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): January 16, 2013

MELA Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 000-51481 (Commission File Number) 13-3986004 (IRS Employer Identification No.)

50 South Buckhout Street, Suite 1 Irvington, New York (Address of principal executive offices)

10533 (Zip Code)

Registrant's telephone number, including area code (914) 591-3783

(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 (see General Instructions A.2. below):

□ 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))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 — Regulation FD Disclosure

On January 16, 2013, MELA Sciences, Inc. (the "Company") provided a presentation to investors discussing, among other topics, an overview of the Company's business and growth strategy. A copy of the investor presentation is being furnished as Exhibit 99.1 to this Form 8-K and is incorporated into this Item 7.01 by this reference.

Information in this Form 8-K includes "forward-looking statements" within the meaning of the Securities Litigation Reform Act of 1995. These statements include but are not limited to the Company's plans, objectives, expectations and intentions and other statements that contain words such as "expects," "contemplates," "anticipates," "plans," "intends," "believes," "assumes," "predicts" and variations of such words or similar expressions that predict or indicate future events or trends, or that do not relate to historical matters. These statements are based on the Company's current beliefs or expectations and are inherently subject to significant known and unknown uncertainties and changes in circumstances, many of which are beyond the Company's control. There can be no assurance that the Company's beliefs or expectations will be achieved. Actual results may differ materially from the Company's beliefs or expectations due to financial, economic, business, competitive, market, regulatory and political factors or conditions affecting the Company and the medical device industry in general, as well as more specific risks and uncertainties facing the Company such as those set forth in its reports on Forms 10-Q and 10-K filed with the U.S. Securities and Exchange Commission (the "SEC"). Factors that might cause such a difference include whether MelaFind® achieves market acceptance. Given the uncertainties affecting companies in the medical device industry such as the Company, any or all of these forward-looking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. The Company urges you to carefully review and consider the disclosures found in its filings with the SEC which are available at <u>www.sec.gov</u> and <u>www.melasciences.com</u>.

Some of the highlights contained in the investor presentation are:

- Information regarding the number of signed user agreements for MelaFind which, as of December 31, 2012, was over 100 units.
- Personnel additions in Germany, including a Regional President and Sales Representative as well as the number of sales representatives in the US.
- The Company's attendance at and participation in several upcoming dermatological conferences and tradeshows, including:
 - a. Orlando Dermatology Aesthetic & Clinical Conf. January (Orlando, Florida)
 - b. Winter Clinical Dermatology Meeting January (Koloa, Hawaii)
 - c. Winter Skin Seminar January (Park City, Utah)
 - d. Annual American Academy of Dermatology Meeting March (Miami, Florida)
- The Company's launch of pilot programs focused on achieving practice acceptance of MelaFind with an emphasis on training the full staff and intensifying and concentrating the initial usage period required for medical conversion to MelaFind.
- The Company's goal to significantly reduce its manufacturing costs in 2013.

The investor presentation attached as Exhibit 99.1 to this Form 8-K is being furnished and shall not be deemed "filed" for 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. The information in Item 7.01 of this Form 8-K (including Exhibit 99.1) shall not be incorporated by reference in any filing or other document under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in any such filing or document.

Item 9.01 — Financial Statements and Exhibits

(d) <u>Exhibits</u>

99.1 Investor Presentation

SIGNATURES

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

MELA Sciences, Inc.

Date: January 16, 2013

By: /s/ Joseph V. Gulfo, M.D.

Joseph V. Gulfo, M.D. President and Chief Executive Officer



Needham Growth Conference

MELA Sciences, Inc.

January 16, 2013

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Forward Looking Statements

This presentation includes "forward-looking statements" within the meaning of the Securities Litigation Reform Act of 1995. These statements include but are not limited to our plans, objectives, expectations and intentions and other statements that contain words such as "expects," "contemplates," "anticipates," "plans," "intends," "believes" and variations of such words or similar expressions that predict or indicate future events or trends, or that do not relate to historical matters. These statements are based on our current beliefs or expectations and are inherently subject to significant uncertainties and changes in circumstances, many of which are beyond our control. There can be no assurance that our beliefs or expectations will be achieved. Actual results may differ materially from our beliefs or expectations due to economic, business, competitive, market and regulatory factors. The proposed offering is confidential. Anyone receiving or viewing the Management Presentation should keep it confidential and not use it for any purpose other than to consider an investment in the Company in connection with the offering.

