Zacks Small-Cap Research

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Miramar Labs (MRLB-OTC)

MRLB: Strong Growth in North America, Europe. Cash Raise Needs To Be Imminent

Our 10-year DCF, which uses a 10% discount rate and 2.5% terminal growth rate values MRLB at approximately $4/share.
CYNO and ZLTQ acquisition prices also confirms approximate $4/share valuation.

Current Price (05/26/17)	$1.60
Valuation	**$4.00**

OUTLOOK

Miramar reported financial results for the first quarter ending March 31st. While revenue slid on both a yoy and sequential basis, there were some positives in the top-line details. Most notably was relative strength in North America and Europe, both of which posted double-digit percentage increases in revenue compared to the prior year. Meanwhile, Asia, which was fingered as a laggard in Q4 of last year, turned in another disappointing showing with Q1 sales falling more than 50% yoy. Encouraging, however, is management indicating that the slide in sales from Asia is largely due to timing of orders in China and Japan (as well as to changes in distributors in some countries) – perhaps signaling expectations of a near-term rebound in revenue from those countries. The other bit of encouraging detail in the numbers was that while console sales were relatively very weak, consumables revenue was relatively strong. As consumables contribute the majority of margin, act as a proxy for utilization and demand, and represent the bulk of the long-term opportunity for growth (or revenue, margin, cash flow and profitability), the 10% yoy (+$204k) and 18% sequential (+$335k) growth in this line item was a meaningful highlight in Q1. Cash balance at quarter-end was just $1.1M – as such a capital raise needs to be imminent.

SUMMARY DATA

52-Week High	**$6.50**
52-Week Low	**$0.90**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**6,977**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$15**
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 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
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)
2016	4,287 A	7,445 A	4,303 A	4,411 A	20447 A
2017	3,815 A	3,897 E	4,469 E	4,872 E	17052 E
2018					24996 E
2019					33954 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$8.32 A	-$4.10 A	-$0.42 A	-$0.37 A	-$3.82 A
2017	-$0.78 A	-$0.50 E	-$0.12 E	-$0.10 E	-$0.89 E
2018					-$0.26 E
2019					-$0.16 E

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

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WHAT'S NEW…

Q1 Financials: *North America, Europe Remain Robust. Asia Could Come Back in Near-Term..*

Miramar reported financial results for the first quarter ending March 31st. While revenue slid on both a yoy and sequential basis, there were some positives in the top-line details. Most notably was relative strength in North America and Europe, both of which posted double-digit percentage increases in revenue compared to the prior year. Meanwhile, Asia, which was fingered as a laggard in Q4 of last year, turned in another disappointing showing with Q1 sales falling more than 50% yoy. Encouraging, however, is management indicating that the slide in sales from Asia is largely due to timing of orders in China and Japan (as well as to changes in distributors in some countries) – perhaps signaling expectations of a near-term rebound in revenue from those countries.

The other bit of encouraging detail in the numbers was that while console sales were relatively very weak, consumables revenue was relatively strong. As consumables contribute the majority of margin, act as a proxy for utilization and demand, and represent the bulk of the long-term opportunity for growth (for revenue, margin, cash flow and profitability), the 10% yoy (+$204k) and 18% sequential (+$335k) growth in this line item was a meaningful highlight in Q1.

Consumable sales accounted for 58% of total revenue in Q1 – which looks to be (by far) the greatest proportional contribution ever (or at least as far back as MRLB's publicly available financials). And despite consoles placements underperforming in Q1, the installed base continues to grow and now sits at approximately 900 units – up from ~873 at the end of 2016. Even modest growth in the size of the installed base can be meaningful in accelerating revenue as a result of the multiplier-effect of the razor-razor blade business model.

Total revenue was $3.8M, down 11% yoy (-$472k) and 14% sequentially (-$596k), and consisted of $1.5M in console sales and $2.2M in consumable sales. The aforementioned strength in consumable sales was more than offset by a 30% yoy (-$623k) and 38% sequential (-$907k) decrease in console revenue. As compared to Q1 2016, MRLB noted that while console revenue increased ~$100k in North America, it fell ~$800k in Asia (which also implies Europe/Middle East console sales were up slightly).

