p = 0.019$) [see table 3] and
- 69% at 9 and 12 months for the treatment group (final follow-up for sham was 6 months) [see table 4]

TABLE 3. Hyperhidrosis Disease Severity Scale (HDSS) Efficacy Results Through the 6-Month Follow-Up Visit, Comparing Responder Rate in the Active (n = 81) and Sham (n = 39) Groups

	30-Day Visit %			*3-Month Visit %*			*6-Month Visit %*		
Definition of Success	*Active Group*	*Sham Group*	*P-Value*	*Active Group*	*Sham Group*	*P-Value*	*Active Group*	*Sham Group*	*P-Value*
HDSS score 1 or 2	89	54	<.001	74	44	=.001	67	44	.02
HDSS score reduced by ≥2 points	67	13	<.001	57	13	<.001	47	13	<.001

TABLE 4. Hyperhidrosis Disease Severity Scale (HDSS) Efficacy Results Through the 12-Month Follow-Up Visit for the Active Group (n = 81)

Definition of Success	*30-Day Visit %*	*3-Month Visit %*	*6-Month Visit %*	*9-Month Visit %*	*12-Month Visit %*
HDSS = 1 or 2	89	74	67	69	69
HDSS reduces by ≥2	67	57	47	42	38

SOURCE: Glaser D, et al. Dermatol Surg 2012;38:185–191

No serious adverse events were reported. Treatment-related adverse events were considered mild and all but one resolved over time. The most common adverse events in the treatment cohort were numbness (10%) and axillary pain requiring medication (6%).

The study results were presented as a Late Breaking Abstract at the 2010 American Society of Dermatological Surgery / American Society of Cosmetic Dermatology and Aesthetic Surgery Joint Annual Meeting and published in the journal Dermatologic Surgery in February 2012.

➢ A **long-term study** involving 31 patients with severe hyperhidrosis showed miraDry reduced sweating by at least 82% through 12 months following treatment and effectively and significantly reduced sweating of 90% and 100% of subjects through 12 months and 24 months, respectively.

This was a two-center, single-arm study with 31 individuals with primary axillary hyperhidrosis rated as 3 or 4 on the HDSS scale and with sweat production of at least 50mg/5 minutes in each armpit. Primary efficacy measure was percentage of subjects in which HDSS score was reduced to 1 or 2. Secondary efficacy was the percentage of subjects which achieved at least 50% reduction in gravimetric (i.e. weight of sweat) score. Change from baseline in average Dermatology Life Quality Index (DLQI) score as well as the percentage of patients that achieved at least a 5-point reduction in DLQI were also measured. Similar to HDSS, DLQI assesses severity of hyperhidrosis and its effect on quality of life (see Appendix for DLQI questionnaire). A 5 point or more reduction in DLQI is established as being a clinically meaningful improvement. Finally, patients were queried as to their satisfaction of treatment as well as for odor reduction.

Results (see table below) through 12-month follow-up, which were published in 2012 in the journal Dermatologic Surgery in 2012, showed the **primary endpoint** (i.e. reduction in HDSS score to 1 or 2) **was met with 90% or more patients at all four follow-up visits** (i.e. 30 days, 3 months, 6 months and 12 months). A dramatic reduction in sweat at all timepoints was further supported by the secondary endpoints including;

- Gravimetric:
  - 90% or more patients experienced at least 50% reduction in sweat at all four follow-up visits
  - average reduction in sweat for all patients was 82% or higher at all four follow-up visits
- DLQI:
  - percentage of patients experiencing 5-point or more reduction in DLQI score was 96% at 30 days, 89% at both 3 months and 6 months, and 85% at 12 months
  - average DLQI reduction was 10.4 (30 days), 10.2 (3 months), 9.6 (6 months) and 9.9 (12 months) - all of which were statistically significantly ($p < 0.001$) higher than 5 points

All Endpoints Indicate Dramatic Reduction in Sweat at All Timepoints

Efficacy Measure	*30 Days*	*3 Months*	*6 Months*	*12 Months*
HDSS reduction to score of 1 or 2, *n* (%) [95% CI]	28 (90.3) [74.3–98.0]	29 (93.6) [78.6–99.2]	28 (90.3) [74.3–98.0]	28 (90.3) [74.3–98.0]
≥50% reduction in sweat (gravimetric), *n* (%) [95% CI]	28 (90.3) [74.3–98.0]	29 (93.6) [78.6–99.2]	28 (90.3) [74.3–98.0]	28 (90.3) [74.3–98.0]
Average reduction in sweat (gravimetric), % [*n* = 31]	83.1	82.3	82.1	81.7
Average DLQI score [*n* = 31]	2.5	2.7	3.1	3.0
Reduction in DLQI score, average [95% CI]*	10.4 [8.3–12.4]	10.2 [7.9–12.4]	9.6 [7.3–12.0]	9.9 [7.5–12.2]
Reduction of DLQI by ≥5 points, *n* (%) [95% CI]*	26 (96.3) [81.0–99.9]	24 (88.9) [70.8–97.7]	24 (88.9) [70.8–97.7]	23 (85.2) [66.3–95.8]

*Included only patients with a baseline DLQI of ≥5 [*n* = 27].
CI, confidence interval; DLQI, Dermatologic Life Quality Index.
95% confidence intervals are shown in square brackets.

SOURCE: Hong H. et al. Dermatol Surg 2012;1–8. DOI: 10.1111/j.1524-4725.2012.02375.

Regarding the percentage of patients that reported being either very or somewhat **satisfied**; 90% said they were at 30 days, 96% said they were at 3 months, 93% at 6 months and 87% at 12 months.

miraDry treatment also appeared to substantially **reduce odor**. At baseline, 13% of subjects reported no odor - this increased to 68% at 30 days, 71% at 3 months, 74% at 6 months and 61% at 12 months. The difference between baseline and all time points was statistically significant ($p < 0.001$).

No serious adverse events were reported. Treatment-related adverse events were considered mild and all resolved over time. The most common adverse events in the treatment cohort were short-lived edema, redness, vacuum marks and discomfort.

➢ **Through 24 months**: Nineteen of the thirty one patients consented to a survey at 24 months. Efficacy appeared to be maintained with 100% of the 19 patients reporting a reduction in HDSS score to 1 or 2 at the 24-month follow-up. In addition, average DLQI score fell from 11.8 at baseline to approximately 1.4 at 24 months with 100% of patients experiencing a (clinically relevant) reduction of 5 or more points. Results were presented at the American Society for Dermatologic Surgery Annual Meeting in October 2012 and subsequently published in Dermatologic Surgery.

Efficacy Maintained Through 24 Months

Efficacy Measure	*Baseline*	*30 days (n = 30)*	*3 months (n = 29)*	*6 months (n = 27)*	*12 months (n = 26)*	*15 months (n = 18)*	*18 months (n = 18)*	*21 months (n = 18)*	*24 months (n = 19)*
Percent of subjects with HDSS reduction to score of 1 or 2	NA	28/30 = 93.3%	28/29 = 96.6%	26/27 = 96.3%	26/26 = 100%	17/18 = 94.4%	18/18 = 100%	18/18 = 100%	19/19 = 100%
DLQI score (mean ± SD)	11.8 ± 6.4	1.87 ± 2.46	1.86 ± 3.56	1.81 ± 3.43	1.23 ± 1.53	2.00 ± 2.38	1.50 ± 1.72	1.44 ± 1.89	1.37 ± 1.54
Reduction of DLQI score* (mean ± SD)	NA	11.0 ± 4.8	10.7 ± 5.5	10.4 ± 5.94	11.2 ± 5.6	10.3 ± 4.79	11.2 ± 6.6	10.5 ± 5.9	11.4 ± 6.3
Reduction of DLQI by ≥5 points*	NA	25/25 = 100%	23/24 = 96%	21/22 = 95%	21/21 = 100%	13/13 = 100%	13/14 = 93%	13/13 = 100%	14/14 = 100%
DLQI—clothing	84%	10%	3%	7%	0%	0%	0%	0%	11%
DLQI—embarrassed or self-conscious	71%	7%	3%	7%	0%	0%	0%	0%	0%
DLQI—prevented work or studying	52%	0%	3%	0%	0%	0%	0%	0%	0%
DLQI—affected social or leisure	45%	0%	3%	4%	0%	0%	11%	0%	11%
Odor: % with "not a problem"	16%	80%	83%	81%	88%	83%	89%	89%	89%

*Only included patients who had a baseline DLQI of 5 or greater (excluded 5 patients).

SOURCE: Lupin M1, Hong HC, O'Shaughnessy KF. Dermatol Surg. 2014 Jul;40(7):805-7.

In addition to maintaining efficacy in sweat reduction, the analysis showed odor reduction also persisted through the 24-month follow-up. Of the 19 patients followed through 24 months, 89% stated that odor "was not a problem" at the two-year mark – compared to just 16% at baseline.