MELA: Nasdaq CM

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Development History

A Sciences 2012	3 MelaFin					
1Q 2012	Commercial launch in US (Northeast) and Europe (Germany)					
11/2011	FDA Approval					
9/2011	CE Mark approval; FDA Approvable letter					
7/2011	Congressional Hearing - FDA admits not approvable letter "wrong"; if data match revised claim, will approve it					
5/2011	Amended MelaFind claim – limited to dermatologists; Citizen Petition; Amended PMA – training program					
2010	Not approvable letter; favorable FDA Advisory Panel meeting					
2009	PMA (Pre-Market Approval Application) Filed					
2007-08	Execute pivotal trial					
2006	Establish commercial-grade manufacturing methods & supplier					
2005	Initial Public Offering					
2004	Protocol Agreement with FDA					
1998	Initiation of development of MelaFind					
1995	First application of computer vision technology to melanoma					

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Launch Progress Since March 2012



25 States in US

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Commercial Strategy 1st 12 months

- Placement of MelaFind system ~\$10,000
- ~\$50/exam
- Self-pay initially
- Dermatologists
 - US goal of 200 signed contracts
 - Germany goal of 75 signed contracts



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5

Revenue Contributions



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MelaFind

▶ 43.7 M Medical & Cosmetic Procedures in the US per Year



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MelaFind® increases dermatologist compensation, ► without taking time away from the patient

MelaFind® can add >\$96,000/per year to a dermatologist's compensation if used once an hour and charging \$100 per session



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> 2012 Accomplishments

- Launched MelaFind (March)
- Product upgrades
- Developed infrastructure for national business
- Many examples of clinical benefit of MelaFind

✓ Melanomas detected

✓ Unnecessary biopsies averted

- Ended year with over 100 signed user agreements
- Cleveland Clinic Top 10 Innovations for 2013; other unsolicited media attention (print and TV)
- German Reader Study results
- Initiated FDA post-Approval study
- Refined messaging and strategies for increased usage
 MelaFind

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2013 Goals

- Drive toward goal of 275 signed use agreements by March 31, 2013
- Expedite MelaFind practice integration & increased usage:
 - 1. Practice commitment at time of placement
 - 2. Peer to peer medical communications
 - 3. Patient communications
 - 4. Enhanced client services
- Reduce manufacturing costs significantly
- Begin push to cash flow positive

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10

2013 Key Tactics

Dermatology meetings

1. Winter Clinical

2. Orlando Derm Aesthetic & Clinical

3. Winter Skin

4. Annual AAD meeting

- 1Q 2013

• Agency (Rpr) efforts

- 1. Consumer Media & Skin Cancer Detection campaigns
- 2. Health & Beauty Magazine PR
- 3. Melanoma Monday campaign
- 4. Targeted patient mobilization
- In office integration and awareness efforts

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11



Usage

Rolling-out tactics to increase awareness of melanoma and MelaFind... increasing usage

Do you have any moles on your body that look like these?



Melanoma is the deadliest form of skin cancer, responsible for 75% of all skin cancer fatalities! But when treated early, melanoma is often curable?

What can you do if you spot a mole that looks like this?



#2 Ask your dermatologist if MelaFind® is right for you.



MELA 13



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MelaFind Advertisements by dermatologists



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1

MelaFind Advertisements by MELA



IF YOU HAVE SKIN, YOU'RE AT RISK FOR MELANOMA.

EVERY HOUR, ONE PERSON IN THE U.S. DIES FROM MILLANOMA, AND THE SADDEST PART IS THAT MELANOMA IS CURABLE WHEN CAUGHT EARLY.

elaFind" is a diagnostic tool that heips your demotologis ose a decision about whether or not to biopsy on husual mole. That's important because it's sometimes not opietely clear which moles might be concerous, and writhe most experienced doctor can have a doubt.

Netofind" lists your doctor see beneach the surface of the skin to get a better took at what's going on with the questionable motes and marks you might have. The lackud data your doctor gets can help with making a decision to boops, Metofind" is paniess, and its been tested in clinical finals and approved by the TGA.