Asia revenue was just $825k in Q1, down 54% from $1.8M in the comparable prior year period. As all of the revenue decline was attributable to Asia (at least as related to console sales), had it not been for the adverse timing-related issue, Q1 total revenue may have looked much better. In fact, had Asia just turned in flat growth, Q1 total revenue would have been almost $4.9M, or up 14% yoy. As a reminder, Asia generated $6.2M of revenue in 2016, up 6% from the prior year. Given the continued strength in Europe and North America, if Asia (which now accounts for ~25% of total revenue) returns to even modest growth, this should have an outsized positive impact on the top-line.

Meanwhile North America and Europe both remain quite robust. North America revenue increased 18% yoy – with both console and consumable sales strong in Q1. This follows 38% revenue growth in North America in 2016. With North America now accounting for slightly more than 50% of total revenue, growth in this territory is a clear positive. We think sales in North America, where MRLB details with a direct sales force, are benefitting from greater awareness from the implementation of the company's newly implemented marketing and social media efforts. Additionally, the recent label expansion ('reduction of hair' in June '15 and 'reduction of odor' in Oct '16) as well as the attractive economics for physicians may also benefitting uptake in the U.S.

European sales, which account for almost 25% of total revenue, were up 26% yoy – MRLB notes most of the growth is from consumables. As noted, growth in consumables sales is particularly encouraging and should aid in driving gross margin higher.

Relative to the rest of the income statement…

Gross margin continues to march upwards, widening to 55.6% in Q1 from 52.7% in the comparable prior year period and 55.3% average throughout 2016. Gross margin is benefitting from a higher proportion of total sales coming from consumables as well as from economies of scale from higher production volumes. We continue to model incremental widening of gross margin as higher margin consumables grow to account for a larger percentage of total revenue.

Q1 operating expenses were $5.3M, roughly flat and down 6% from Q1 and Q4, respectively, in 2016. Control in OpEx helped to offset much of the relatively weakness on the top-line. So while revenue fell 11% yoy and 14% sequentially, operating loss increased by only 5% and less than 1% compared to those same periods.

Cash used in operating activities in Q1 was $2.8M ($3.1M ex-changes in working capital). Cash balance at quarter-end was just $1.1M – as such a capital raise needs to be imminent. While we had hoped the balance sheet would have been shored up before now, MRLB has shown the ability in the past to raise capital when necessary – including $2.7M (net) via the sale of convertible notes in January.

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 **20 U.S. and 57 international patents**. Another 10 U.S. and 35 international patent applications are currently outstanding.