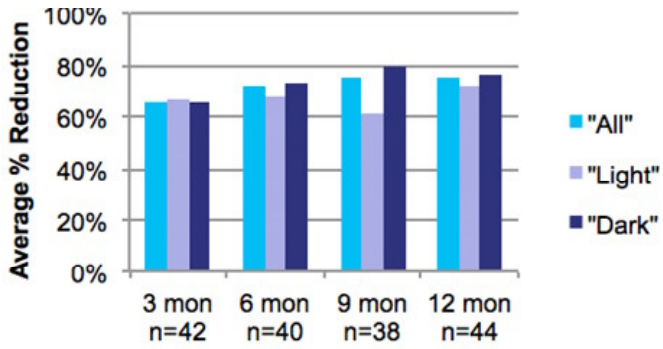
miraDry Also Effective in Reducing Axillary Hair of All Colors…

miraDry has also demonstrated the ability to permanently reduce underarm hair as the heat energy not only destroys sweat glands but also affects the hair bulb, leading to hair loss. While conventional laser-based hair reduction technologies employ photothermolysis, which matches wavelengths of light to destroy dark matter (such as hair) while sparing lighter colored surrounding tissue, laser technologies are ineffective on light colored or red hair. As such, miraDRY is the only energy-based device with FDA clearance for the permanent reduction of axillary hair of all colors.

miraDry's ability to reduce axillary hair was validated in a clinical trial which enrolled 56 subjects, the majority of which had Fitzpatrick skin type I-IV (i.e. pale white, white, cream white and moderately brown). Primary endpoint was >30% reduction in axillary hair (as assessed by hair count) from baseline to 3 month follow-up in more than 50% of subjects. Secondary endpoint was > 30% reduction in axillary hair (as assessed by photos) at 12 month follow up, to support a claim of permanent hair reduction (FDA defines permanent hair reduction as “long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime”).

42 and 44 subjects were evaluable for the primary and secondary endpoint measures, respectively. Results showed that both endpoints were met with 77% of patients showing at least 30% reduction in hair at 3 months and 86% of patients showing at least 30% reduction at 12 months. Analysis was also done at interim periods, which showed 89% and 92% of patients had at least 30% hair reduction at six and nine month follow-up, respectively. Additionally, 81% and 70% of patients were either "very satisfied" or “somewhat satisfied" with the results at the 3 and 12 month follow-up, respectively. The results, presented at the American Society for Laser Medicine and Surgery’s annual meeting in April 2015, were used to support an FDA filing seeking clearance for permanent reduction of axillary hair of all colors for Fitzpatrick skin types I-IV. Miramar received that clearance in June 2015 (510(k) No. K150419).

miraDRY Reduces Hair of All Colors



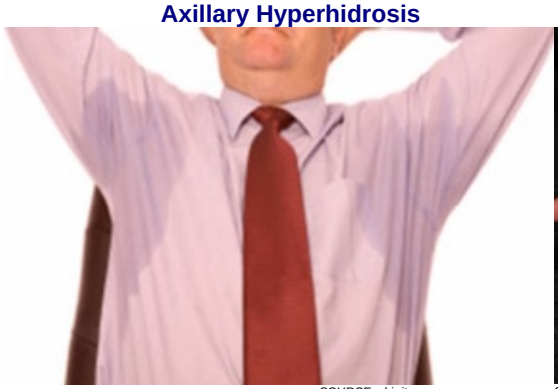
SOURCE: Miramar Labs

Primary Hyperhidrosis Has Profound Negative Effect on Quality of Life

Hyperhidrosis, sweating in excess of that required for thermoregulation…

Hyperhidrosis is defined as sweating excessively, uncontrollably and beyond what is necessary for thermoregulation. There are two distinct types of hyperhidrosis; primary and generalized. The **primary** form is idiopathic and mostly affects the palms, soles and underarms (or axilla). Less common is **generalized** hyperhidrosis, which can involve sweating of the whole body and is usually related (or secondary) to other variables such as medications or other diseases and conditions such as anxiety disorders, certain cancers, cardiovascular problems and hormonal conditions. As miraDry (currently) addresses only primary hyperhidrosis, we contain our discussion solely to that form.

Axillary Hyperhidrosis



SOURCE: chir.it

Palmar Hyperhidrosis



SOURCE: hyperhidrosisonthego.blogspot.com

Onset of primary hyperhidrosis usually takes place early in life, often during adolescence (and sometimes earlier). While the exact cause is unknown, there is evidence indicating that it may be an inherited genetic disorder. Primary hyperhidrosis can be further delineated into **palmoplantar hyperhidrosis**, or excessive idiopathic sweating of the hands (palm) and soles (plantar), **craniofacial hyperhidrosis**, or excessive seating of the face or scalp, and **axillary hyperhidrosis**, or excessive idiopathic sweating of the underarms.

Based on a survey[3] of 150k households, prevalence of hyperhidrosis in the U.S. is estimated to be 2.8% (7.8M). It is further estimated that of the Americans with hyperhidrosis, 51% (4M) have axillary hyperhidrosis (either only axillary or in combination with palmoplantar), 30% have plantar, 24% palmar and 10% cranofacial. Of those with axillary hyperhidrosis, 18.7% (750k) have axillary alone.

Hyperhidrosis Negatively Effects Quality of Life

Living with primary hyperhidrosis often means compromised emotional well-being, lack of confidence, embarrassment, depression and avoidance of social situations. Regularly changing clothes and frequent showering is typical of the daily routine of someone with axillary hyperhidrosis. Behavioral modification in order to manage the physical and emotional symptoms of primary hyperhidrosis can be severely life-limiting, both socially and professionally. This can result in underperformance at work and hinder personal relationships. In fact, a review of literature (which we discuss further below) indicates that among all dermatological diseases and conditions, hyperhidrosis is the one that has the greatest negative affect on quality of life.

A large study[4] (Henning Hamm, et al) published in the journal Dermatology in 2006 compared 345 patients with primary hyperhidrosis (165 axillary, 116 palmar and 64 in other locations) to 154 healthy individuals (i.e. control group) in the assessment of quality of life impacts associated with the condition using the validated 41-item **Hyperhidrosis Impact Questionnaire** (HHIQ). The HHIQ asks the respondent to rate the degree by which hyperhidrosis (or sweating) affects their life related to work, emotional well-being, social situations, management of their symptoms and leisure time. Response options are (or are similar to); not at all, a little, moderately, quite a bit and extremely.

The study's findings, which are widely cited in hyperhidrosis literature, indicates that primary hyperhidrosis has a profound negative effect on quality of life, including emotional and physical well-being. Also noteworthy is that, with the exception of 'shaking hands', axillary hyperhidrosis appears to be more limiting to overall quality of life than does palmar hyperhidrosis. Findings, listed by category, are below;

- Work-related limitations
  - 63% of primary hyperhidrosis (PH) patients felt moderately-to-extremely **limited at work** vs.1% of control
  - 44% of PH patients' **effectiveness at work** was moderately-to-extremely impaired vs. 0% of control
  - 42% of PH patients reported that their sweating prevented them from **pursuing a particular career**
  - 31% of PH patients reported that they **accomplished less at work** vs. 0% of control
  - 43% of PH patients reported that they **made changes in the way they worked** vs. 0% of control
  - 25% of PH patients reported that they **worked less carefully** in the way they worked vs. 0% of control
  - there were no significant differences on any of the work-related measures between palmar and axillary
- Emotional well-being impacts
  - 74% of PH patients reported being moderately-to-extremely **emotionally damaged** or injured vs. 0% of control
  - 74% of PH patients were **less confident** than they would like vs. 3% of control
  - 63% of PH patients were **unhappy or depressed** vs. 0% of control
    - 71% of primary axillary hyperhidrosis (**PAH**) patients were **unhappy or depressed**
    - 54% of primary palmar hyperhidrosis (**PPH**) patients were **unhappy or depressed**
- Social-related limitations
  - 71% of PH patients were moderately-to-severely **limited in meeting people** for the first time vs. 2% of control

[3] Strutton, et al. US prevalence of hyperhidrosis and impact on individuals with axillary hyperhidrosis: Results from a national survey. J Am Acad Dermatol. August 2004. Vol 51, No. 2. 241-248

[4] Hamm, Henning, et al. Primary Focal Hyperhidrosis: Disease Characteristics and Functional Impairment. Dermatology 2006;212:343–353

- 59% of PH patients were moderately-to-severely **limited in developing personal relationships** vs. 2% of control
- 54% of PH patients were moderately-to-severely **limited in participating in family events** or spending time with friends vs. 1% of control
- 34% of PH patients were moderately-to-severely **limited in sexual activities** vs. 0% of control
- **Shaking hands** was a major limitation with **PPH** (97%) but was also a limitation with PAH (33%) vs. 2% of control
- **Being in public places** was a major limitation with **PAH** (65%) but was also a limitation with PPH (45%) vs. 1% of control
- **Decreasing leisure time** was more of a limitation with **PAH** (59%) then with PPH (41%)

➢ Managing hyperhidrosis symptoms

- **Changing clothes** was a serious limitation with **PAH** (70%) and less so with PPH (31%)
- **Treating symptoms** for 15 minutes or more per day was reported by 38% with PAH and 22% with PPH
- Those that bathed or **showered two or more times per day** included 27% with PAH and 10% with PPH
- PAH patients were significantly more likely than those with PPH to engage in each of the above three activities

➢ Leisure time

- 53% of PH patients **changed the types of leisure activities** vs. 2% of control
- 42% of PH patients **decreased their leisure time**, including 59% of axillary and 41% of palmar, vs. 1% of control
- 38% of PH patients **missed outings** with friends and family, including 59% of axillary and 41% of palmar, vs. 0% of control

DLQI: hyperhidrosis impairs quality of life and more so than any other dermatological disease…

In addition to HHIQ, the same patients from the large study just discussed were assessed using the Dermatology Life Quality Index, a validated and widely used questionnaire to assess the effects of dermatological diseases on quality of life. DLQI is a 10-item questionnaire covering six domains. Maximum score is 30 and the higher the score, the greater that quality of life is negatively affected. DLQI has been used extensively for over 40 different types of skin conditions and diseases.

