# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 8-K

# CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): February 26, 2019



#### STRATA SKIN SCIENCES, INC.

(Exact Name of Registrant Specified in Charter)

Delaware 000-51481 13-3986004 (State or Other (Commission File (I.R.S. Employer Jurisdiction of Number) Identification No.) Incorporation) 19044 5 Walnut Grove Drive, Suite 140, Horsham, Pennsylvania (Address of Principal Executive Offices) (Zip Code) Registrant's telephone number, including area code: 215-619-3200 (Former Name or Former Address, if Changed Since Last Report) Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions: Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 □ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 □ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 □ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
 Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).
 Emerging growth company □
 If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

#### **Item 7.01 Regulation FD Disclosure**

On February 26, 2019, Strata Skin Sciences (the "Company") posted an investor presentation to its website at http://investors.strataskinsciences.com/investors/home. A copy of the investor presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed subject to the requirements of amended Item 10 of Regulation S-K, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing. The furnishing of this information hereby shall not be deemed an admission as to the materiality of any such information.

## **Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

99.1 Strata Skin Sciences Investor Presentation dated February 26, 2019.

#### Exhibit Index

Date: February 26, 2019

Exhibit No. Exhibit Description

99.1 <u>February 26, 2019 STRATA Skin Sciences, Inc. Investor Presentation</u>

## SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

STRATA SKIN SCIENCES, INC.

By:/s/ Matthew C. Hill

Matthew C. Hill Chief Financial Officer



Driving Value to Dermatology Partners

Matching Patients and Clinics

**Investor Presentation** 

February 2019



## Safe Harbor Statement

This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any statements of the plans, strategies and objectives of management for future operations; any statements regarding product development, product extensions, product integration or product marketing; any statements regarding continued compliance with government regulations, changing legislation or regulatory environments; any statements of expectation or belief and any statements of assumptions underlying any of the foregoing. In addition, there are risks and uncertainties related to successfully integrating the products and employees of the Company, as well as the ability to ensure continued regulatory compliance, performance and/or market growth. These risks, uncertainties and other factors, and the general risks associated with the businesses of the Company described in the reports and other documents filed with the SEC, could cause actual results to differ materially from those referred to, implied or expressed in the forward-looking statements. The Company cautions readers not to rely on these forward-looking statements. All forward-looking statements are based on information currently available to the Company and are qualified in their entirety by this cautionary statement. The Company anticipates that subsequent events and developments will cause its views to change. The information contained in this presentation speaks as of the date hereof and the Company has or undertakes no obligation to update or revise these forward-looking statements, whether as a result of new information, future events or otherwise.





## STRATA Investment Highlights



# Excimer Laser Technology for Dermatology Indications

Psoriasis, Vitiligo, Eczema, Atopic Dermatitis and Leukoderma

## **Large Market Opportunity**

Over 35 Million available patients in the United States alone

## **Proven Strategy and Unique Business Model**

Best in class XTRAC® and VTRAC® Excimer Laser technologies
Features stable base of recurring revenue
Patient generation to dermatology practices using DTC techniques

## Seasoned Management Team - with Deep Domain Knowledge

Dr. Dolev Rafaeli, CEO returns with the Accelmed transaction

STRATA

# Treatment Batabase XTRAC (proprietary system) DTC Appointments DTC Appointments INTEREST CREATION INTEREST CREATION INTEREST CREATION INSURANCE ADVOCACY VERIFY APPOINTMENT Prescription of treatment VERIFY XTRAC TREATMENT VERIFY XTRAC TREATMENT

REOCCURRENCE

WIN WIN WIN DOCTOR PATIENT STRATA

(AND PAYER)

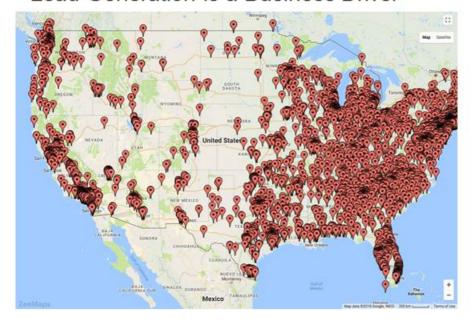
STRATA

# XTRAC DTC Advertising





# Lead Generation is a Business Driver



Patient leads in one quarter Leads turn into appointments

# Appointments lead to

- XTRAC partner revenue
- Other revenue for the partner clinic
- · Revenue for STRATA