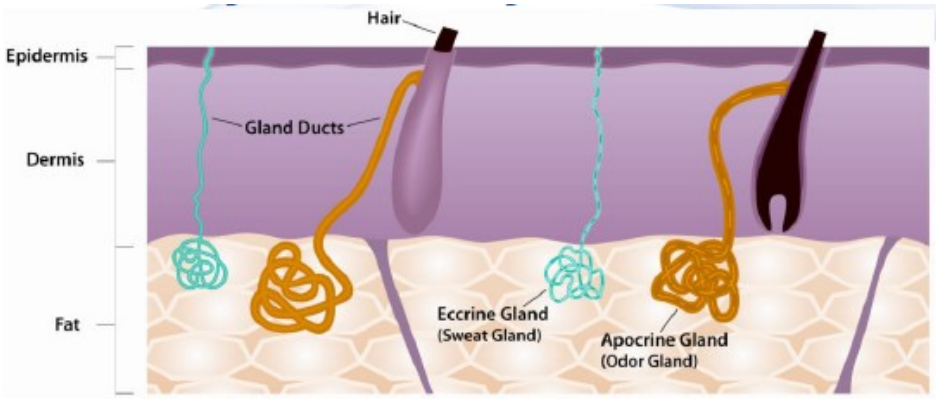
Sweat Glands

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

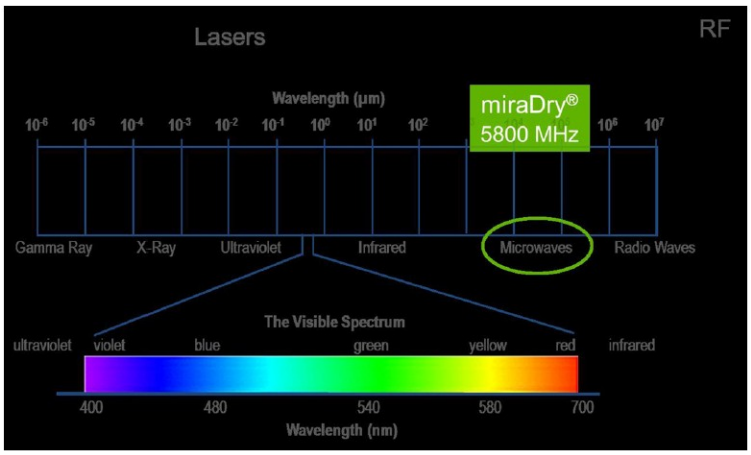


SOURCE: Miramar Labs

Microwaves ideally suited for sweat gland ablation…

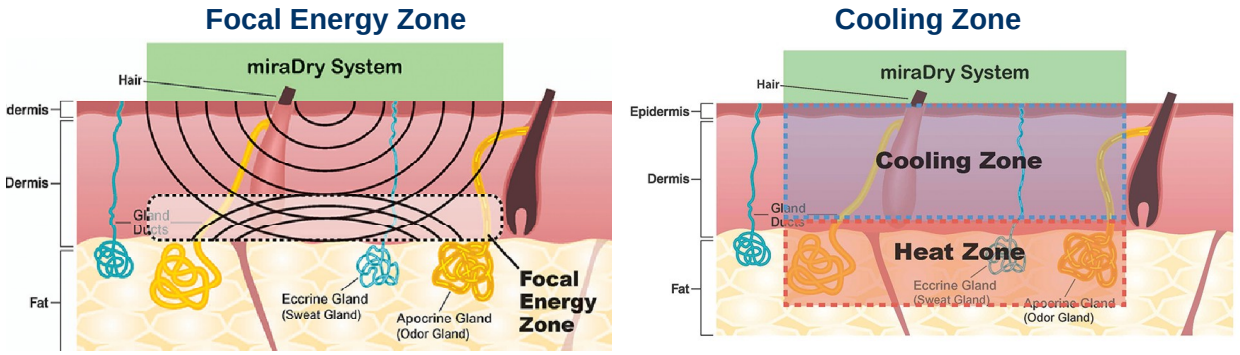
Microwave radiation causes dielectric heating which occurs when a high frequency electric field causes rapid rotation of dipole molecules. Friction from the molecules' rotation results in heat. Water has a high electric dipole moment, or high polarity, meaning that it is easily absorbed by microwaves 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.

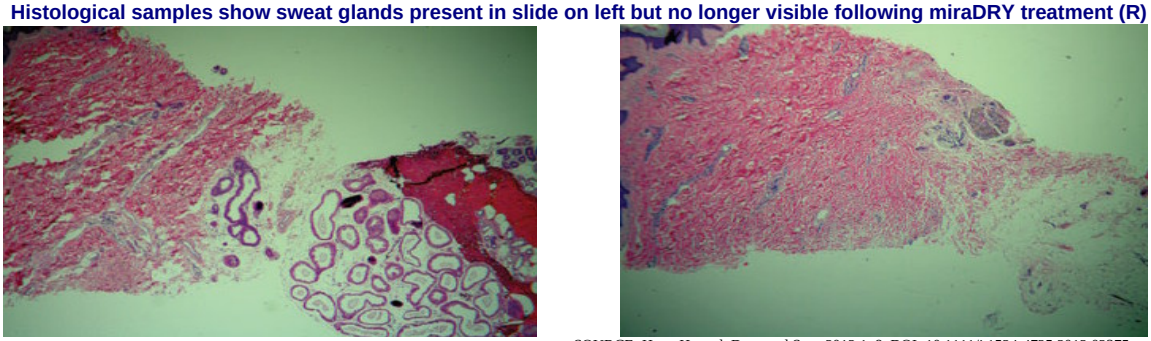


SOURCE: Miramar Labs

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.[1]

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

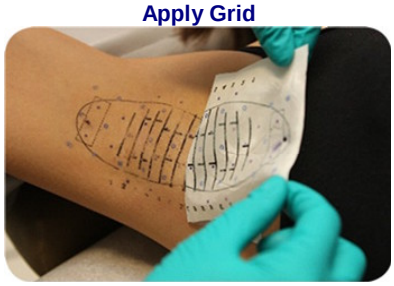
miraDry Procedure…

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

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

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.