Similar to HHIQ, DLQI indicated that hyperhidrosis patients had significantly greater impairment to their quality of life due to their dermatological condition as compared to control subjects. Average DLQI score of all hyperhidrosis patients was 9.2 (10.0 axillary, 8.8 palmar) compared to just 0.7 for control - the difference is highly statistically significant ($p<0.001$), as was the difference between hyperhidrosis patients and control in each of the six domains (i.e. 'symptoms and feelings, daily activities', etc.). Results are in the chart below.

DLQI domain	DLQI score, mean (SD)			
	controls (n = 134)	hyperhidrosis		
		all (n = 319)	axillary (n = 152)	palmar (n = 109)
Total score (range 0–30)[1]	0.7 (2.0)	9.2 (5.8)	10.0 (5.6)	8.8 (5.9)
Symptoms and feelings (range 0–6)[1]	0.4 (0.9)	2.1 (1.3)	2.2 (1.3)	2.1 (1.2)
Daily activities (range 0–6)[1, 2]	0.1 (0.5)	2.6 (1.8)	3.2 (1.5)	2.1 (1.8)
Leisure (range 0–6)[1]	0.0 (0.3)	1.8 (1.7)	1.9 (1.7)	1.6 (1.7)
Work and school (range 0–3)[1]	0.1 (0.4)	1.0 (0.9)	1.0 (0.9)	1.0 (0.8)
Personal relationships (range 0–6)[1]	0.0 (0.3)	1.5 (1.6)	1.5 (1.6)	1.7 (1.6)
Treatment (range 0–3)[1, 2]	0.0 (0.3)	0.2 (0.6)	0.2 (0.4)	0.4 (0.7)

[1] Statistically significant differences between controls and all hyperhidrosis.
[2] Statistically significant difference between axillary and palmar.

SOURCE: Hamm, et al. Dermatology 2006;212:343–353

Comparably telling of the quality of life hardships associated with hyperhidrosis are the results of a literature review by the authors of this study (i.e. Hamm and colleagues) which found that **among dermatological diseases with DLQI scores of eight or higher, hyperhidrosis was associated with the greatest impairment to quality of life** (list below). This includes conditions such as inpatient (i.e. severe) psoriasis,

inpatient dermatitis and pruritus which, as the pictures below elucidate, can be quite emotionally and physically debilitating.

Disease	DLQI score
Palmar hyperhidrosis [3, 4, 11]	18–9.1
Axillary hyperhidrosis [3, 4, 11]	17–11.6
Dermatitis/eczema (inpatient) [18]	16.2
Focal hyperhidrosis (general) [3, 9]	15.5–10.1
Psoriasis (inpatient) [18]	13.9
Forehead hyperhidrosis [11]	12.5
Atopic eczema/dermatitis [13, 21–24, 27]	12.5–5.8
Psoriasis (outpatient) [19–24]	11–4.5
Contact dermatitis [21]	10.8
Pruritus [13, 20]	10.5–10
Urticaria [20, 21, 29]	9.5–3.9
Acne [13, 20, 21, 23, 26]	9.3–4.3
Birthmarks [20]	9
Nodular prurigo [21]	8.7
Dermatitis/eczema (outpatient) [13, 19, 20, 23, 30]	8.7–4.1
Scabies [20]	8.6

SOURCE: Hamm, et al. Dermatology 2006;212:343–353

Psoriasis



Dermatitis



Pruritus



SOURCES: pinterest.com patient.info digestground.com

COMPETITION

While there is no widely accepted standard of care for treatment of axillary hyperhidrosis, several other types of therapies have been used to address the condition. This includes prescription antiperspirants, botulinum toxin, surgery and other energy-based ablation modalities. All of these, however, have certain drawbacks, particularly as compared to miraDry.

Prescription, or clinical strength, antiperspirants are usually considered the first-line treatment for axillary (as well as palmoplantar) hyperhidrosis. Antiperspirants typically use one or more aluminum-based compounds as the active ingredients, which may include aluminum chloride, aluminum chlorohydrate and aluminum tetracholorohydrex glycine. Antiperspirants work when the aluminum-based compounds mix with sweat and form into a gel-like substance which acts to plug the sweat glands. Prescription antiperspirants contain similar active pharmaceutical ingredients but in higher quantities than the over-the-counter products.



SOURCE: Walmart.com

One potential drawback of antiperspirants is that aluminum can cause skin irritation – the risk of which is greater with prescription strength. But more significantly, antiperspirants, regardless of the aluminum content, are largely ineffective in controlling severe sweating. In fact, the regulatory threshold that manufacturers are required to meet for their products to be labeled as 'antiperspirants' may imply that relatively low effectiveness is an appropriate expectation. FDA requires that OTC antiperspirants demonstrate 20% reduction in sweat in 50% of patients tested, while the clinical (or extra) strength hurdle is just slightly higher at a 30% reduction in sweat. This clearly pales in comparison to miraDry, which in clinical trials demonstrated 80%+ sweat reduction and effectiveness in 90%+ of patients for as long as two years. And per Procter & Gamble, 30% of women apply their deodorant more than one time

per day, many of which keep it with them throughout the day[5] – which also points to the relative lack of effectiveness of topical treatments.

Botulinum toxin, better known by Allergan's (AGN) name-brand Botox, is a neurotoxin produced by the bacterium Clostridium botulinum. When injected, it causes temporary muscle paralysis by blocking the release of acetylcholine, the main neurotransmitter responsible for the activation of muscles. This can provide benefits for a variety of problematic muscle conditions such as strabismus (an eye disorder), chronic migraine headaches and involuntary facial spasms. Most commonly, botulinum toxin is used for facial cosmetic procedures wherein the toxin paralyzes muscles responsible for causing wrinkles.

Botox also has utility in the treatment of axillary hyperhidrosis. Botox received FDA clearance for the treatment of severe axillary hyperhidrosis "that is inadequately managed by topical agents" (i.e. antiperspirants) in 2004. As acetylcholine is also responsible for activating eccrine sweat glands, when injected in the area of axillary sweat glands, Botox is able to effectively reduce sweating by inhibiting the release of the chemical. Placebo-controlled clinical studies have shown Botox reduced severe axillary hyperhidrosis by 82% - 87% for a duration lasting between 4 and 14 months.

Botox



SOURCE: yourskin.dov.blogspot

While effective, botulinum toxin also has drawbacks including that due to its extremely high toxicity (it is believed that just one gram of the toxin could kill one million people), it carries a black-box warning related to potential life-threatening complications if the toxin spreads significantly from the injection site. But beyond that, since the beneficial effects of Botox dissipate rather quickly (typically within 4 to 12 months)[6,7], it is a temporary solution for hyperhidrosis. And at approximately $1k per treatment (i.e. every 4 – 12 months), it is also expensive.

While some insurers consider botulinum toxin for axillary hyperhidrosis as 'medically necessary', from our research we found that this typically only applies after failing at least six months of topical treatments and other non-invasive means, including oral medications, as well as documentation that the condition is causing significant functional impairment. Anecdotally (again based on our research), it may be likely that patients with policies that list Botox for axillary hyperhidrosis as a covered procedure, may have difficulty in meeting the (perhaps somewhat ambiguous) criteria required by insurers for reimbursement.

Given the invasive nature and related risks, **surgery** is typically considered the next-to-last resort after other less invasive options have failed to sufficiently control axillary hyperhidrosis. As such we do not consider surgery a direct competitor to miraDry. Techniques aimed at surgical removal of axillary sweat glands include suction-curettage, liposuction and excision.

Curettage



SOURCE: www.chir.it

- Curettage scrapes sweat glands from the underside of the skin. Under local anesthesia, one or more small incisions are made near the arm pit. A curette (small scraping instrument with a loop on the end) is inserted and, with a criss-cross motion, sweat glands in both the subcutaneous tissue and dermis are scraped off. Suction can also be used with curettage to remove the debrided tissue. Based on our research, curettage typically costs between $4k and $7k.

  While some insurers cover the procedure if other non-invasive methods have failed and there is documented significant compromise to quality of life associated with axillary hyperhidrosis, others do not. A study by Ibrahaim, et al.[8], which is cited by Anthem BC/BS (which does not cover suction-curettage) in their 2016 coverage policy of primary hyperhidrosis, found that suction-curettage was inferior to Botox in both reducing sweat production and improvement to quality of life. The difference was particularly pronounced in heavy sweaters.

[5] Elizabeth Holmes. Is Your Deodorant Working? The Wall Street Journal. July 26, 2016

[6] Grunfeld, A, Murray CA, Solish N. Botulinum Toxin for Hyperhidrosis: A Review. Am J Clin Dermatol 2009; 10(2): 87-102

[7] Heckmann M, Schaller M, Ceballos-Baumann A, et al. Follow-up of Patients With Axillary Hyperhidrosis After Botulinum Toxin Injection. Arch Dermatol. 1998;134(10):1298-1299

[8] Ibrahim O. et al. The comparative effectiveness of suction-curettage and onabotulinumtoxin-A injections for the treatment of primary focal axillary hyperhidrosis: a randomized control trial. J Am Acad Dermatol. 2013 Jul;69(1):88-95.