NYC, NJ, Long Island



# DTC Results – Lead generation – by quarter 2017 and 2018



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# The Market Opportunity

## XTRAC cleared in four indications

- Psoriasis
- Vitiligo
- · Eczema and Atopic Dermatitis
- · Leukoderma

## Over 35 million domestic patients

## 3 CPT codes (\$150 - \$250 based on BSA)

- \$170 average reimbursement rate per treatment
- Clinical Protocol 6.2 treatments to PASI 75
- Average of 23 treatments per patient lifetime
- Patient Life Time Value ~ \$4,000
- · Codes 96920, 96921, 96922







Erythrodermic





PASI - A 75% reduction in the Psoriasis Area and Severity Index (PASI) score (PASI 75) is the current benchmark of primary endpoints for most clinical trials of psoriasis. BSA = Body Surface Area affected

## Excimer Laser Technology - XTRAC® / VTRAC®

## **Technology**

- XTRAC excimer laser uses highly targeted (308nm) beam of UVB light to treat affected skin area without damaging surrounding tissue
- · VTRAC is a lamp based 308nm laser
- · Treatment avoids side effects, cost of biologics and messy topicals

## Treatments are safe and efficacious

- · Multiple FDA 510(k) and other international clearances
- · Over 500,000 patients treated
- · Over 2,000 devices installed base WW

## Compelling partner clinic economics

- · XTRAC DTC provides a significant revenue source
- · Halo effect of XTRAC DTC marketing platform
- · Center of Excellence partner clinic revenue approx. \$500,000/year
- · Charge revenue on a per-use basis





## How XTRAC Works - Psoriasis







Beam of UVB light applied to the affected area

UVB light induces apoptosis of the keratinocytes and T cells in the dermis

Promotes immunosuppression

Induces alterations in cytokine profile 140+ peer reviewed published clinical studies



# How XTRAC Works - Vitiligo



Danielle K., NC

- Long-term skin condition characterized by patches of skin losing its pigment
- Disease is believed to be due to genetic susceptibility where the autoimmune disease is then triggered
- Potentially the immune system is attacking and destroying melanocytes of the skin
- Life-altering disease that leads to low self esteem
- UVB light reduces the immune system's attack on the melanocytes and enhances the migration and proliferation of melanocytes resulting in repigmentation

STRATA

EXCLUSIVE LICENSE FOR TREATMENT USING EXCIMER LASER

## Domestic Market: Installed Base



## Overview

750 Partner XTRAC

138 sold XTRAC

4 Regions

22 Sales Territories

15 Field Service Techs

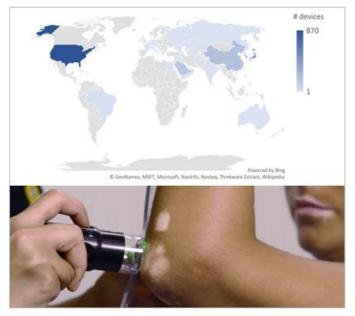
In-house call center to qualify leads

Only one competitor in U.S.



Territories color coded

## International Market: Installed Base



## Strategic Growth Target

OUS sales are through distribution with no current recurring revenue model applied

Major Markets - China, Japan, Saudi Arabia, South Korea

Insurance covered in most markets

Usage/device higher than domestic market – untapped potential in U.S.

Over 1,200 OUS devices sold and in service

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## **Turnaround Strategy**

## DOMESTIC MARKET

Rebuild XTRAC value proposition for partner dermatologists

- o DTC is a revenue driver: Online and offline advertisement, in-house call center
- o Patient Communication: For both referrals and enrollment patients
- Practice Development Programs: increase prescriptions for XTRAC
- o Optimize Clinical Outcomes: Deploy Education for High Dose/OTD and 8N6 as drivers

Current Excimer owners – Revisit "Comeback Program" (>250 dermatologists "came back" to recurring revenue model between 2012-2014)

Expanding installed base (location within 10 miles of every patient)

Improving XTRAC market share across all disease indications

## **OUS MARKETS**

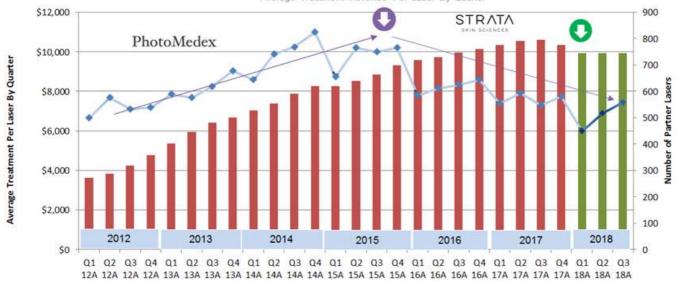
Enhance technology offering Expand geographical reach in certain markets