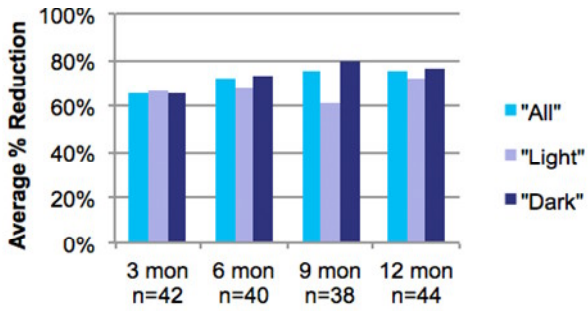
miraDry Also Effective in Reducing Axillary Hair of All Colors…

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



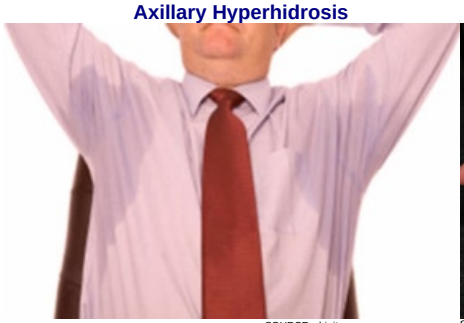
SOURCE: Miramar Labs

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[2] 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[3] (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
  - 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

[2] 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

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

- **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[4] – 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)[5,6], 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.[7], 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.

- 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,

[4] Elizabeth Holmes. Is Your Deodorant Working? The Wall Street Journal. July 26, 2016
[5] Grunfeld, A, Murray CA, Solish N. Botulinum Toxin for Hyperhidrosis: A Review. Am J Clin Dermatol 2009; 10(2): 87-102
[6] 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
[7] 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 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.[8] Similar to suction-curettage, under certain circumstances liposuction may be covered by some insurers.

- 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.

Excision: Heavy Scarring



SOURCE: www.chir.it

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.

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.

PrecisionTX



SOURCE: cynosure.com

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[9] 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 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.

[8] 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

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

- The Caplin case study[10] 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[11] 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[12] (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[13]
- 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). 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. Miramar notes that the device has been sold in over 40 international territories including in parts of Asia, Europe, the Middle East and South America.

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

[11] 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.

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

[13] Per MRLB's August 2016 investor presentation

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. 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 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 only about 4% penetrated (based on the current number of 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.

Aesthetics-Related M&A Activity Also Suggests Growing Demand…
We also note that there has recently been considerable M&A activity in the domestic aesthetics market which we think also speaks to the attractiveness and growth in interest of the space. In the same month of February 2017 Allergan (AGN) announced the acquisition of ZELTIQ Aesthetics (ZLTQ) and Hologic (HOLX) the acquisition of Cynosure (CYNO). Both ZELTIQ and Cynosure are medical device companies focused entirely on aesthetics including 'body contouring' (non-invasive fat reduction). While Allergan has had significant presence in aesthetics (Botox accounts for ~20% of total sales), Hologic has not as their focus is largely related to women's health: diagnosis, imaging and treatment. So while we are not suggesting MRLB is necessarily a take-out candidate (although we are also not discounting that possibility), we do think these M&A deals of pure-play aesthetics companies do speak to the potential significant upside growth of the aesthetics segment in the U.S. and, by extension, continued significant growth in Miramar's domestic 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 19% in 2016, including 38% growth in North America. North America revenue was up another 18% (yoy) in Q1 2017.

Miramar has indicated that they expect to incrementally grow their North American direct sales force (although this will likely need to wait until after they raise additional funds) 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. Sales in Asia, which account for approximately 30% of total revenue (compared to 34% in 2015) increased by 6% in 2016 but were softer than we had expected in the last two quarters (i.e. Q4 2016 and Q1 2017) – some of which we think relates to a recent distribution transition. We believe China, which ranks third (behind only the U.S. and Brazil)[14] in

[14] ISAPS Global Statistics: ISAPS International Survey on Aesthetic/Cosmetic Procedures Performed in 2015

total number of plastic surgeons and has a cosmetic surgery market which analysts expect "will explode in the next few years"[15] 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 150+ systems and where the company will soon begin targeting additional countries. Europe has recently shown greater promise with revenue growing 26% in Q1 2017 – much of which was attributed to strong consumable sales.

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.

While it is too early to determine what effect the recent 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.