- Liposuction is similar to curettage but instead of a scraping tool, suction is used to remove sweat glands. In addition, while curettage generally removes glands from both the subcutaneous tissue and dermis, liposuction typically only removes sweat glands from the subcutaneous tissue. Bechar et al. found that suction curettage is more effective in reducing sweat as compared to liposuction.[9] Similar to suction-curettage, under certain circumstances liposuction may be covered by some insurers.

Excision: Heavy Scarring



SOURCE: www.chir.it

- Surgical excision is significantly more invasive than curettage and involves removing both the skin and the underlying sweat glands. While this is often effective in reducing (or completely eliminating) axillary sweat production, the International Hyperhidrosis Society recommends against the procedure. This is due to the risk of certain potential complications including heavy scarring and problems with range of motion associated with the significant removal skin and tension required to suture the edges of the wound.

Endoscopic thoracic sympathectomy (ETS) is a highly invasive surgery and often results in irreversible severe compensatory sweating and other complications associated with alteration of nerve function. As such, the procedure is highly controversial and is considered the last resort if all other options to treat axillary hyperhidrosis have failed. ETS, performed under general anesthesia, involves disruption of nerve signals responsible for activating axillary sweat glands.

ETS



SOURCE: hyperhidrosis.thailand

PrecisionTx, an energy-based modality which uses a 1440nm laser to ablate sweat glands is the most similar competitive technology to miraDry. PrecisionTx is manufactured and marketed by Cynosure Inc. (CYNO), a $1.2B (market capitalization) company that offers a variety of aesthetic-related devices that, in addition to Precision Tx for hyperhidrosis, include devices that are used for hair removal, cellulite reduction, nail fungus, tattoo removal and vascular treatment, among others.

PrecisionTX



SOURCE: cynosure.com

CYNO launched PrecisionTX in 2013. Their delivery device (SideLaze800) received FDA clearance (510(k) K141511) for the treatment of primary axillary hyperhidrosis in January 2015 (miraDry was cited as a predicate device). While Cynosure markets PrecisionTX for axillary hyperhidrosis as well as for the removal of fat in small areas around the neck and jaw, based upon a review of their website as well as a recent investor presentation (which does not even mention PrecisionTx or hyperhidrosis), it appears CYNO's main focus is on larger aesthetic-related markets such as fat reduction, women's health and skin rejuvenation. This is in contrast to Miramar, which is solely focused on miraDry and axillary hyperhidrosis.

Axillary hyperhidrosis treatment with PrecisionTx involves first numbing the area with anesthesia. A physician then makes a small incision near the armpit and inserts a small cannula which houses the SideLaze laser delivery fiber. The laser energy is then directed upward towards the skin and sweat glands.

Clinical data cited on the PrecisionTx product page on Cynosure's website includes one clinical study (n=17) and a single-patient case study. We also found in the public domain an abstract of a 15-patient, single-arm, 12-month study;

- Goldman and Wollina[10] included 17 patients with axillary hyperhidrosis who were treated with a 1,064nm (legacy) laser. Evaluation of effectiveness was done by Minor's iodine starch test - which allows the physician to judge the reduction in area of sweat (it does not, however, provide a quantitative measure of sweat reduction such as gravimetric weight test). The iodine starch test was done immediately prior to treatment and at least 8 weeks afterwards. Of the 17 patients, investigators determined that 10 (59%) showed 'excellent' results, 4 (24%) 'good' results, 3 (18%) 'fair' results and none had 'poor' results. Patients were also queried as to their assessment; 12 (71%) 'excellent', 3 (18%) 'good', 2 (12%) 'fair' and none 'poor'. One patient required a second

[9] Bechara FG, Sand M, Sand D, Altmeyer P, Hoffmann K. Surgical treatment of axillary hyperidrosis: a study comparing liposuction cannulas with a suction-curettage cannula. Ann Plast Surg. 2006;56:654–657

[10] Goldman A., Wollina, W. Subdermal Nd-YAG Laser for Axillary Hyperhidrosis. Dermatologic Surgery 34(6):756-62. July 2008

treatment at week five, all other patients remained asymptomatic through at least 12 months. Treatment was well-tolerated with no reported serious treatment-related complications.

- The Caplin case study[11] involved one female subject with axillary hyperhidrosis with a self-assessed HDSS score of 4. Treatment was performed with CYNO's 1440nm laser and SideLaze 800 delivery device (i.e. currently marketed product). Internal temperature during the procedure was measured at 37-38º C. The patient reported a 90% reduction in sweat at 3 months and reduction in HDSS score to 1. Iodine starch test showed 75% and 91% reduction in sweat in the right and left arm pits, respectively, at 3 months. At 6 months the patient affirmed reduction in sweating and iodine starch test showed a minor improvement in month three – to 78% (R) and 96% (L).
- Caplin and Austin[12] included 15 patients with axillary hyperhidrosis. Primary endpoint was reduction in HDSS score of 1 or 2 following treatment. Patients were treated with CYNO's 1440nm laser using SideLaze. Results at 12 month follow-up showed that all patients reported HDSS score reduction of 1 or 2, including 72% with a two point reduction and 28% with a one point reduction.

We think there are substantive differences between PrecisionTX and miraDry which favors the latter. These include;

- the more invasive nature of PrecisionTx requires the laser to be inserted under the skin as opposed to miraDry, which delivers treatment non-invasively. Not only does this introduce additional risk, it also means that success with PrecisionTx may be less consistent and technique-dependent due to the inability of the user to visualize exactly where the laser is treating
- PrecisionTx heats the target tissue to approximately 45º C, compared to miraDry which heats to more than 60º C. The difference is important as cell death is instantaneous at 60º C but takes longer at lower temperatures. In fact, it takes approximately 6 minutes to cause cell death when cellular temperature reaches 50º C[13] (and presumably longer at temperatures lower than that). In practice, higher heat and related more rapid cell death may translate into lower chance that sweat glands survive treatment with miraDry as compared to with PrecisionTx
- miraDry is supported with a more extensive clinical trial database including larger and more robustly-designed studies – this includes the pivotal 120-patient, sham-controlled study used as support for the FDA filing. By contrast, the clinical study database of PrecisionTx is relatively scant
- capital cost of Cynosure is console is approximately $135k, significantly more expensive than miraDry at ~$65k[14]
- miraDry is the only FDA-cleared device indicated for the permanent reduction of underarm hair of all colors as well as for the potential reduction of odor
- a perhaps more subjective difference favoring miraDry over PrecisionTx is that the former is recommended by the International Hyperhidrosis Society as an option to treat axillary hyperhidrosis while the latter is not

COMMERCIALIZATION / STRATEGY

miraDry treatment may only be performed by or under the supervision of a licensed physician (depending on individual state laws). The company's customer accounts include dermatologists, plastic surgeons and aesthetic-related clinics – most of which have expressed an interest in growing their aesthetic-related customer bases and related business.

Miramar markets miraDry with a direct sales force in North America (U.S. and Canada). The direct sales force currently consists of 8 territory managers and 10 practice development managers. Territory managers are largely responsible for making the initial sale while the practice managers maintain the account (i.e. training, marketing support, etc). Outside of North America, miraDry is sold via third-party distribution.

[11] Caplin D. Treatment of sweat glands associated with excessive sweating with unique targeted laser energy through SideLaze800TM delivery system

[12] Caplin D., Austin J. Clinical evaluation and quantitative analysis of axillary hyperhidrosis treated with a unique targeted laser energy delivery method with 1-year follow up. J Drugs Dermatol. 2014 Apr;13(4):449-56.

[13] Thomsen S. Pathologic analysis of photothermal and photomechanical effects of laser tissue interactions. Photochem Photobiol. 1991;53:825–35

[14] Per MRLB's August 2016 investor presentation

Miramar notes that the device has been sold in 40 international territories including in parts of Asia, Europe, the Middle East and South America.

Value Proposition: Highly Effective Treatment and Profitable…

The value proposition to prospective customers (i.e. clinicians) is straightforward and potentially very compelling. That is, miraDry is highly effective and a better option than other available therapies in treating axillary hyperhidrosis, a condition that is associated with significant compromises to quality of life. In addition, miraDry is a potential significant profit center for clinicians. In other words, miraDry is a win-win for both patients and physicians.

Relative to physician economics – it is critical that the economics 'work' for the clinician to drive demand for any medical device – this is particularly true for devices for which reimbursement is not available. While Miramar has not disclosed specifics in terms of miraDry console and consumable pricing, in their recent investor presentation they provide what we interpret as (at least generally close) estimates of what customers can expect to pay for the miraDry system (and consumable tips) and procedure pricing and operating cost. Based on these estimates (see calculation from investor deck below), physicians can expect to break even on their miraDry investment by (approximately) the 46th treatment.

miraDRY Break-Even Analysis		
	Per-treatment pricing	$1,950
less:	Consumable cost	$350
	Operating expense	$200
	Per-treatment profit	$1,400
	Capital cost	$65,000
	Treatments to break even	$65,000/$1,400 = **46**

We think a reasonable expected per-system utilization rate is approximately four to five per month. Based on consumable sales through the first nine months of 2016 and a current installed base of approximately 780 systems, utilization calculates to 5x per month, per system. So break-even on the capital cost of a miraDry system may reasonably be expected to be achieved in less than one year (i.e. 46 treatments / 5 treatments per month = ~9 months). Based on our experience covering razor/razor-blade business models, break-even on the capital investment in one year or less is atypically short. Using information from analyst reports and other publicly available data, MRLB also compared miraDry to Zeltiq's (ZLTQ) CoolSculpting (non-invasive fat reduction) and Cynosure's SculpSure relative to the number of treatments required to recoup the cost of the console. As the slide below indicates, miraDry's break-even is approximately one-half the number of the average of the other two systems. Relatively short break-even periods can be significantly alluring for physicians, particularly in the highly competitive and non-reimbursable cosmetic dermatology market.

