

# **NEWS RELEASE**

For Immediate Release: Thursday, November 13, 2014

# STATEMENT OF VASCULAR SOLUTIONS ON GRAND JURY INDICTMENT

MINNEAPOLIS – (November 13, 2014) – In response to an indictment returned today by a federal grand jury in the Western District of Texas, Vascular Solutions, Inc. (Nasdaq: VASC) issued the following statement:

"The allegations against us are false and we will contest them vigorously. The indictment is the profoundly flawed product of government attorneys who have conducted a misguided and abusive investigation. Without the company being able to present any information to the grand jury, today's action is not surprising. It is, however, fundamentally wrong and profoundly unjust.

"As previously disclosed, the U.S. Attorney's Office in San Antonio and the Consumer Protection Branch of the Department of Justice conducted a four-year investigation concerning the since-discontinued Short Kit version of our Vari-Lase product for the treatment of varicose veins in the leg. That investigation led to today's indictment, which alleges that members of Vascular Solutions' sales force spoke to physicians about the use of the Short Kit to treat varicose perforator veins in the leg. The indictment further alleges that the treatment of a leg's perforator veins, as opposed to the more-commonly treated saphenous veins, is outside the Short Kit's labeled indications and therefore constitutes an 'off-label' use.

*"We vehemently disagree with both allegations: we did not engage in any illegal offlabel promotion of the Short Kit, nor did we engage in any false or misleading conduct.* 

"Sales of the Short Kit for all clinical uses during the seven years it was on the U.S. market were \$534,000, representing just 0.1% of our total U.S. sales during those years. Over two-thirds of our sales representatives never sold even a single Short Kit, and the Short Kit has never been the subject of any reported serious adverse event in any patient.

"The discrepancy between the insignificance of our Short Kit product and the severity of the government's actions in this matter is simply astonishing. The reason for that discrepancy will become readily apparent when the government attorneys' stated motives and abusive conduct in this investigation are disclosed in our upcoming court filings.

"We cooperated fully during the government's investigation and pointed out the flaws in the government's theories and evidentiary assumptions. While confident in our innocence, in order to avoid the costs and distractions of this matter we tried repeatedly to find a reasonable resolution, just as we achieved with the related civil lawsuit that settled earlier this year, but to no avail. "We will defend our company and our employees against these improper and false allegations through trial where we are confident of prevailing. We have the resources to vigorously contest the allegations and an excellent legal team in place.

"While proceeding with our legal defense, we plan to make no change to our business operations or personnel as a result of this matter."

John Erb, Chairman of the Board of Vascular Solutions, added the following statement:

"I have led the independent members of the Board of Directors in providing active direction to and oversight of the company's response to this investigation. The Board of Directors unanimously supports management's handling of this matter and the company's defense against these unwarranted charges. The Board of Directors has determined that it is appropriate and in the best interests of Vascular Solutions that Howard Root continue as CEO throughout this legal process and to its successful resolution at trial.

"To put this matter into perspective, since its inception in 1997, Vascular Solutions has created over 450 well-paid American jobs and developed over 80 new medical devices that improve patients' lives. The company has a complete and detailed compliance program, and this matter is the only allegation of a sales promotion issue that the company has received in its 17-year history. In that context, today's indictment is both disproportionate and unjust."

A grand jury indictment is not a verdict or finding of guilt, but rather a determination of whether a crime should be charged. Only the prosecuting attorney is allowed to present evidence to the grand jury, and no judge or defense attorney is present during the grand jury sessions. The validity of the charges included in the indictment is determined only by a jury following trial.

#### Background

The Vari-Lase Short Kit was sold in the U.S. from October 2007 through July 2014 under an FDA 510(k) clearance for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein and for treatment of incompetence and reflux of superficial veins in the lower extremity.

The criminal investigation is related to a *qui tam* "whistle-blower" civil lawsuit filed in 2010. The U.S. Attorney's office for the Western District of Texas intervened in the civil lawsuit, in part, in 2012. On January 22, 2014, the company reached an agreement with the Department of Justice to settle the civil lawsuit, and a settlement agreement was fully executed on July 28, 2014. Under the terms of that agreement, the company paid \$520,000 with no admission of fault or liability, and the U.S. Attorney's office supported dismissal of the civil lawsuit with prejudice and released all civil claims brought against the company in the civil lawsuit. As previously disclosed, the settlement of the civil lawsuit had no effect upon the criminal investigation.

The indictment returned today by a federal grand jury in in the Western District of Texas charges Vascular Solutions and its Chief Executive Officer with introducing adulterated and misbranded medical devices into interstate commerce and conspiracy to introduce adulterated and misbranded medical devices into interstate commerce.

As has been previously disclosed, conviction of the company of a crime under statutes related to fraud could result in the company's exclusion from participation in all U.S. government health

care programs including Medicare and Medicaid, which would substantially adversely affect the company's ability to continue to conduct its business. Conviction of an employee of a crime under statutes related to misbranding and health care fraud could result in termination of the employee's employment with the company and prohibition from employment with any health care company that contracts with the federal government.

Additional information concerning this matter is included in a Form 8-K report filed today with the Securities and Exchange Commission and available on the SEC website.

## **About Vascular Solutions**

Vascular Solutions, Inc. is an innovative medical device company that focuses on developing unique clinical solutions for coronary and peripheral vascular procedures. The company's product line consists of more than 80 products and services in three categories: catheter products, hemostat products and vein products. Vascular Solutions delivers its products and services to interventional cardiologists, interventional radiologists, electrophysiologists, and vein specialists through its direct U.S. sales force and international independent distributor network.

For further information on Vascular Solutions, connect to <u>www.vasc.com</u>.

## **Contacts**

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