# 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): November 15, 2016

# Skyline Medical Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware001-3679033-1007393(State or Other Jurisdiction of Incorporation)(Commission File Number)(I.R.S. Employer Identification Number)

2915 Commers Drive, Suite 900, Eagan, Minnesota 55121

(Address of Principal Executive Offices) (Zip Code)

(651) 389-4800

(Registrant's telephone number, including area code)

# Not Applicable

(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) 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))
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))

# Item 2.02. Results of Operations and Financial Condition.

On November 15, 2016, Skyline Medical Inc. issued a press release announcing its third quarter 2016 financial results. A copy of the press release is furnished as Exhibit 99.1 to this report.

# Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description/Exhibit

99.1 Press Release of Skyline Medical Inc. dated November 15, 2016

# 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.

Skyline Medical Inc.

By: <u>/s/ Bob Myers</u>
Bob Myers
Chief Financial Officer Date: November 15, 2016

#### Skyline Medical Reports Third Quarter 2016 Financial Results

Conference call and webcast to be held today at 4:30 p.m. Eastern time

MINNEAPOLIS, Nov. 15, 2016 (GLOBE NEWSWIRE) - **Skyline Medical Inc.** (NASDAQ:SKLN) ("Skyline" or "the Company"), developer of the innovative STREAMWAY® waste fluid disposal system for medical applications, reports financial results for the three and nine months ended September 30, 2016.

Highlights of the third quarter of 2016 and recent weeks include:

- Signed an agreement with GLG Pharma, Inc. to be the exclusive distributor of the STREAMWAY System in the U.K., Poland and certain Central European countries
- Entered into a partnership with GLG Pharma, LLC to develop diagnostic kits to be used with the STREAMWAY System
- Signed a Letter of Intent to form a joint venture with Electronic On-Ramp (EOR)
- Sold a sixth and a seventh STREAMWAY System unit to a top-ranked U.S. hospital system for its headquarters location
- Appointed Timothy A. Krochuk and J. Melville ("Mel") Engle to the Board of Directors
- Appointed Dr. Paul Sweetnam to the Medical Advisory Board
- Hired Peter Alex as Vice President of Sales to lead renewed initiative targeting both direct and distributed channels

#### **Management Commentary**

"The third quarter and recent weeks have been extremely active as we took a number of decisive steps to support Skyline's growth in the coming months, and to establish a foundation for highly significant longer-term opportunities. We are grateful to our shareholders for their support and their shared optimism for our future," said Dr. Carl Schwartz, Executive Chairman of Skyline Medical. "We broadened the management team with the hire of Peter Alex as Vice President of Sales, and appointed world-class, accomplished advisors and board members in Dr. Paul Sweetnam, Tim Krochuk and Mel Engle. Collectively these additions are improving our sales channels and pipeline of potential products, and open new opportunities for Skyline Medical.

"The recent announcement of a partnership with GLG Pharma and a letter of intent for a joint venture with EOR could be transformative, when completed. In GLG Pharma we have a partner with distribution capability in the EU and a pipeline of products in development for rapid diagnostic tests that would utilize fluid and tissue collected by the STREAMWAY System during procedures. EOR brings to the joint venture a Native American Indian, (8a) certified Small Disadvantaged Business owned by a Service Disabled Veteran. EOR's Partner contracts with the U.S. National Institutes of Health (NIH) and Department of Defense are expected to provide Skyline Medical with access to bid on procurement contracts for up to \$550 million or more in federal funds budgeted for health, security, life safety systems support, humanitarian assistance and disaster preparedness, and in particular mobile operating rooms."

Dr. Schwartz added, "Revenue for the third quarter was up 57% over the prior year, reflecting two new purchases of STREAMWAY Systems by a world-renowned institution during the period, and the additional revenue derived from the ongoing sale of disposable products. Gross margin was 80%, compared with 77% in the prior year's third quarter. We expect continued gross margin expansion during the next several quarters as manufacturing processes become more consistent and higher sales allow us to achieve volume purchasing discounts on equipment components and cleaning solution.

"Subsequent to the quarter's end, we effected a 1-for-25 reverse stock split. This is an important step to maintaining our listing on NASDAQ, as it brings our stock price above the \$1 minimum bid requirement. We are working to cure our stockholders' equity shortfall as well, and were pleased stockholders voted to increase our authorized share capital as this gives us additional flexibility to raise funds. We have a meeting on December 15, 2016, with the Nasdag Hearing Panel to request an extension and present our plan for regaining compliance.

"Looking to our near-term milestones, we expect to receive clearance to market STREAMWAY in Canada in the coming weeks, followed by the expected receipt of the CE Mark allowing the Company to sell and distribute in Europe potentially during the first quarter. Peter Alex has redoubled our sales efforts and has generated a vastly improved backlog of product inquiries. Munro Enterprises, an Economically-Disadvantaged, Woman-Owned Small Business, is working to distribute the STREAMWAY System to the U.S. federal government including U.S. Department of Veterans Affairs, U.S. Department of Defense and U.S. Health and Human Services facilities, and expects to make progress now that a new federal government fiscal year has begun. We are optimistic we can achieve our goals and are working to put the requisite funding in place," Dr. Schwartz added.

