#### **Table of Contents**

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

## **FORM 10-K**

(MARK ONE)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED OCTOBER 1, 2006

OR TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FORTHE TRANSITION PERIOD FROM

**COMMISSION FILE NUMBER 0-20225** 

TO

# **ZOLL MEDICAL CORPORATION**

(Exact name of registrant as specified in its charter)

MASSACHUSETTS (State or other jurisdiction of incorporation or organization) 269 MILL ROAD, CHELMSFORD, MASSACHUSETTS (Address of principal executive offices) Provistment's telephone number including area code (97)

04-2711626 (I.R.S. Employer Identification No.)

> 01824 (Zip Code)

> > None

**Registrant's telephone number, including area code (978) 421-9655** 

Securities registered pursuant to Section 12(b) of the Act: Teach class Name of each exchange on which registered

Title of each class

None

Securities registered pursuant to Section 12(g) of the Act:

Se

Common Stock, \$.02 Par Value Stock Purchase Rights

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🗆 No 🖾

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes 🗆 No 🗵

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\boxtimes$  No  $\square$ .

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.  $\Box$ 

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer  $\Box$  Accelerated filer  $\boxtimes$  Non-accelerated filer  $\Box$ 

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes 🗆 No 🗵

The aggregate market value of the voting stock held by non-affiliates of the registrant as of April 2, 2006 was \$254,574,045 based on a closing sales price of \$26.34 per share as reported for the NASDAQ-composite transactions.

The number of shares of the registrant's classes of common stock outstanding, as of December 8, 2006 was 9,950,130.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive Proxy Statement dated on or about December 20, 2006 to be delivered to shareholders in connection with the Annual

Find authenticated court documents without watermarks at docketalarm.com.

#### ZOLL MEDICAL CORPORATION

#### Annual Report on Form 10-K For the Year Ended October 1, 2006

#### **Table of Contents**

Page No.

<u>Part I</u>		
Item 1.	Business	3
Item 1A.	Risk Factors	20
Item 1B.	Unresolved Staff Comments	31
Item 2.	Properties	31
Item 3.	Legal Proceedings	31
Item 4.	Submission of Matters to a Vote of Security Holders	31
<u>Part II</u>		
Item 5.	Market for Registrant's Common Equity and Related Stockholder Matters and Issuer Purchases of Equity	
	Securities	32
Item 6.	Selected Financial Data	33
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operation	33
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	45
Item 8.	Financial Statements and Supplementary Data	47
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	73
Item 9A.	Controls and Procedures	73
Item 9B.	Other Information	74
<u>Part III</u>		
Item 10.	Directors and Executive Officers of the Registrant	75
Item 11.	Executive Compensation	77
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	77
Item 13.	Certain Relationships and Related Transactions	77
Item 14.	Principal Accounting Fees and Services	77
Part IV		
Item 15.	Exhibits and Financial Statement Schedules	79
<u>Signatures</u>		82
Index to Consolidated Financial Statements		47



DOCKET ALARM Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

#### PART I

Except for historical information, the matters discussed in this Annual Report on Form 10-K are forward-looking statements that involve risks and uncertainties. The Company makes such forward-looking statements under the provision of the "Safe Harbor" section of the Private Securities Litigation Reform Act of 1995. Actual future results may vary materially from those projected, anticipated, or indicated in any forward-looking statements as a result of certain risk factors. Readers should pay particular attention to the considerations described in Part I, Item 1A of this report entitled "Risk Factors." Readers should also carefully review the risk factors described in the other documents that the Company files from time to time with the Securities and Exchange Commission. In this Annual Report on Form 10-K, the words "anticipates," "believes," "expects," "intends," "future," "could," and similar words or expressions (as well as other words or expressions referencing future events, conditions or circumstances) identify forward-looking statements.

#### Item 1. Business.

#### Overview

ZOLL Medical Corporation (ZOLL or the Company), a Massachusetts corporation incorporated in 1980, develops technologies and software that help clinicians, emergency medical services (EMS) personnel and lay rescuers advance the practice of resuscitation.

To understand resuscitation, it is important to first provide background information about:

- The anatomy of the heart;
- Sudden cardiac arrest (SCA) and how rapid, life-saving interventions can help SCA patients;
- The different arrhythmias that can lead to SCA;
- The issue of traumatic injury and its effects that can also lead to SCA;
- Recent developments and new research in the areas of emergency cardiovascular care and the performance of cardiopulmonary resuscitation (CPR); and
- A definition of the resuscitation technology market.