Operation by Canil Zelies

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MelaFind Chosen as One of Top 10 Medical Innovations for 2013 by Cleveland Clinic

Criteria for Inclusion are Significant Clinical Impact, High Probability of Commercial Success, and Significant Human Interest

GlobeNewswire Press Release: MELA Sciences, Inc. - Mon, Nov 5, 2012 7:00 AM EST

NEW YORK, Nov. 5, 2012 (GLOBE NEWSWIRE) -- MELA Sciences, Inc. (MELA), the medical device company that has developed MelaFind^(R), a breakthrough device intended to help dermatologists detect melanoma when it is still curable, announced today that it has been included in the Top 10 Medical Innovations for 2013 compiled by the Cleveland Clinic.

Top 10 Medical Innovations: 2013 | 15

Handheld Optical Scan for Melanoma

Skin cancer is the most common cancer in the United States, affecting millions each year. One in five Americans will develop this cancer in their lifetime. According to the National Cancer Institute, the incidence of melanoma, the least common but most lethal type of skin cancer, has been increasing for at least 30 years, mainly due to UV radiation from sunlight. More than 76,000 Americans develop melanoma annually and 9,000 are expected to die from it this year.

The survival rate of patients diagnosed with early melanoma is almost 99%, while survival for patients diagnosed with advanced stage cancer drops to about 15%.



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MelaFind Presence 2013 Conference Schedule – US Orlando Dermatology Aesthetic & Clinical Conf. – Jan. (Orlando, FL) Winter Clinical Dermatology Meeting – Jan. (Koloa, HI) Winter Skin Seminar – Jan. (UT) Annual American Academy of Dermatology Meeting – Mar. (Miami, FL) Atlantic Dermatological Conference – April (Washington, D.C.) South Beach Symposium – April (Miami Beach, FL) FL Society of Dermatology for Residents Conference – June (Las Vegas, NV) American Academy of Dermatology Summer Meeting – July/Aug. (NY, NY) American Dermoscopy Meeting – Aug. (Whitefish, MT) Fall Clinical Dermatology Meeting – TBD (Las Vegas, NV)

American Society for Dermatologic Surgery Annual Meeting – Oct. (Chicago, IL)
 Annual Mount Sinai Winter Symposium – TBD (TBD)

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17

MelaFind[®] Presence

Upcoming Dermatology Conferences - Germany

- Dermatologische Praxis Mar. (Frankenthal, Germany)
- 47th DDG-Session May (Tagung, Germany)
- European PostASCO Meeting TBD (Germany)
- Practical Dermatology & Venerology Conference (FOBI) TBD (Germany)
- 8th World Congress of Melanoma July (Hamburg, Germany)
- German Skin Cancer Society Meeting (ADO) Sept (Germany)

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Why Melanoma?

- Melanoma kills 1 US citizen per hour
- 80% of all skin cancer deaths
- 50% increase in mortality since 1973
- · Fastest growing cancer 6% per year
- 50% increase in women 15-39
- Most common cancer in women 25-29
- #1 cancer killer in women 30-35
- Affects all age groups
- No cure for late stage disease...must diagnose EARLY
- Stage IV is 10 and 22 more costly to treat than Stage 1 & MMIS, respectively
- 9-fold increase incidence if had a prior melanoma

healthyBEAUTY

 and had to be taken out. "Anything that wen remotely suspicious I have thecked," or, "Ick truly an engoing barten." HET-SEER HODE NOT that developing melanomia it 75 percent is to people who used taxoning both as the top begin who used taxoning both as

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Manager Control International International

"I have 30-somethings come in for Botox or other skin treatments but they still tan at the beach or in tanning beds. I explain there is no point in targeting lines now if they are just going to end up with a scar on their face from skin cancer."

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MelaFind

Early Detection is the Only Hope for a Cure



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20

How Does MelaFind Work?

Hardware:

- MelaFind acquires multi-spectral data
- Uses light in 10 wavelengths from 430 nm (blue) to 950 nm (near infrared)
- Depth up to 2.5 mm into the skin
- 20 micron-resolution (sees clusters of 3 melanocytes)

Software:

- Sophisticated proprietary automatic algorithms analyze data
- Provides MelaFind output High or Low Disorganization



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• Example 1

Figure	6. Standard images	Figure 8. Asymmetry images [waveleng Invasive melanoma (2)		
rview	Invasive melanoma (2P)	Low-grade dysplastic nevus (3J)	430 nm (0.4 mm)	
Clinical ove			460 nm (0.7 mm)	
se-up	1		510 nm (0.9 mm)	
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		and the state of the	880 nm (2.2 mm)	()

Melanoma has eccentric and intense asymmetry at all depths versus benign lesion.