# **Financial Results**

Revenue for the third quarter of 2016 was \$134,605, compared with \$85,792 for the third quarter of 2015, an increase of 57%. Revenue was derived from the sale of two STREAMWAY systems and sales of disposable products during the third quarter of 2016, compared with sales of STREAMWAY Systems as well as disposable products in the third quarter of 2015.

Gross profit for the third quarter of 2016 was \$108,124, or 80% of revenue, compared with \$66,019, or 77% of revenue, for the same period in 2015.

Total operating expenses for the third quarter of 2016 were \$1,163,717 compared with \$1,182,421 for the third quarter of 2015. The decline in operating expenses was primarily due to lower general and administrative expenses, partially offset by higher sales and marketing expense and operations expense.

Net loss available to common shareholders for the third quarter of 2016 was \$1,055,593 or \$0.32 per share, compared with a net loss available to common shareholders for the third quarter of 2015 of \$1,116,402, or \$7.09 per share. Weighted average shares used in calculation of loss per common share was 3,320,139 in the 2016 quarter compared with 157,445 in the 2015 quarter.

Revenue for the nine months ended September 30, 2016 was \$316,931, compared with \$471,078 for the same period of 2015. Revenue was derived from the sale of disposable products and STREAMWAY System sales during the 2016 period, compared with sales of a greater number of STREAMWAY Systems as well as disposable products in the same 2015 period.

Gross profit for the nine months ended September 30, 2016 was \$167,801 or 53% of revenue, compared with \$271,771, or 58% of revenue, for the nine months ended September 30, 2015. Gross margin was reduced due to the replacement of original STREAMWAY units with latest-generation product at no charge to customers. This replacement is now complete and the gross margin for 2016 is expected to be higher than the gross margin for 2015.

Net loss available to common shareholders for the nine months ended September 30, 2016 was \$5,793,242, or \$2.57 per share, compared with a net loss available to common shareholders for the nine months ended September 30, 2015 of \$2,527,524 or \$18.39 per share. Weighted average shares used in the calculation of loss per share was 2,250,315 for the nine months ended September 30, 2016, compared with 137,428 for the nine months ended September 30, 2015.

The Company had cash, cash equivalents and marketable securities of \$1,211,366 as of September 30, 2016, compared with \$4,856,232 as of December 31, 2015. The Company used \$3,704,307 in cash to fund operations during the first nine months of 2016.

#### Conference call and Webcast

Skyline Medical management will host a conference call beginning at 4:30 p.m. Eastern time today to discuss third quarter financial results and answer questions. Management will also provide a business update and discuss recent events and upcoming milestones.

To access the conference call, dial 844-751-1093 from within the U.S. or 574-990-2954 from outside the U.S. All listeners should provide passcode 12947526. Individuals interested in listening to the live conference call via the internet may do so by logging on to the Company's website at www.skylinemedical.com.

Following the conclusion of the conference call, a telephone replay will be available through November 21, 2016 and can be accessed by dialing 855-859-2056 from within the U.S. or 404-537-3406 from outside the U.S. All listeners should provide passcode 12947526. The webcast will be available for 30 days.

# About the STREAMWAY System

Skyline's revolutionary, FDA-cleared STREAMWAY system is the first true direct-to-drain fluid disposal system designed specifically for medical applications, such as radiology, endoscopy, urology and cystoscopy procedures. It connects directly to a facility's plumbing system to automate the collection, measurement and disposal of waste fluids. As of September 30, 2016, Skyline Medical customers have installed 96 STREAMWAY systems in 50 facilities across 19 states.

The STREAMWAY minimizes human intervention for better safety and improves compliance with Occupational Safety and Health Administration (OSHA) and other regulatory agency safety guidelines. It also provides unlimited capacity for increased efficiency in the operating room, which leads to greater profitability. Furthermore, the STREAMWAY eliminates canisters to reduce overhead costs and provides greater environmental stewardship by helping to eliminate the approximately 50 million potentially disease-infected canisters that go into landfills annually in the U.S. For a demonstration please visit www.skylinemedical.com or call 855-785-8855.

# **About Skyline Medical**

Skyline Medical produces a fully automated, patented, FDA-cleared waste fluid disposal system that virtually eliminates staff exposure to blood, irrigation fluid and other potentially infectious fluids found in the healthcare environment. Antiquated manual fluid handling methods that require hand carrying and emptying filled fluid canisters present an exposure risk and potential liability. Skyline Medical's STREAMWAY System fully automates the collection, measurement and disposal of waste fluids and is designed to: 1) reduce overhead costs to hospitals and surgical centers; 2) improve compliance with OSHA and other regulatory agency safety guidelines; 3) improve efficiency in the operating room, and radiology and endoscopy departments, thereby leading to greater profitability; and 4) provide greater environmental stewardship by helping to eliminate the approximately 50 million potentially disease-infected canisters that go into landfills each year in the U.S. For additional information, please visit www.skylinemedical.com.