Revenue = # of lasers x # of treatments/pt x # patients x cost/tx x recurrence factor



# Transformative Transaction – "Back to the Future" Average Treatment Revenue Per Laser By Quarter



----- Average Treatment Per Laser By Quarter

 $STR\Lambda T\Lambda$  Note the numbers prior to Jan 1, 2018 do not reflect adjustments for the adoption

Number of Partner Lasers

Of ASC 606

Based on STRATA 10-k Annual Report; Dec 31, 2017 and quarterly filings \* STRATA bought XTRAC business from PhotoMedex in 2015

# Media Spend to Recurring XTRAC Treatment Revenue: The Opportunity





Based on STRATA and PhotoMedex Investor Presentations \* STRATA bought XTRAC business from PhotoMedex in 2015

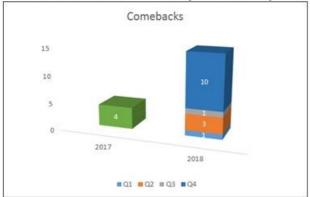
# **Financial Metrics**

	Q1	2017	Q	2 2017	Q	3 2017	Q	4 2017	Q	1 2018	Q	2 2018	Q:	2018
Dermatology recurring procedures revenue	\$	5,556	\$	5,971	\$	5,525	\$	5,588	\$	4,498	\$	5,167	\$	5,556
Dermatology procedures equipment revenue	\$	1,537	\$	2,500	\$	1,751	\$	3,008	\$	1,968	\$	2,366	\$	2,333
Systems placed under dermatology procedure recurring revenue model		791		795		776		753		746		746		746
Average recurring revenue per consigned system per quarter	\$	7,024	\$	7,511	\$	7,120	\$	7,421	\$	6,029	\$	6,926	\$	7,448
Dermatology recurring procedures segment margin percent		63.2%		69.1%		62.3%		56.7%		56.7%		63.6%		68.49
Total Company gross margin percent, including Nordlys inventory and fixed asset write off		61.5%		62.5%		55.0%		49.8%		49.0%		53.6%		61.49

respectively, in the cancelled Nordlys product line.



# Comebacks - Important path to growing recurring revenue

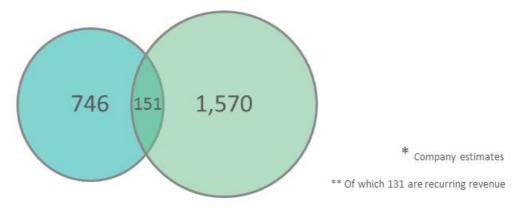


 Existing excimer laser-sites: comeback drives revenue quicker



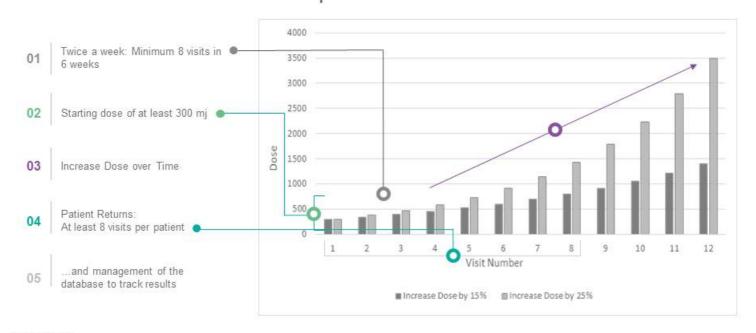
# Changing Dynamic in Healthcare - Clinic Roll-Ups\*

- · Mapped 1,570 PE and private national group roll ups
- · 58 different groups identified
- XTRAC placement penetration 151\*\* 9.5% Huge Opportunity
- August 20, 2018 Company announces "Strategic Agreement with a Large Private Equity Backed Group of Dermatology Clinics"
- · Additional agreements executed since



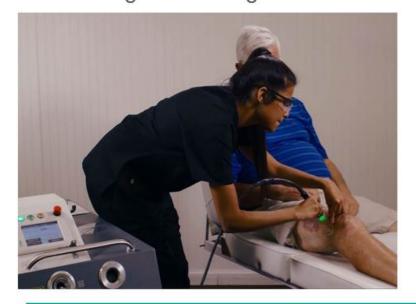


# Current Clinical Protocol For Optimal Patient Outcomes: 8N6 Protocol





# Maximizing Dermatologist Partner Clinical Revenue







Revenue = # of lasers x # of treatments/pt x # patients x cost/tx x recurrence factor



Data collected directly from the lasers demonstrates the importance of following treatment guidelines 21

# Optimal Therapeutic Dose ("OTD") – 510(k) <u>Received August/2018</u> The Path to Optimal Clinical Outcomes and Patient Retention