VALUATION

DCF and P/S Values MRLB at $4/share
We have made some updates to our model. Cash balance has dwindled to a point where a capital raise needs to be imminent. With just $1.1M on the balance sheet as of the close of Q1 and average cash burn of ~$3M/quarter, the cash constraints may have slowed, or at least delayed, certain sales and marketing initiatives which we think may adversely impact revenue, at least in the near-term. We also note that, as it relates to a potential equity raise (prior to the convertibles' January 28, 2018 maturity) and the potential effect on the outstanding share count, the convertibles will convert (either automatically or at the holder's option, depending on the size the raise) at a price per common that is effectively equal to 20% of the price of issued shares. As such, conversion would result in meaningful dilution to current shareholders.

While we have no insight into the status of MRLB's capital raising efforts, we think based on the meager cash balance and late-hour in bringing on additional operating capital, that it is prudent to model an assumed near-term capital infusion in our model. In addition to the $2.7M in convertible notes, the capital structure also includes $10M in secured promissory notes (senior to the convertibles). As such, we think additional debt financing, at least on favorable terms, is unlikely in the immediate term and, therefore, model an assumed equity raise and subsequent triggering of conversion of the convertibles.

Our assumptions imply revenue will grow from $20.5M in 2016 to just under than $100M in 2026, the out-year in our 10-year DCF model (for comparison CYNO, prior to being acquired earlier in 2017, generated over $400M in annual revenue). Gross margin expansion and improvement in operating leverage could result in MRLB reaching a point of cash flow break even in 2022 or 2023. Using these inputs along with a 10% discount rate and 2.5% terminal growth rate, our 10-year DCF values MRLB at $4/share (adjusted down from $10/share due mostly to inclusion of assumed share count dilution).

We also use CYNO and ZLTQ as comps – in February 2017 AGN announced the acquisition of ZLTQ and HOLX announced the acquisition of CYNO. The acquisition prices value ZLTQ at approximately 5.4x estimated 2017 sales and 4.7x estimated 2018 sales and CYNO at approximately 3.3x estimated 2017 sales and 3.0x estimated 2018 sales. Using these averages and our estimated MLRB revenue in 2017 and 2018

[15] Laura He. China's cosmetic surgery market to explode in the next few years, analysts say. South China Morning Post. Feb 15, 2016

revenue values Miramar Labs at between $3.40/share and $3.90/share – which largely supports our $4/share DCF valuation.

We note that our current price target is significantly influenced by our assumed and modeled significant increase in outstanding shares due to an assumed near-term equity raise and resultant conversion of the convertible debt. If MRLB raises funds on more favorable terms than what is assumed in our model, this could result in an upward revision to our price target while less than favorable funding terms could have the opposite effect.

FINANCIAL MODEL

Miramar Labs, Inc.