	Invasive melanoma (21	P) Low-g	prade dysplastic nevus (3J)
430 nm (0.4 mm)		430 nm 0.4 mm	
460 nm (0.7 mm)		460 nm 0.7 mm	
510 nm (0.9 mm)		510 nm 0.9mm	
600 nm (1.3 mm)	۵	600 nm 1.7mm	
660 nm (1.7 mm)	٢	660 nm 1.7mm	
780 nm (2.0 mm)	٠	780 nm 2.0mm	
880 nm (2.2 mm)		880 nm 2.2mm	0
950 nm (2.5 mm)		950 nm 2.5mm	1

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• Example 2

	Invasive Melanoma	Low Grade Dysplastic Nevus	Invasive Melanoma	Low Grade Dysplastic Nevus	Invasive Melanoma	Low Grade Dysplastic Nevus
430 nm 0.4 mm					9	0
460 nm 0.7 mm				0	Q	0
510 nm 0.9mm				0	Ç,	Q
600 nm 1.7mm	۱				Q	D.
660 nm 1.7mm	٢				۲	S.
780 nm 2.0mm				<i></i>	s.	189 - C.
880 nm 2.2mm	() ()			<i>(</i>)	1	63
950 nm 2.5mm				0		
	Melanoma has ecco	entric and intense	Benign lesion has	s more homogenous	Benign lesion wi	th more robust and
asyr	nmetry at all depth	s versus benign lesion	texture ver	sus melanoma	ordered structur	e versus melanoma

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Summary of MelaFind Performance

Pivotal Trial (n = 1612 lesions in primary endpoint)							
Biopsy Sensitivity	98.3% (112/114*) 95% LCB = 95.1%						
Biopsy Specificity	<u>Average</u> : MelaFind: Dermatologists:	9.5% 3.7%	p = 0.02				
Adjunctive Reader Study (110 Dermatologists)							
Biopsy Sensitivity	MelaFind: Dermatologists:	97% (63/65) 72% (47/65)	p < 0.0001				

*45% melanoma in situ; median Breslow thickness (depth) 0.365 mm

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Arch Dermotol. February 20, 2012

- Dr. Darrell Rigel, New York University
- 179 attending dermatologists participated
- 24 pigmented skin lesions (5 melanomas, 19 non-melanomas)
- Biopsy decision before and after provision of MelaFind result recorded

Metric	Before MelaFind	After MelaFind	Comments
Sensitivity	69%	94%	
% of Derms who Would Biopsy all 5 MM's	13%	70%	Improved Biopsy Performance
Specificity	54%	40%	Modest decrease in specificity
% of MelaFind True Negatives Biopsied	42%	25%	Lower biopsy rates for MelaFind [®] True Negatives
% of Non-Evaluable Lesions Biopsied	37%	42%	No significant impact of "no result"
Kappa Statistic	0.32	0.45	Variability in biopsy decisions decreased

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29

Published in Premier Academic Journals

STUDY

M SF

The Performance of MelaFind

A Prospective Multicenter Study

Gary Monheit, MD; Armand B. Cognetta, MD; Laura Ferris, MD, Pl Mary Martini, MD: James M. Grichnik, MD, PhD; Martin Mihm, M Roy King, MD; Alicia Toledano, ScD; Nikolai Kabelev, BCSc; Maci

Objective: To demonstrate the safety and effective-Objective: to genonstrate the satety ang effective ness of MelaFind, a noninvasive and objective computer-vision system designed to aid in detection of early pig-mented cutaneous melanoma.

Design: A prospective, multicenter, blinded study. Design: A prospective, multicenter, blinded study. The diagnostic performance of MelaFind and of study clinicians was evaluated using the histologic reference standard. Standard images and patient information for a subset of 50 randomly selected lesions (25 melanomas) were used in a reader study of 39 independent deman-tologists to estimate clinicians' biopsy sensitivity to melanoma. melanoma.

Sotting: Three academic and 4 community practices in the United States with expertise in management of pig-mented skin lesions.