## **MECHANISM**

Tip applies 4 simultaneous doses of energy to the patient's plaque



## **PURPOSE**

To minimize number of treatments to clearance



### USE

Dose allows provider to determine blister threshold unique to each patient and each plaque. 510(k) submission Approved

## Clinical Studies















## Recent news

## **OTD Clinical Study**

- 92% of the included participants responded to treatment by achieving a reduction in mPASI score of 75% or more
- Compared to current average of 16-20 treatments with NB-UVB 308nm devices, OTD treatment produced statistically significant mPASI improvement by the <u>second</u> treatment
- · It took an average of four sessions for patients to reduce mPASI by 50% or more relative to baseline
- · Statistical survival models predict mPASI scores to stay below 50% of baseline for 78 days

## \$3 Launch

- · Smaller, Faster, Smarter
- · Exclusively pairs with the OTD Approach
- · Allows physicians to maximize results efficiently

## Aggressive IP strategy

- · Vitiligo patent license from Mt Sinai
- · XTRAC trademark enforcement



# Strong Leadership Team

Dr. Uri Geiger	Chairman of the Board	Building Medical Device Companies Example Breathtaking Solutions
Dr. Dolev Rafaeli	Chief Executive Officer	PhotoMedex RADIANCY Smart Stan Solutions
Matthew C. Hill	Chief Financial Officer	simply better dentistry  Velcera
Dr. Daniel Siegel	Consultant	AMD AMERICAN ACADEMY of DERMATOLOGY   ASSOCIATION AMA



# XTRAC used by leading teaching institutions



































































# Recent Financial Highlights

# Q2

Total Revenue	\$7.5 million	+17% versus Q1 2018
Recurring XTRAC Revenue	\$5.2 million	+15% versus Q1 2018
Gross Margin	54%	+5% versus Q1 2018
Dermatology Recurring Procedures Revenue Margin	64%	+7% versus Q1 2018

# Q3

Total Revenue	\$7.9 million	+8% versus Q3 2017		
Recurring XTRAC Revenue	\$5.6 million	+1% versus Q3 2017		
Gross Margin	61%	+6% versus Q3 2017		
Dermatology Recurring Procedures Revenue Margin	68%	+6% versus Q3 2017		
Cash and Cash Equivalents	\$15.9 million	+\$1.5 million versus Q2 2018		



# Financial Profile Shares and Share Equivalents - Market cap\*- \$109M (As of Feb 19, 2019)

Common stock outstanding 31.0M

Series C preferred shares\* 2.6M

Total\*\* 33.6M



<sup>\*</sup> On an as converted basis of the convertible preferred stock

Does not include 2.4M warrants with a weighted average exercise price of \$5.22 as of September 30, 2018 of which 1.6M expire in the first 7 months of 2019 to Does not include 4.4M options with a weighted average exercise price of \$2.06

## STRATA Investment Highlights



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# Large Market Opportunity Over 35 Million available patients in the United States alone

Proven Strategy and Unique Business Model

Best in class XTRAC and VTRAC Excimer Laser technologies

Features stable base of recurring revenue

Patient generation to dermatology practices using DTC techniques

Seasoned Management Team – with Deep Domain Knowledge Dr. Dolev Rafaeli, CEO returns with the Accelmed transaction

STRATA



Driving Value to Dermatology Partners Matching Patients and Clinics

**Investor Presentation** 

February 2019



# Appendix

# XTRAC is to excimer what Xerox is to photocopy



## Over 150 peer-reviewed published clinical-studies

Multiple academic institutes in U.S. use XTRAC



## Over 2,000 device installed base worldwide

Over 1000 dermatology practices in the U.S have XTRAC providing device access to over 3,000 dermatology providers



## Over 5 Million treatments performed

More than 500,000 patients treated



## Best in class excimer technology

Latest product launched in 2018 with advanced features Only platform with Vitiligo and OTD protocol



## Sample studies from 150+ clinical studies

#### Multicenter Psoriasis Study<sup>1</sup>

124 patients were enrolled and 80 completed the protocol. 72% achieved at least 75% clearing in an average of 6.2 treatments. 84% of patients reached improvement of 75% or better after 10 or fewer treatments. 50% of patients reached improvement of 90% or better after 10 or fewer treatments. Common side effects included erythema, blisters, hyperpigmentation, and erosions, but were well tolerated.

#### Scalp Study

All patients improved, 17/35 (49%) of patients cleared>95% (mean: 21 treatments; range: 6-52) and 16/35 (45%) cleared 50-95%. Conclusion - The excimer laser is a successful approach to treatment of psoriasis of the scalp being a simple treatment that can be performed in a short period of time and which has a high rate of effectiveness.