Company	ZELTIQ®	CynoSure®	Miramar®
Product	CoolSculpting	SculpSure	miraDRY
Physician Revenue(1)	$1,400	$1,400	$1,950
Consumable Cost(2)	$275	$200	$350
Operating Expense	n/a	n/a	$200
Profit per Treatment	**$1,125**	**$1,200**	**$1,400**
Capital Cost(2)	$100,000	$135,000	$65,000
# Treatments to Breakeven	89	113	**46**

(1) Source: Piper Jaffray
(2) Source: ZELTIQ and CynoSure

SOURCE: MRLB 8/2016 Investor Presentation

New Marketing Program Focused On Aesthetics Expected to Broaden Target Market…

Miramar has been and expects to continue to lead their marketing program with compelling clinical trial data and positive patient feedback supporting the benefits of miraDry. While that part of their commercialization strategy will not change, they have recently implemented a shift related to their (direct sales) market-

positioning – specifically moving more towards aesthetic-related treatment providers (such as plastic surgeons, aesthetic clinics and cosmetic dermatologists) with less of a focus on medical therapy (such as medical dermatologists). This is expected to help broaden the overall target market for the system as well as focus resources on those practitioners and patients most likely to have interest in miraDry treatment. Miramar estimates that there are approximately 10k aesthetic-related practices in North America – a market which miraDry is less than 4% penetrated (based on the current ~370 miraDry system installations in North America).

While the clinically defined primary hyperhidrosis market in the U.S. is estimated at approximately 2.8% of the population (~7.8M), the broader market that may have interest in miraDry therapy could be significantly larger. A study sponsored by MRLB and performed by market research firm, Kalan and Associates, found that 63% of the 925 general consumers think about sweating at least sometimes and 27% believed their sweating was 'noticeable' or 'extremely noticeable'. Another Miramar-sponsored Kalan study found that among the general public, 45% of the 500 respondents indicated that they were 'very interested' or 'extremely interested' in a treatment that would eliminate their sweat or odor. Extrapolating this 45% to the total U.S. adult population implies a potential target market of almost 110M Americans. Miramar's updated marketing message to reach the broader population focuses on sweat reduction/elimination being a "lifestyle procedure" as opposed to clinical treatment, the latter which connotes formal diagnosis of a medical condition and which may be somewhat of an impediment to adoption among those interested in sweat reduction but not clinically diagnosed with hyperhidrosis.

Aesthetics Market: Rapidly Growing and Non-Reimbursable Offers Attractive Opportunity…
Approximately 90% of all cosmetic procedures performed each year are of the non-invasive category. According to the American Society of Plastic Surgeons, the number of cosmetic procedures performed in the U.S. has grown 115% since the year 2000. The global market, per research firm MarketsandMarkets, is expected to grow at an annual rate of almost 11% through 2020.

The rapidly growing demand for cosmetic procedures has been a boon for aesthetic-related clinics and plastic surgeons. This has been particularly true since these are largely patient-pay, non-reimbursable procedures which affords clinics the benefit of virtually no exposure to denied insurance claims or otherwise uncollectable or aged accounts receivables. This has helped facilitate growth in the number of medical dermatologists that also now offer aesthetic procedures as a supplemental source of revenue.

New Marketing Message, Focused Sales Force, Expanded Distribution Driving Revenue Growth…
Miramar's Practice Development Managers provide their physician practice customers with training and sales and marketing services. In addition, Miramar has been more aggressive in building overall awareness of miraDry. The company's recently revamped marketing message and aesthetic-related focused targeting has resulted in steepening revenue growth. Revenue grew 36% through the first nine months of 2016 to $16.0M from $11.8M in the 2015 comparable period.

Miramar has indicated that they expect to incrementally grow their North American direct sales force and further expand their 40-territory international presence with consummation of additional third-party distribution agreements.

And while the U.S. will likely remain the single most important market for miraDry, overseas, particularly in Asia, holds significant promise for outsized opportunity for growth. miraDry just launched (Q1 2016) in China through China Meheco, Miramar's distribution partner in that country which has already placed ~50 systems. We believe China, which ranks third (behind only the U.S. and Brazil)[15] in total number of plastic surgeons and has a cosmetic surgery market which analysts expect "will explode in the next few years"[16] as particularly attractive for Miramar. Japan ranks fourth in the number of plastic surgeons and is somewhat unique in that deodorant and perfume are not commonly used, despite the Japanese being culturally fervent in good hygiene. For these reasons, Japan is also expected to be a potent market for miraDry given its effectiveness in ablating both sweat and odor producing axillary glands. Miramar also expects to beef up its presence in Europe and the Middle East, where they currently have an installed base of approximately 150 systems and where the company will soon begin targeting additional countries.

[15] ISAPS Global Statistics: ISAPS International Survey on Aesthetic/Cosmetic Procedures Performed in 2015
[16] Laura He. China's cosmetic surgery market to explode in the next few years, analysts say. South China Morning Post. Feb 15, 2016

Label Expansion Could Further Broaden miraDry's Target Market…
We expect expanded sales, marketing and distribution, coupled with focused customer targeting and increased awareness to result in further growth in the installed base. Average utilization, which we estimate at approximate 4 – 5 treatments per system per month, also has the potential to benefit from continued growth in the overall aesthetics-related market as well as label expansion of the miraDry system.

Miramar expects to begin marketing for the recently obtained FDA clearance for odor reduction early next year. While it is too early to determine what effect this odor reduction indication will have, we think that it is not unreasonable that miraDry could be positioned as an alternative to deodorant and antiperspirant for the general population. The deodorant/antiperspirant market is relatively enormous at approximately $3B annually in the U.S. And with an estimated 90% of Americans using these products daily (many of which reapply throughout the day), we think it is conceivable that some consumers will be receptive to a long-lasting (or potentially permanent) alternative similar to what Lasik eye surgery has provided for contact lens users. Additional indications could be future endeavors, including potentially for palmoplantar hyperhidrosis.

OUTLOOK / VALUATION

Investment Considerations

- ✓ MRLB was created by The Foundry, a Silicon Valley-based medical device incubator with an impressive track record of finding compelling ideas and products and transforming them into successful companies
- ✓ Hyperhidrosis, which affects 220M people worldwide, is associated with the most profound negative effect on quality of life among all dermatological diseases
- ✓ miraDry is the only non-invasive device cleared by the FDA for permanent reduction of underarm sweat as well as the only device cleared by the FDA for permanent reduction of underarm hair of all colors and for the potential reduction of odor
- ✓ Additional label expansion, including for the treatment of palmar / plantar hyperhidrosis, would further expand the market for miraDry. Miramar has indicated that commencement of a palmar / plantar clinical program could be a future endeavor
- ✓ miraDry offers attractive economics for clinicians with payback on the console expected within 12 months and, afterwards, represents a potentially lucrative revenue and profit source
- ✓ miraDry's safety and effectiveness have been validated in clinical studies including a randomized, sham-controlled trial which served as support for initial FDA clearance
- ✓ Additional validation of the benefits of miraDry treatment is supported by; the International Hyperhidrosis Society recommending it as a safe and effective treatment, patient satisfaction of 90%+ and the fact that more than 80k total treatments have been performed to-date
- ✓ Other axillary hyperhidrosis treatments have drawbacks as compared to miraDry including;
  - Antiperspirants: usually considered a first-line therapy but often fail to effectively control sweating, aluminum content can cause skin irritation and oftentimes must be reapplied
  - Botox: while effective, it is a temporary solution with symptoms typically returning within one year. Cost, at approximately $1k per treatment, can also be prohibitive
  - Laser ablation: includes Cynosure's PrecisionTx system which is more invasive than miraDry treatment, may not be as effective as miraDry (there is scant clinical data of PrecisionTx for hyperhidrosis) and appears to be (based on publicly available pricing) more expensive than miraDry
  - Curettage: drawbacks include high cost, invasiveness and inconsistent effectiveness
  - Surgery: endoscopic thoracic sympathectomy is highly invasive and involves a surgeon interrupting the nerves responsible for activating the sweat glands in the underarm areas. Due to the relatively high risks, permanent nature and high cost of the procedure, ETS is often considered a last resort after all other options have failed
- ✓ MRLB's revamped marketing strategy focused on aesthetics and miraDry as a 'lifestyle procedure", along with expanded international distribution in high-potential territories such as China and Japan is already paying dividends with revenue +36% through the first nine months of 2016
- ✓ Razor/razor-blade business model means that revenue and margin expansion can be expected to accelerate with continued growth of the installed base

Financial Model
Revenue grew 36% through the first nine months of 2016 to $16.0M from $11.8M in the 2015 comparable period. Importantly, revenue growth is coming from both consoles (i.e. capital sale) as well as from consumables (i.e. utilization). The second quarter 2016 saw record sales of both consoles and consumables, the latter which generates 90%+ gross margin and is a proxy for utilization. miraDry console and consumables revenue grew 39% and 33%, respectively and accounted for 54% (consoles) and 43% (consumables) of total revenue through the first nine months of 2016.