	2015 A	Q1A	Q2A	Q3A	Q4A	2016 A	Q1A	Q2E	Q3E	Q4E	2017 E	2018	2019
YOY Growth	*-13.7%*	*56.7%*	*51.6%*	*9.9%*	*-24.3%*	*17.9%*	*-29.7%*	*-65.6%*	*-6.2%*	*0.7%*	*-32.7%*	*34.4%*	*45.1%*
YOY Growth	*47.2%*	*34.6%*	*42.1%*	*19.2%*	*-8.7%*	*20.9%*	*10.1%*	*-24.1%*	*12.8%*	*20.5%*	*16%*	*22.8%*	*28.5%*
Total Revenues	$17,199.5	$4,287.3	$7,444.7	$4,303.3	$4,411.2	$20,446.5	$3,814.9	$3,896.8	$4,468.8	$4,871.6	$17,052.0	$21,895.0	$29,799.9
YOY Growth	*7.1%*	*44.8%*	*46.9%*	*13.4%*	*-18.0%*	*18.9%*	*-11.0%*	*-47.7%*	*3.8%*	*10.4%*	*-16.6%*	*28.4%*	*36.1%*
Cost of Goods Sold	$8,257.0	$2,028.6	$3,394.8	$1,787.8	$1,927.6	$9,138.7	$1,692.8	$1,691.9	$1,958.4	$2,099.9	$7,443.0	$8,997.4	$12,113.1
Gross Income	$8,942.5	$2,258.8	$4,049.9	$2,515.5	$2,483.6	$11,307.9	$2,122.1	$2,204.9	$2,510.4	$2,771.7	$9,609.1	$12,897.6	$17,686.8
Gross Margin	*52.0%*	*52.7%*	*54.4%*	*58.5%*	*56.3%*	*55.3%*	*55.6%*	*56.6%*	*56.2%*	*56.9%*	*56.4%*	*58.9%*	*59.4%*
R&D	$4,974.1	$921.6	$823.4	$817.5	$756.5	$3,319.0	$752.7	$802.0	$849.0	$828.0	$3,231.7	$2,802.6	$2,980.0
%R&D	*28.9%*	*21.5%*	*11.1%*	*19.0%*	*17.2%*	*16.2%*	*19.7%*	*20.6%*	*19.0%*	*17.0%*	*14.1%*	*12.8%*	*10.0%*
S&M	$11,757.7	$3,023.0	$3,503.3	$3,449.0	$3,575.4	$13,550.6	$3,003.7	$3,422.0	$3,578.0	$3,654.0	$13,657.7	$14,012.8	$15,555.6
%S&M	*68.4%*	*70.5%*	*47.1%*	*80.1%*	*81.1%*	*66.3%*	*78.7%*	*87.8%*	*80.1%*	*75.0%*	*80.1%*	*64.0%*	*52.2%*
G&A	$5,468.9	$1,338.0	$1,507.3	$1,871.7	$1,319.4	$6,036.4	$1,540.1	$1,692.0	$1,880.0	$1,479.0	$6,591.1	$5,911.6	$6,019.6
% G&A	*31.8%*	*31.2%*	*20.2%*	*43.5%*	*29.9%*	*29.5%*	*40.4%*	*43.4%*	*42.1%*	*30.4%*	*28.0%*	*27.0%*	*20.2%*
Operating Income	($13,258.3)	($3,023.8)	($1,784.0)	($3,622.7)	($3,167.7)	($11,598.2)	($3,174.3)	($3,711.1)	($3,796.6)	($3,189.3)	($13,871.4)	($9,829.4)	($6,868.3)
Operating Margin	*-77.1%*	*-70.5%*	*-24.0%*	*-84.2%*	*-71.8%*	*-56.7%*	*-83.2%*	*-95.2%*	*-85.0%*	*-65.5%*	*-81.3%*	*-44.9%*	*-23.0%*
Total Other Income (Expense)	($1,227.2)	($289.3)	($7,984.0)	($291.5)	($263.2)	($8,828.0)	($4,083.4)	($1,005.5)	($228.4)	($201.7)	($5,519.0)	($540.4)	($110.3)
Pre-Tax Income	($14,485.5)	($3,313.1)	($9,768.0)	($3,914.2)	($3,430.9)	($20,426.2)	($7,257.8)	($4,716.6)	($4,025.0)	($3,391.0)	($19,390.4)	($10,369.8)	($6,978.6)
Tax expense (benefit)	$8.7	$1.5	$0.0	$7.8	$0.0	$9.3	$2.5	$0.0	$0.0	$0.0	$2.5	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Income	($14,497.4)	($3,314.6)	($9,768.0)	($3,922.0)	($3,430.9)	($20,435.5)	($7,260.3)	($4,716.6)	($4,025.0)	($3,391.0)	($19,392.9)	($10,369.8)	($6,978.6)
YOY Growth	*-7.5%*	*# DIV/0!*	*-37.7%*	*-13.5%*	*-2.9%*	*41.0%*	*164.9%*	*-67.5%*	*214%*	*-65.3%*	*-5.1%*	*-46.5%*	*-32.7%*
Net Margin	*-84.3%*	*-77.3%*	*-131.2%*	*-91.1%*	*-77.8%*	*-99.9%*	*-190.3%*	*-121.0%*	*-90.1%*	*-69.6%*	*-113.7%*	*-47.4%*	*-23.4%*
EPS (continuing ops)	($37.33)	($8.32)	($4.10)	($0.42)	($0.37)	($3.82)	($0.78)	($0.50)	($0.12)	($0.10)	($0.89)	($0.26)	($0.16)
YOY Growth	*-9.6%*	*# DIV/0!*	*-90.1%*	*-96.4%*	*-96.0%*	*-89.8%*	*-88.8%*	*-98.7%*	*-98.6%*	*-97.6%*	*-76.7%*	*-70.6%*	*-39.6%*
Diluted Shares O/S	388	399	2,380	9,256	9,366	5,350	9,335	9,400	34,000	34,500	21,809	39,600	44,150

Brian Marckx, CFA

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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

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