#### Vitiligo Study<sup>2</sup>

Out of 221 vitiligo patchestreated, 50.6% showed 75% pigmentation or more, 25.5% achieved 100% pigmentation of their patches, and 64.3% showed 50% pigmentation or more. Lesions on the face responded better than lesions elsewhere. Conclusion: The 308-nm xenon chloride excimer laser is an effective and safe modality for the treatment of vitiligo, with good results achieved in a relatively short duration of time

#### Pediatric Study

4 children with a mean age of 11.0 years and 12 adults with a mean age of 48.8 years completed the protocol. Both the children and the adult groups yielded a significant decrease in psoriatic severity scores of their respective target lesions. The children's group had a greater reduction (91.3% reduction) as compared to the adult treatment group (61.6% reduction).

\*Multicenter Psoriesis Study - Feldman SR, Mellen BG, Housman TS, Fitzpatrick RE, Geronemus RG, Friedman PM, Vasily DB, Morison WL. Efficacy of the 308-nm excimer laser for treatment of psoriasis: Results of a multicenter study. J Am Acad of Dermatol; vol. 46, no. 6, June 2002, pp. 900-905 Vitiligo Study - Suhail Hadi, Patricia Tinio, Khalid Al-Ghaithi, Haithan

i, Haitham Al-Qari, Mohammad Al-Helalat, Mark Lebwohl, and James Spencer. Photomedicine and Loser Surgery. Treatment of Vitiligo Using the 308-nm Excimer Laser. Jun 2006 ahead of printhttp://doi.org/10.1089/pho.2006.24.354

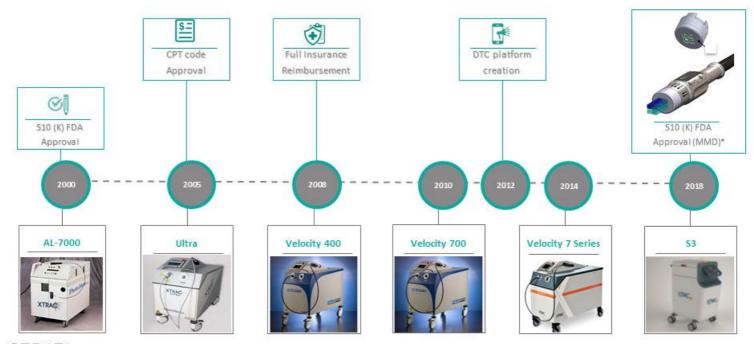
\*Scalp Study - Morison Wt., Aktinson DF and Worthman L. Effective treatment of scalp psoriasis using the excimer (308nm) laser. Photodermatol Photoimmunol Photomed 2006; 22: 181-183

\*Pedietric Study - Pahlajani N, Katz BJ, Lonzano AM, Murphy F and Gottlieb A. Comparison of the Efficacy and Safety of the 308nm Excimer laser for the Treatment of Localized Psoriasis in Adults and in Children: A Pilot Study.

Pediatric Dermatology Vol. 22 No. 2, March/April 2005, pp. 161-165
Induration Protocol Study - Taneja A, Trehan M, Taylor C. 308-nm Excimer Laser for the Treatment of Psoriasis – Induration-Based Dasimetry. Arch Dermatol, Vol. 139, June 2003, pp. 759-764
High Dose Protocol Study - Michael Abrouk, 1 Ethan Levin, 2 Merrick Brodsky, 1 Jessica R Gandy, 1 Mio Nakamura, 2 Tian Hao Zhu, 3 Benjamin Farahnik, 4 John Koo, 2 and Tina Bhutani2 Excimer laser for the treatment of psoriasis: safety, efficacy, and patient acceptability. Published online 2016 Dec 12. doi: 10.2147/PTT.5105047



# Continuous technology investment and business growth



STRATA

\*MMD tip is a diagnostic accessory for XTRC used in optimal therapeutic dose (OTD) protocol that helps patients achieve Optimal Clinical Outcomes leading to increased Patient Retention

# Patient Rebate Program

# Up to \$500 Toward Out-of-Pocket Costs





www.xtrachelps.com

# Practice development program



- In Office Patient Education Materials for psoriasis, vitiligo & atopic dermatitis:
  - ✓ Patient Brochures
  - ✓ Counter Cards
  - ✓ In Office Branding
- "Patient-Directed" marketing initiative:
  - ✓ Patient Education Mailings
  - ✓ Outreach Programs
  - ✓ Eblasts