Much of the growth is coming from North America (i.e. direct sales territories), which saw revenue increase 45% and accounted for 47% of total revenue through Q3 of this year. This domestic growth is being facilitated by greater market awareness of miraDry as well as, potentially, from MRLB's recently introduced 'optimized treatment protocol' which helps to shorten procedure times. Meanwhile, China is off to a strong start with ~50 systems already placed in that country since the miraDry launch in Q1 of this year.

Awareness-building campaigns surrounding the clinical and lifestyle benefits of miraDry, attractive physician economics and superiority compared to alternative therapies such as Botox and relatively invasive and technique-dependent treatments such as laser ablation, already appear to be resonating with customers as evidenced in the record console and consumables sales. With MRLB is still on the front-end of introducing a marketing strategy targeting the North American aesthetic-related market, a segment which is currently less than 4% penetrated, we think there is significant near-upside in the company's direct sales territories. And, the recent odor indication provides additional and potentially compelling marketing firepower and could dramatically expand miraDry's target markets.

Currently, just over 50% of system installations are in international territories. Miramar has noted that utilization has been particularly strong in Europe but we believe other areas of the globe may hold even greater promise for growth. We think the cultural and market dynamics in the company's Asian territories, particularly China and Japan, are ripe and ideally suited to experience growing demand for miraDry.

China ranks third in the total number of plastic surgeons in the world and is expected to see aesthetic-related procedure growth double by 2019 to $120B. With Miramar just entering China earlier this year, that country could be a particularly potent revenue driver. Japan, which ranks fourth in the number of plastic surgeons, is a country in which deodorant and antiperspirant use is not commonplace but where body odor is considered almost taboo. Miramar has indicated that uptake of miraDry in Japan has largely been driven by share gains against more invasive sweat gland ablation techniques. Greater awareness of miraDry's odor reduction efficacy could provide additional sales and utilization stimulus in that country.

Modeling Continued Double-Digit Revenue Growth, Margin Expansion…
We think incremental additions to the direct sales force, expanded distribution in current international territories and initial entry in others, coupled with the clinical benefits of miraDry, superiority to other axillary hyperhidrosis therapies, attractive physician economics and significant size of the aesthetic-related market will drive double-digit console and consumables revenue growth for at least the next five to seven years. We model miraDry's penetration of the U.S. aesthetic market at 10% (~1,100 system installed base vs. ~370 today) by the year 2022 – which could prove conservative as this assumes an average annual console placement rate of less than 150 units and does not include any contribution related specifically to the antiperspirant-replacement segment.

Gross margin improved from 51% in the first nine months of 2015 to 55% in the comparable period in 2016. Growth in utilization (i.e. consumable sales) on just an aggregate basis due to growth in the installed base will have a disproportionately positive effect on profitability due to the high margins (90%+) of the bioTips – but growth in the installed based coupled with growth in utilization per system should have an even more significant positive impact on revenue and profitability. As we detailed earlier, while we believe a reasonable utilization expectation is 5x/system per month, we more conservatively assume an average of approximately 4.5x in the near-to-mid term of our financial model given forecasted ramping console-placement rates. Longer-term, as growth in the installed base slows, we think average utilization per system will increase.

We have gross margin expanding from ~55% in the current year to ~63% in 2019. Gross margin should benefit from both higher utilization as well as greater console production volumes (i.e. economies of scale).

Relative to operating expenses, aside from some potential incremental sales force additions, expenses related to operating as a publicly traded company and higher sales commissions related to revenue growth, we do not foresee much in the way of growth in SG&A. R&D may tick up in the near-term as Miramar has

indicated the possibility of pursuing a palmoplantar indication and requisite clinical trials. Nonetheless, we expect revenue growth and even nominal margin expansion will more than offset any increase in OpEx and look for operating income to experience consistent improvement from 2016 and onwards. We think the company reaches operating break-even in 2020 or 2021.

Cash and liquidity…

Cash balance as of September 30, 2016 was $6.1M. Additional liquidity is provided by a $20M term loan. The balance begins equal monthly principal amortization in 2017 with final payment due in September 2019. The loan is divided into three tranches;

- $10M ('A' tranche): drawn in August 2015
- $5M: ('B' tranche): available if over the prior 6 months MRLB generated at least $10M of revenue
- $5M: ('C' tranche): available if over the prior 6 months MRLB generated at least $15M and raised at least $15M in equity

Cash used in operating activities was $8.3M ($7.5M ex-changes in working capital) through the first nine months of 2016, compared to $6.8M ($7.4M ex-changes in working capital) in the 2015 comparable period.

Valuation: DCF and P/S Values MRLB at $10/share

Our assumptions imply revenue will grow from $21M in 2016 to just under than $100M in 2026, the out-year in our 10-year DCF model (for comparison CYNO currently generates over $400M in annual revenue). Gross margin expansion and improvement in operating leverage should result in MRLB reaching a point of cash flow break even in 2020 or 2021. Using these inputs along with a 10% discount rate and 2.5% terminal growth rate (which is also arguably conservative given the potential for additional label and related market expansion), our 10-year DCF values MRLB at approximately $10/share.

We also use CYNO and ZLTQ as comps for valuation purposes which, combined, trade at an average of approximately 3.7x and 3.3x analysts' estimated 2016 and 2017 revenue – which also implies that fair value of MRLB is approximately $10/share.

We currently value Miramar Labs at $10/share. Our financial model is subject to updating which could influence our calculated value of MRLB.

FINANCIAL MODEL

Miramar Labs, Inc.

	Q1 A	Q2 A	Q3 A	Q4 A	2015 A	Q1 A	Q2 A	Q3 A	Q4E	2016 E	2017 E	2018	2019
Total Revenues	$2,960.4	$5,068.6	$3,793.2	$5,377.2	$17,199.5	$4,287.3	$7,444.7	$4,303.3	$5,297.6	$21,333.0	$26,054.9	$35,362.9	$43,303.4
YOY Growth	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*# DIV/0!*	*7.1%*	*44.8%*	*46.9%*	*13.4%*	*-1.5%*	*24.0%*	*22.1%*	*35.7%*	*22.5%*
Cost of Goods Sold	$1,345.1	$2,657.9	$1,742.4	$2,511.8	$8,257.0	$2,028.6	$3,394.8	$1,787.8	$2,403.6	$9,614.7	$10,809.2	$14,325.8	$15,922.0
Gross Income	$1,615.4	$2,410.8	$2,050.9	$2,865.4	$8,942.5	$2,258.8	$4,049.9	$2,515.5	$2,894.0	$11,718.3	$15,245.7	$21,037.1	$27,381.4
Gross Margin	*54.6%*	*47.6%*	*54.1%*	*53.3%*	*52.0%*	*52.7%*	*54.4%*	*58.5%*	*54.6%*	*54.9%*	*58.5%*	*59.5%*	*63.2%*
R&D	$1,468.4	$1,281.0	$1,192.0	$1,032.8	$4,974.1	$921.6	$823.4	$817.5	$905.0	$3,467.5	$3,673.7	$4,526.5	$4,979.9
%R&D	*97.7%*	*62.3%*	*71.4%*	*49.9%*	*28.9%*	*21.5%*	*11.1%*	*19.0%*	*17.1%*	*16.3%*	*14.1%*	*12.8%*	*11.5%*
S&M	$3,126.8	$3,117.5	$2,736.6	$2,776.8	$11,757.7	$3,023.0	$3,503.3	$3,449.0	$3,622.0	$13,597.2	$15,190.0	$17,221.7	$19,962.9
%S&M	*105.6%*	*61.5%*	*72.1%*	*51.6%*	*68.4%*	*70.5%*	*47.1%*	*80.1%*	*68.4%*	*63.7%*	*58.3%*	*48.7%*	*46.1%*
G&A	$1,327.3	$1,267.0	$1,313.4	$1,561.1	$5,468.9	$1,338.0	$1,507.3	$1,871.7	$1,715.0	$6,432.0	$7,295.4	$8,062.7	$8,444.2
% G&A	*44.8%*	*25.0%*	*34.6%*	*29.0%*	*31.8%*	*31.2%*	*20.2%*	*43.5%*	*32.4%*	*30.2%*	*28.0%*	*22.8%*	*19.5%*
Operating Income	($4,307.2)	($3,254.7)	($3,191.2)	($2,505.2)	($13,258.3)	($3,023.8)	($1,784.0)	($3,622.7)	($3,348.0)	($11,778.5)	($10,913.4)	($8,773.9)	($6,005.5)
Operating Margin	*-145.5%*	*-64.2%*	*-84.1%*	*-46.6%*	*-77.1%*	*-70.5%*	*-24.0%*	*-84.2%*	*-63.2%*	*-55.2%*	*-41.9%*	*-24.8%*	*-13.9%*
Total Other Income (Expense)	($214.0)	($249.2)	($468.7)	($295.3)	($1,227.2)	($289.3)	($7,984.0)	($291.5)	($306.0)	($8,870.8)	($1,302.1)	($886.3)	($153.4)
Pre-Tax Income	($4,521.2)	($3,503.9)	($3,659.9)	($2,800.5)	($14,485.5)	($3,313.1)	($9,768.0)	($3,914.2)	($3,654.0)	($20,649.2)	($12,215.5)	($9,660.2)	($6,158.9)
Tax expense (benefit)	$1.4	$0.0	$7.3	$0.0	$8.7	$1.5	$0.0	$7.8	$0.0	$9.3	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Income	($4,535.6)	($3,534.0)	($3,687.2)	($2,740.5)	($14,497.4)	($3,314.6)	($9,768.0)	($3,922.0)	($3,654.0)	($20,658.5)	($12,215.5)	($9,660.2)	($6,158.9)
YOY Growth	*# DIV/0!*	*# REF!*	*# DIV/0!*	*# DIV/0!*	*-7.5%*	*# DIV/0!*	*-37.7%*	*-13.5%*	*3.4%*	*42.5%*	*-40.9%*	*-20.9%*	*-36.2%*
Net Margin	*-153.2%*	*-69.7%*	*-97.2%*	*-51.0%*	*-84.3%*	*-77.3%*	*-131.2%*	*-91.1%*	*-69.0%*	*-96.8%*	*-46.9%*	*-27.3%*	*-14.2%*
EPS (continuing ops)	($11.77)	($9.17)	($9.57)	($6.92)	($37.33)	($8.32)	($4.10)	($0.42)	($0.39)	($3.87)	($1.19)	($0.74)	($0.42)
YOY Growth	*# DIV/0!*	*-*	*# DIV/0!*	*# DIV/0!*	*-9.6%*	*# DIV/0!*	*-90.1%*	*-96.4%*	*-95.7%*	*-89.6%*	*-69.4%*	*-37.3%*	*-42.8%*
Diluted Shares O/S	385	385	385	396	388	399	2,380	9,256	9,300	5,334	10,300	13,000	14,500