#### Anatomy of the Human Heart

The normal human heart has four chambers, and expands and contracts more than 100,000 times each day. The two smaller, upper chambers are the atria, and the two larger, lower chambers are the ventricles. The walls of the atria and the ventricles are made up of cardiac muscle, which contracts rhythmically when stimulated by an electrical current. Normally, the heartbeat starts in the right atrium when a specialized group of cells sends an electrical signal. This signal spreads through the atria and then moves to the ventricles. As a result, the atria contract a fraction of a second before the ventricles. This exact pattern must be followed to ensure that the heart beats properly. This contraction and relaxation of the four chambers pumps blood to the lungs and the rest of the body.

#### Sudden Cardiac Arrest

Sudden cardiac death results from the sudden, abrupt loss or disruption of heart function. This abrupt loss of function, also known as sudden cardiac arrest (SCA), causes lack of blood flow to vital organs. SCA results in a loss of blood pressure, pulse, and consciousness. Most commonly, SCA is caused by an abnormal heart rhythm called ventricular fibrillation, which occurs when the heart beats too rapidly and/or chaotically, or not at all (cardiac standstill from other non-fibrillation dysrhythmias such as pulseless electrical activity).

According to the Center for Disease Control and Prevention, there are an estimated 460,000 deaths from SCA annually in the United States, and approximately 1,000 people die of SCA every day. SCA strikes without



**DOCKET A L A R M** Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

#### **Table of Contents**

warning and can kill its victims within minutes; most victims have no prior symptoms. Many of these deaths are from ventricular fibrillation. For SCA victims, time is the most critical element for survival. For every minute of delay in the restoration of effective cardiac function provided by defibrillation—the process of delivering electrical current to the heart to stop the fibrillation and permit the return of coordinated cardiac contractions—survival decreases by as much as 10%. According to the American Heart Association (AHA), more than 95% of SCA victims in the U.S. die, in many cases because life-saving defibrillators arrive too late, if at all.

#### Different Arrhythmias that Can Lead to SCA

Arrhythmias are abnormal rhythms of the heart caused by insufficient circulation of oxygenated blood, drugs, electrical shock, mechanical injury, disease, or other causes. The three types of major arrhythmias are ventricular fibrillation and tachycardia; atrial fibrillation and flutter; and symptomatic bradycardia. It is possible for a patient to experience more than one type of arrhythmia during SCA. In these situations, it is important for trained rescuers to have equipment that has defibrillation and pacing capabilities, as well as technology that can assist with CPR performance.

*Ventricular Fibrillation*. Ventricular fibrillation is a condition in which disorganized electrical activity causes the ventricles to contract in a rapid, unsynchronized, and uncoordinated fashion. When this occurs, an insufficient amount of blood is pumped from the heart. Ventricular fibrillation is the most common arrhythmia thought to cause SCA. The onset of ventricular fibrillation often occurs without warning and causes the heart to cease pumping blood effectively. This sudden stopping of the heart is known as cardiac arrest, which is the cause of sudden cardiac death.

The only accepted treatment for ventricular fibrillation is defibrillation. In emergency situations, external defibrillation was conventionally administered through hand-held paddles placed on the patient's chest. However, external defibrillation is now more likely to be administered through disposable adhesive electrodes, which are believed to be safer and easier to use than paddles.

According to the AHA, early defibrillation of ventricular fibrillation is the single most effective intervention in the rescue of a victim of SCA. Each minute of delay in returning the heart to its normal pattern of beating decreases the chance of survival by 7% to 10%. Furthermore, there is an increasing body of evidence that other actions, in addition to defibrillation, must occur to maximize the chance of a successful resuscitation. These actions comprise a "Chain of Survival" consisting of early access, early CPR, early defibrillation, and early advanced care.

*Atrial Fibrillation.* The AHA estimates that close to 2 million Americans suffer from atrial fibrillation. Atrial fibrillation is a condition in which disordered electrical activity causes the atria to contract in a rapid, unsynchronized and uncoordinated fashion. This inefficient contraction results in a smaller amount of blood entering the ventricles, which in turn results in an insufficient level of circulation. Since blood is not pumped completely out of the atria, the blood can pool and clot. While not immediately life threatening, atrial fibrillation can lead to significant health threats, such as stroke. Over time, poorly functioning atria can also cause the ventricles to work harder, wear out sooner, and eventually lead to cardiac arrest.