# Forward-looking Statements

Certain of the matters discussed in this announcement contain forward-looking statements that involve material risks to and uncertainties in the Company's business that may cause actual results to differ materially from those anticipated by the statements made herein. Such risks and uncertainties include, among other things, current negative operating cash flows and a need for additional funding to finance our operating plan; the terms of any further financing, which may be highly dilutive and may include onerous terms; unexpected costs and operating deficits, and lower than expected sales and revenues; uncertain willingness and ability of customers to adopt new technologies and other factors that may affect further market acceptance, if our product is not accepted by our potential customers, it is unlikely that we will ever become profitable, adverse economic conditions: the potential delisting of the Company's common stock on The Nasdag Capital Market as a result of the Company's failures to comply with listing standards, in which case the liquidity of our common stock would likely be impaired and there would likely be a reduction in our coverage by security analysts and the news media, thereby resulting in lower prices for our common stock than might otherwise prevail; adverse results of any legal proceedings; the volatility of our operating results and financial condition; inability to attract or retain qualified senior management personnel, including sales and marketing personnel; our ability to establish and maintain the proprietary nature of our technology through the patent process, as well as our ability to possibly license from others patents and patent applications necessary to develop products; the Company's ability to implement its long range business plan for various applications of its technology, including the possibility that the development of applicable technologies by GLG Pharma, LLC will be delayed, will not occur or will not receive applicable regulatory approvals on a timely basis; the Company's ability to consummate its joint venture with Electronic On-Ramp, Inc.; the Company's ability to enter into agreements with any necessary marketing and/or distribution partners; the impact of competition, the obtaining and maintenance of any necessary regulatory clearances applicable to applications of the Company's technology; and management of growth and other risks and uncertainties that may be detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, which are available for review at www.sec.gov. This is not a solicitation to buy or sell securities and does not purport to be an analysis of the Company's financial position. See the Company's most recent Annual Report on Form 10-K, and subsequent reports and other filings at www.sec.gov.

SKYLINE MEDICAL INC.
CONDENSED BALANCE SHEETS
(Unaudited)

	September 30, 2016		De	December 31, 2015	
ASSETS					
Current Assets: Cash and Cash Equivalents	\$	634,478	\$	4,856,232	
Marketable Securities		576,888	·	-	
Accounts Receivable		45,017		38,283	
Inventories		289,249		231,740	
Prepaid Expense and other assets		163,188		271,579	
Total Current Assets	_	1,708,820	_	5,397,834	
Fixed Assets, net		110,910		139,598	
Intangibles, net		97,335		94,987	
Total Assets	\$	1,917,065	\$	5,632,419	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current Liabilities:					
Accounts Payable	\$	648,061	\$	650,413	
Accrued Expenses		820,114		864,295	
Deferred Revenue		5,000		5,000	
Total Current Liabilities	_	1,473,175		1,519,708	
Accrued Expenses		432,376		-	
Total Liabilities		1,905,551		1,519,708	
Commitments and Contingencies		-		-	
Stockholders' Equity:					
Series B Convertible Preferred Stock, \$.01 par value, 20,000,000 authorized, 79,246 and 1,895,010 outstanding Common Stock, \$.01 par value, 8,000,000 authorized, 3,404,860 and 208,259		792		18,950	
outstanding		34,048		2,080	
Additional paid-in capital		46,257,774		44,584,118	
Accumulated Deficit		(46,285,679)		(40,492,437)	
Accumulated Other Comprehensive Income		4,579		· -	
Total Stockholders' Equity	_	11,514		4,112,711	
Total Liabilities and Stockholders' Equity	\$	1,917,065	\$	5,632,419	

# SKYLINE MEDICAL INC. CONDENSED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE INCOME (Unaudited)

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2016		2015		2016		2015
Revenue	\$	134,605	\$	85,792	\$	316,931	\$	471,078
Cost of goods sold		26,481		19,773		149,130		199,307
Gross Margin		108,124		66,019		167,801		271,771
General and administrative expense		733,074		861,098		4,684,130		1,589,522

Operations expense		292,856	202,799	928,062	375,429
Sales and marketing expense		137,784	66,720	348,848	439,703
Interest expense		3	51,804	3	394,641
Total expense	_	1,163,717	1,182,421	5,961,043	2,799,295
Net loss available to common shareholders		(1,055,593)	(1,116,402)	(5,793,242)	(2,527,524)
Other comprehensive income Unrealized gain (loss) from marketable securities		(1,299)		4,579	
Comprehensive loss	\$	(1,056,892)	(1,116,402)	(5,788,663)	(2,527,524)
Loss per common share - basic and diluted	\$	(0.32) \$	(7.09) \$	(2.57) \$	(18.39)
Weighted average shares used in computation - basic and diluted		3,320,139	157,445	2,250,315	137,428

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