Brian Marckx, CFA

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

APPENDIX

Hyperhidrosis Disease Severity Scale

HDSS is an industry-standard tool that provides a measure of the severity of a particular individual's condition.

HDSS Score	*Definition*
1	My underarm sweating is never noticeable and never interferes with my daily activities
2	My underarm sweating is tolerable but sometimes interferes with my daily activities
3	My underarm sweating is barely tolerable and frequently interferes with my daily activities
4	My underarm sweating is intolerable and always interferes with my daily activities

SOURCE: Hong H. et al. Clinical Evaluation of a Microwave Device for Treating Axillary Hyperhidrosis

Dermatology Life Quality Index

Dermatology Life Quality Index (DLQI) is a validated and widely used questionnaire to assess the effects of dermatological diseases on quality of life. DLQI is a 10-item questionnaire covering six domains. Maximum score is 30 and the higher the score, the greater that quality of life is negatively affected. DLQI has been used extensively for over 40 different types of skin conditions and diseases.

DERMATOLOGY LIFE QUALITY INDEX

Hospital No: Date: **DLQI**
Name: Score: ☐
Address: Diagnosis:

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick ■ one box for each question.

1.	Over the last week, how **itchy, sore, painful** or **stinging** has your skin been?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	
2.	Over the last week, how **embarrassed** or **self conscious** have you been because of your skin?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	
3.	Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	 Not relevant ☐
4.	Over the last week, how much has your skin influenced the **clothes** you wear?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	 Not relevant ☐
5.	Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	 Not relevant ☐
6.	Over the last week, how much has your skin made it difficult for you to do any **sport**?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	 Not relevant ☐
7.	Over the last week, has your skin prevented you from **working** or **studying**?	Yes No	☐ ☐	 Not relevant ☐
	If "No", over the last week how much has your skin been a problem at **work** or **studying**?	A lot A little Not at all	☐ ☐ ☐	
8.	Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	 Not relevant ☐
9.	Over the last week, how much has your skin caused any **sexual difficulties**?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	 Not relevant ☐
10.	Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	☐ ☐ ☐ ☐	 Not relevant ☐

Please check you have answered EVERY question. Thank you.

SOURCE: AY Finlay, GK Khan, April 1992 www.dermatology.org.uk

© Copyright 2016, Zacks Investment Research. All Rights Reserved.

LEADERSHIP

Management

R. Michael Kleine
President & Chief Executive Officer
Mike Kleine has been with Miramar Labs since January 2014. Mr. Kleine is an established leader with a proven track record of success in leading several global biomedical companies. With nearly two decades of experience in C-suite positions he has experience commercializing new technologies, increasing revenues, and growing organizations. Previous positions held include President and CEO roles with EndoGastric Solutions, Biosensors International Group, LTD, a publicly traded company, and MicroVention, a start-up which was acquired by Terumo.

Brigid A. Makes
Sr. Vice President and Chief Financial Officer
Brigid Makes has been with Miramar Labs since September 2011. Ms. Makes is a successful financial executive with over 30 years of experience in leading and building strong organizations, and delivering results. Her experience with IPOs and M&A in high growth and technology focused businesses, including large and small companies, was evident in her successful transition of AGA Medical through its IPO process and acquisition by St Jude Medical. Ms. Makes has also served in executive roles in finance, operations and R&D at Nektar Therapeutics, and in senior financial roles in Haemonetics, Lotus Development and GE.

Steven W. Kim
Chief Technology Officer
Steve Kim is an entrepreneur who co-founded Miramar Labs in 2007. Mr. Kim is passionate about medical technology innovation with over 100 issued patents and 23 years of experience in start-up medical device ventures. He has held various executive management positions in R&D, operations, and general management. Mr. Kim has experience working in various medical specialties including dermatology, oncology, cardiology, interventional radiology, and surgery. The product categories that he has developed include thermal ablation devices, capital equipment, disposables, implants, catheters, and surgical tools. Other start-up ventures include AneuRx (acquired by Medtronic), TransVascular (acquired by Medtronic), and Vivant Medical (acquired by Tyco Healthcare).

Robert Ellis
Vice President, Marketing
Rob Ellis has been with Miramar Labs since July 2014. Mr. Ellis brings over 20 years of experience in healthcare sales and marketing, with a focus in the last 12 years of building and leading global marketing teams with aesthetic device companies including Solta, Sciton, and Lumenis. His leadership has driven many successful global product launches in dermatology and plastic surgery. Mr. Ellis' programs have captured the attention of physicians and patients through national exposure on The Today Show, Entertainment Tonight, The Doctors, People and Glamour magazine and he has been recognized with the Silver SABRE award for Public Relations. Mr. Ellis holds a BS in Biochemistry/Biophysics and an MBA.

Daniel Francis
Vice President, R&D
Dan Francis has been with Miramar Labs since November 2007. Mr. Francis is a Research and Development specialist with over 15 years of industry experience, including 12 years developing therapeutic energy delivery devices. With a history of new product innovation at LuMend and Cierra Inc. and expertise in design, materials and manufacturing processes, Mr. Francis contributes a strong technical background to the Miramar team.

Steven M. Higa
Vice President, Manufacturing
Steve Higa has been with Miramar Labs since April 2012. Mr. Higa is a proven leader with over seventeen years of experience leading operations, manufacturing, and product development teams in the medical device industry. With a reputation of fostering a culture of continuous improvement, Mr. Higa has successfully managed operations growth to support company revenue and sales goals. Prior companies include ZOLL Medical, Amira Medical (acquired by Roche), and Johnson & Johnson.

Robert Tyson
Senior Director Sales – US & Canada
Robert Tyson has been with Miramar Labs since September 2014. Mr. Tyson is a proven sales leader with over 20 years of medical device experience including a strong early foundation of more than ten years with Ethicon-Endo Surgery and Edwards Heart Valve Therapy. Since 2003 Mr. Tyson participated in launching several breakthrough aesthetic technologies while holding various sales leadership positions of increasing responsibility with Zeltiq, Ulthera, Reliant Technologies and Thermage. He joined Miramar in the fall of 2014 and helped orchestrate the formation of the Practice Development Team to improve practice support and integrate the new Optimized Treatment Protocol for miraDry customers.

James Lam
Managing Director, Asia Pacific
James Lam has been with Miramar Labs since September 2012. Mr. Lam is a successful leader in the medical device industry with over 33 years of sales, marketing and general management experience in Asia Pacific, extensively in China. Mr. Lam possesses a proven track record managing sales and marketing operations that exceed $120 million and a reputation for driving sales excellence. Prior companies include Siemens AG, Stryker, Sherwood DG, Boston Scientific, AGA Medical and St. Jude Medical.

Board of Directors

Mark E. Deem
Mark E. Deem is one of the founders of Miramar and has served as the Chairman of the board of directors since December 2008 and as a member of the board of directors since August 2007. Mr. Deem serves as a Managing Partner of The Foundry, LLC, a medical device company incubator. Since 2013, Mr. Deem has served as Venture Partner at Lightstone Ventures, a venture capital firm specializing in investing in life sciences companies. Mr. Deem is also a founder of ForSight Labs, an ophthalmic device incubator which has started six companies. From August 2007 to November 2008, Mr. Deem served as Miramar's Interim Chief Executive Officer. Mr. Deem currently serves on the board of directors of Holaira Inc., FIRE1, Ltd., Cala Health, Inc. and as a Board Observer for Aerin Medical, Inc. and Cotera, Inc. Mr. Deem holds a B.S. degree in Biomedical Engineering from Boston University.