Patients: A total of 1383 patients with 1831 lesion rolled from January 2007 to July 2008; 1632 lesions (in-cluding 127 melanomas—45% in situ—with median Brescluding 127 melanomas—45% in stut—with medan area-low thickness of invasive lesions, 0.36 mm) were eligible and evaluable for the study end points.

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ARCHIVES OF DERMATOLOGY

Online First: February 20, 2012 Research Letters

TABLE OF CONTENTS >

ONLINE FIRST

Impact of Guidance From a Computer-Aided Multispectral Digital Skin Lesion Analysis Device on Decision to Biopsy Lesions **Clinically Suggestive of Melanoma**

Darrell S. Rigel, MD, MS; Mrinalini Roy, BA; Jane Yoo, MD, MPP; Clay J. Cockerell, MD; June K. Robinson, MD; Richard White, MA

Arch Dermatol. Published online February 20, 2012. doi:10.1001/archdermatol.2011.3388

A major challenge faced daily by clinical dermatologists is to determine which pigmented lesions are appropriate for biopsy. The present study was designed to determine the effect of guidance provided by a multispectral digital skin lesion analysis (MSDSLA) device (MelaFind; MELA Sciences Inc)¹ on dermatologists' decision to biopsy a pigmented lesion and the impact of the information

provided by the device on the associated melanoma biopsy sensitivity and specificity. MelaFind uses light from visible to near-infrared wavelengths to image up to 2.5 mm beneath the skin and analyzes images from subbands of these wavelengths to provide information about the lesion's analyzes images from subbands of these wavelengths to provide information about the less level of structural disorder. The device provides an output of "positive" or "negative" as an additional piece of data that can be integrated into the biopsy decision.



German Reader Study (n = 202 dermatologists)

	Sensitivity	Specificity	Number of dermatologists Sensitivit	Specificity ty > 90%	Percent of melanomas detected by 90% of dermatologists
Arm 1 – 101 dermatologists with clinical information only	70.5%	54%	3	23%	9.2%
Arm 2 – 101 dermatologists with clinical information & MelaFind output	78.4%	45.1%	22	21%	43%
Statistical significance	p < 0.00001	p < 0.00001	p < 0.00006	Not applicable	p < 0.00002

Sensitivity to early melanoma is much more important than specificity
 ~ 1:1 Trade-off of sensitivity : specificity is very clinically meaningful

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31

Clinically Atypical Pigmented Skin Lesions

Pigmented skin lesions having *one or more* clinical or historical characteristics of melanoma:

- 1-4. ABCD: Asymmetry, Border Irregularity, Color Variegation, Diameter > 6 mm¹
- 5. E Evolving^{2,3}
- 6. **P** Patient's Concern^{4,5,6}
- 7. **R** Regression⁷
- 8. U Ugly Duckling⁸
- 9. M MelaFind^{•9} (Objective Measure of 3D Morphological Disorder)

¹Friedman RJ, Rigel DS, Kopf, AW. CA Cancer J Clin. 1985. ²Abbasi NR, Shaw, HM, Rigel, DS, et al. JAMA. 2004. ³Rigel, DS, Friedman, RJ, Kopf, AW, Polsky, D. Arch Dermatol. 2005. ⁴Schwartz, JL, Wang, TS, Hamilton, TA, Lowe, L, Sondak, VK, Johnson, TM. Cancer. 2002. ⁵Brady, MS, Oliveria, SA, Christos, PJ, et al. Cancer. 2000. ⁶Richard, MA, Grob, JJ, Avril, MF, et al. Intern J of Cancer. 2000. ⁷Blessing, K, McLaren, KM. Histopathology. 1992. ⁸Grob, JJ, Bonerandi, JJ. Arch Dermatol. 1998. ⁹Monheit, G, Cognetta, AB, Ferris, L, et al. Arch Dermatol. 2011.

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Patient In the Clinic



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Summary

- Market for melanoma detection is large and growing
- Significant unmet medical need
- MelaFind[®] is a breakthrough product for early detection
- Largest positive prospective trial ever performed in melanoma detection
- Launched March 7, 2012 US & Germany
- Goal: by March 31, 2013 200 systems in US and 75 Germany
- On target; medical utility in customer hands established
- Strong business model for commercialization
- Well capitalized

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• Evolution of MelaFind