Common forms of treatment for atrial fibrillation include cardioversion and drug therapies. During cardioversion, a defibrillator delivers electrical current that is synchronized with a patient's heartbeat to return the atria to a normal rhythm. Cardioversion is usually an elective therapy, scheduled and performed in a controlled environment. All of ZOLL's manual defibrillators include cardioversion capability.

*Bradycardia*. Bradycardia is a condition in which the heart beats too slowly. The principal therapies for the emergency treatment of bradycardia are drugs and temporary cardiac pacing, either or both of which may be used to stimulate effective cardiac contractions and restore circulation. Cardiac pacing utilizes an electrical pulse to stimulate the patient's heartbeat. For the emergency treatment of bradycardia, there are two primary techniques



#### **Table of Contents**

for temporary pacing: invasive endocardial pacing, in which a wire is inserted directly into the heart to provide the electrical stimulus; and noninvasive temporary pacing, which uses gelled electrodes applied to the patient's chest to conduct an electrical stimulus. Non-invasive temporary pacing is an option on most ZOLL defibrillators and is recommended as the first intervention for bradycardia in the AHA's resuscitation protocols.

#### Traumatic Injury and its Effects

Trauma is widely recognized as a major health problem and the third leading cause of death in the U.S. In 2002, there were over 161,000 fatal injuries in the United States. Severe injury is the number one killer of both children and young adults up to age 44. As a disease of young people, it is also the leading cause of life years lost. The leading causes of death following traumatic injury are brain injury, blood loss, and organ failure from excessive inflammation. SCA can also occur in trauma patients.

In 2000, a workshop known as the Post-Resuscitative and Initial Utility in Life-Saving Efforts (PULSE), convened to address resuscitation research in the areas of SCA and injury from trauma. The PULSE report, published in *Circulation*, noted that earlier and better CPR, rapid defibrillation, and earlier hemorrhage control will lead to improvements in survival. One recommendation made was that "technology-based methodologies for monitoring and performing resuscitation should be improved," along with the use of "new and novel devices to produce blood flow during cardiac arrest."

#### Recent Developments and New Research in the Areas of Emergency Cardiovascular Care and CPR Performance

Officially named the 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, the 2005 AHA Guidelines provide recommendations about how lay rescuers and healthcare providers should resuscitate victims of cardiovascular emergencies, including SCA, which is fatal within minutes of onset, if not treated with CPR and/or defibrillation. The Guidelines, which began in the early 1990s, are updated every five years to reflect advancements in resuscitation research and the science. The European Resuscitation Council (ERC) also releases updated Guidelines every five years in conjunction with the AHA.

A major theme in the latest release is the emphasis on performing effective, high-quality CPR. According to the AHA and the ERC, the new focus resulted from studies that showed that "blood circulation increases with each chest compression in a series and must be built back up after interruptions." In addition, the authors of the Guidelines noticed a "striking" difference between data showing the critical role of early, high-quality CPR in increasing cardiac arrest survival rates, and data showing that few victims of cardiac arrest receive CPR—with even fewer receiving high-quality CPR.

The AHA and the ERC also maintain that early CPR can quickly return oxygen-rich blood to the heart and throughout the body. In addition, when CPR is performed in conjunction with defibrillation, which is indicated in approximately 50% of collapsed victims, it can help restore normal heart rhythm, which can double a victim's chance of survival, especially for the 75-80% who suffer cardiac arrest at home. Indeed, without immediate intervention, an SCA victim has only about a 5% chance of survival. But if CPR and defibrillation are provided within the first three minutes after collapse, survival rates can reach as high as 75%.

#### The Resuscitation Technology Market

The Company develops technologies that help clinicians, EMS personnel and lay rescuers advance and improve the practice of resuscitation. In order to advance resuscitation practices, the Company believes it must provide technology that addresses various clinical interventions that are part of resuscitation efforts. These include the following:

Pacing, which helps regulate the heartbeat when the heart's natural native pacemaker is not fast enough, or if blocks in the heart's electrical system prevent impulses from reaching the ventricles. ZOLL has been a leader in pacing technology since its first commercial product was released in 1984.



# DOCKET A L A R M



# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

# **Real-Time Litigation Alerts**



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## **Advanced Docket Research**



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

# **Analytics At Your Fingertips**



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

### API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

#### LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

#### FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

#### E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.