Hanson S. Gifford
Hanson S. Gifford III has served as a member of Miramar's board of directors since April 2006. Mr. Gifford also serves as the Managing Partner of The Foundry, Inc., a medical device company incubator, which he co-founded in 1998. Since November 2013, Mr. Gifford has served as a Venture Partner at Lightstone Ventures, a venture capital firm specializing in investing in life sciences companies. Mr. Gifford is also a founder of ForSight Labs, an ophthalmic device incubator which has started six companies. Mr. Gifford also serves on the boards of Cotera, FIRE1, Forsight Vision 4, Forsight Vision 5, and Ocular Dynamics. Mr. Gifford is an inventor of over 250 issued U.S. patents. Mr. Gifford holds a B.S. degree in Mechanical Engineering from Cornell University.

Henry A. Plain
Henry A. Plain, Jr. has served as a member of Miramar's board of directors since April 2006. Mr. Plain has also served as a General Partner of Lightstone Ventures since 2013 and Morgenthaler Ventures since 2007, both of which are venture capital firms. From 1993 to 2000, Mr. Plain served as the President and Chief Executive Officer at Perclose, Inc., a medical device company. Prior to joining Morgenthaler, Mr. Plain founded several medical device companies. Mr. Plain serves on the board of directors of Claret Medical, Inc., Earlens Corporation, and Setpoint Medical Corporation. Mr. Plain holds a B.S. degree in Finance from the University of Missouri, Columbia.

Stacey D. Seltzer
Stacey D. Seltzer has served as a member of Miramar's board of directors since November 2012. Ms. Seltzer is a Partner of Aisling Capital LLC, a healthcare investment firm. Previously, Ms. Seltzer served as an Associate Director at Schering-Plough, a pharmaceutical company. Prior to her position at Schering-Plough, Ms. Seltzer served as Director of Business Development at Akceli, a biomedical company focusing on the development of new drugs and as a Management Consultant at McKinsey & Company, a consulting firm. Ms. Seltzer serves on the board of directors of Aimmune Therapeutics. Ms. Seltzer holds B.S. and M.S. degrees from Yale University in Molecular Biophysics and Biochemistry and a M.B.A. from The Wharton School at the University of Pennsylvania.

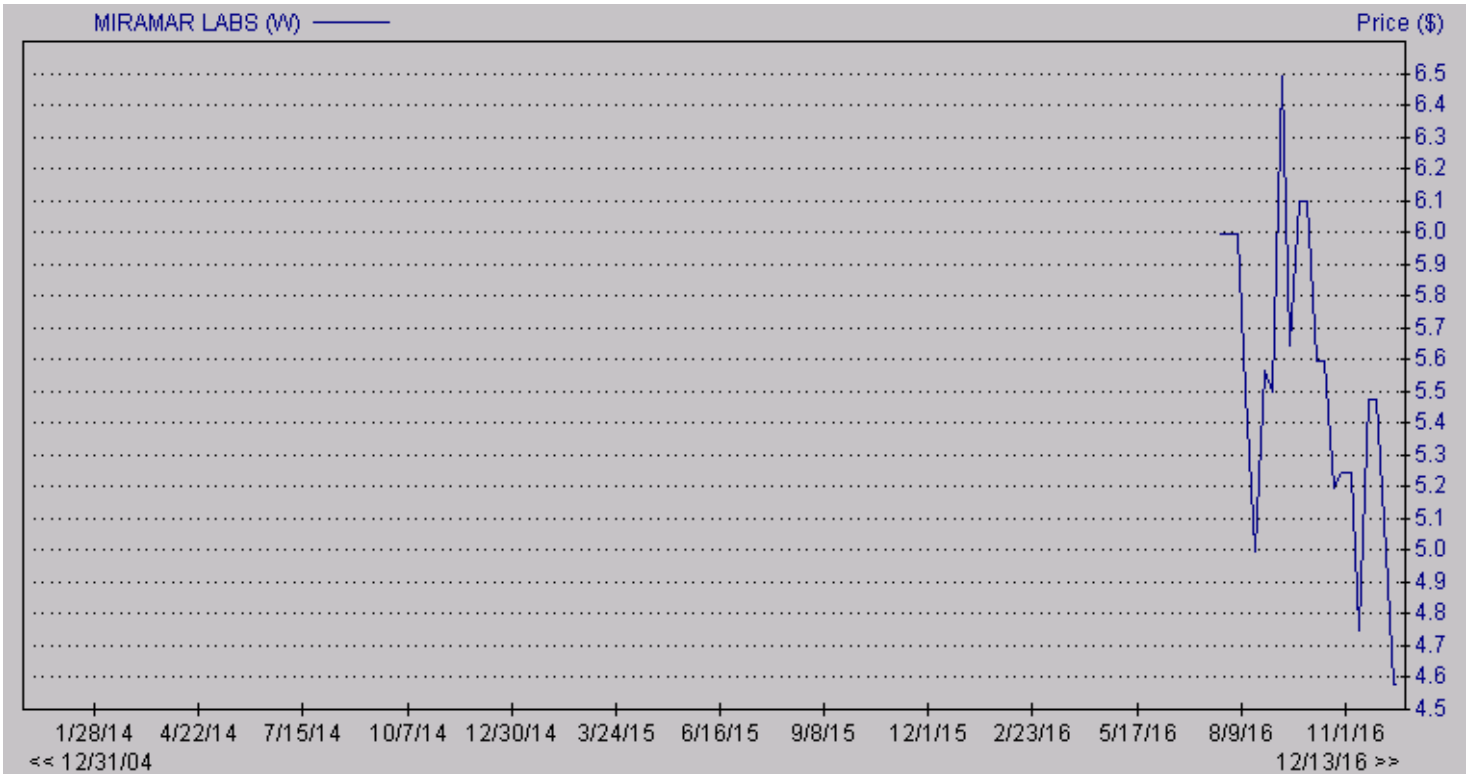
Brian H. Dovey
Brian H. Dovey has served on Miramar's board of directors since May 16, 2016. Mr. Dovey has been a Partner of Domain Associates, L.L.C., a private venture capital management firm focused on life sciences, since 1988. Prior to joining Domain Associates, L.L.C., Mr. Dovey spent six years at Rorer Group, Inc. (now part of Sanofi-Aventis), a pharmaceutical company, including as President from 1986 to 1988. Mr. Dovey serves on the board of directors of Orexigen Therapeutics, Inc. and REVA Medical, Inc. Mr. Dovey was former chairman and currently serves on the board of directors of both the Center for Venture Education (Kauffman Fellows Program) and the Wistar Institute, a leader in preclinical bio-medical research in the non-profit sector. He is also a member of the Board of Trustees of the La Jolla Playhouse. Mr. Dovey holds a B.A degree from Colgate University and an M.B.A from the Harvard Business School.

Maxim Gorbachev
Maxim Gorbachev has served as a member of Miramar's board of directors since December 2013. Since March 2013, Mr. Gorbachev has served as the Managing Partner at RMI Partners, LLC, the management company of RusnanoMedInvest LLC, or RMI LLC, a Russian-based life sciences venture capital firm, founded by RUSNANO State Corporation, which invests in funds and companies supporting innovation in nanotechnologies. Prior to joining RMI Partners, from March 2012 to September 2012, Mr. Gorbachev served as Associate Director, Business Planning at JSC Sukhoi Civil Aircraft, an aircraft manufacturer. From July 2009 to February 2012, Mr. Gorbachev served as Director of Finance and Administration at UCB Pharma LLC., a pharmaceutical company. Mr. Gorbachev currently serves on the board of directors of Atlas Genetics, Neothetics and Celtaxsys. Mr. Gorbachev holds a M.S. degree in Applied Mathematics from Lomonosov Moscow State University, a M.S. degree in Financial Management from the Finance University and an M.B.A. from Vlerick Business School.

Patrick F. Williams
Patrick F. Williams, served as Chief Financial Officer and Senior Vice President from November 2012 to April 2016 and currently serves as a consultant for ZELTIQ (NSDQ: ZLTQ), a medical device company focused on developing and commercializing products utilizing its proprietary controlled-cooling technology platform for the aesthetic market. From June 2007 to November 2012 he worked at NuVasive (NSDQ: NUVA), a medical device company focused on developing minimally disruptive surgical products and procedurally integrated solutions for the spine, most recently as Vice President of Strategy and Investor relations and previously as Vice President of Finance and Investor Relations. Mr. Williams has nearly 20 years of financial management experience in developing long-term growth and operational strategies to support top-line growth and operating margins. He has had responsibility for managing all aspects of investor relations efforts as well as leading information technology groups. Prior to NuVasive, Mr. Williams served as Director of Financial Planning and Analysis at Callaway Golf (NYSE: ELY), where he managed the day-to-day operations of the finance department including budgeting and forecasting, companywide operational analysis and financial reporting. Prior to Callaway, he held senior finance positions at Kyocera Wireless. Mr. Williams holds an MBA in Finance and Management from San Diego State University and a Bachelor of Arts in Economics from University of California, San Diego.

R. Michael Kleine (bio above)

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brian Marckx, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover.

SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.