

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**FORM 10-K**

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

For the fiscal year ended December 31, 2012

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_ .

Commission file number: 0-31271

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**RTI BIOLOGICS, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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**Item 1A. RISK FACTORS**

*An investment in our common stock involves a high degree of risk. You should consider each of the risks and uncertainties described in this section and all of the other information in this document before deciding to invest in our common stock. Any of the risk factors we describe below could severely harm our business, financial condition and results of operations. The market price of our common stock could decline if any of these risks or uncertainties develops into actual events. You may lose all or part of the money you pay to buy our common stock.*

***We depend heavily upon sources of human tissue, and any failure to obtain tissue from these sources in a timely manner will interfere with our ability to process and distribute allografts.***

**The supply of human tissue has at times limited our growth,** and may not be sufficient to meet our future needs. In addition, due to seasonal changes in mortality rates, some scarce tissues that we currently use for allografts are at times in particularly short supply. Other factors, some of which are unpredictable, such as negative publicity and regulatory actions in the industry in which we operate also could unexpectedly reduce the available supply of tissue.

We rely on donor recovery groups for their human tissue supplies and we have relationships with over thirty tissue donor recovery agencies across the country. We also have relationships outside the United States. Donor recovery groups are part of relatively complex relationships. They provide support to donor families, are regulated by the FDA, and are often affiliated with hospitals, universities or organ procurement organizations. Our

relationships with donor recovery groups, which are critical to our supply of tissue, could be affected by relationships recovery groups have with other organizations. Any negative impact of the regulatory and disease transmission issues facing the industry, as well as the negative publicity that these issues create, could adversely affect our ability to negotiate contracts with recovery groups.

We cannot be sure that the supply of human tissue will continue to be available at current levels or will be sufficient to meet our needs. If we are not able to obtain tissue from current sources sufficient to meet our needs, we may not be able to locate additional replacement sources of tissue on commercially reasonable terms, if at all. Any interruption of our business caused by the need to locate additional sources of tissue would significantly impact our revenues. We expect that our revenues would decline in proportion to any decline in tissue supply.

***If we fail to maintain existing strategic relationships or are unable to identify distributors of our implants, revenues may decrease.***

We currently derive the majority of our revenues through our relationships with Medtronic, Zimmer, Davol, Stryker and Exactech. In addition, our spine distributors provide nearly all of the instrumentation, surgeon training, distribution assistance and marketing materials for the lines of spinal allografts they distribute.

Variations in the timing and volume of orders by Medtronic and Zimmer may have a material effect upon our revenues. If our relationships with Medtronic or Zimmer are terminated or reduced for any reason and we are unable to replace these relationships with other means of distribution, we would suffer a material decrease in revenues.

We may need to obtain the assistance of additional distributors to market and distribute our new allografts and technologies, as well as to market and distribute our existing allografts and technologies to new markets or geographical areas. We may not be able to find additional distributors who will agree to and successfully market and distribute our allografts and technologies on commercially reasonable terms, if at all. If we are unable to establish additional distribution relationships on favorable terms, our revenues may decline.

***If third-party payors fail to provide appropriate levels of reimbursement for the use of our implants, revenues could be adversely affected.***

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental change. In March 2010, President Obama signed the Affordable Care Act into law. The new law will result in sweeping changes across the health care industry. The primary goal of this comprehensive legislation is to extend health coverage to approximately 32 million uninsured legal U.S. residents through a combination of public program expansion and private sector health insurance reforms. To fund the expansion of insurance coverage, the legislation contains measures designed to promote quality and cost efficiency in health care delivery and to generate budgetary savings in the Medicare and Medicaid programs. We are unable to predict the full impact of the Affordable Care Act at this time due to the law's complexity and current lack of implementing regulations or interpretive guidance. However, we expect that several provisions of the Affordable Care Act could have a material effect on our business.

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Our revenues will largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Governments and private insurers closely examine medical procedures incorporating new technologies to determine whether the procedures will be covered by payment, and if so, the level of payment which may apply. We cannot be sure that third-party payors will continue to reimburse for our implants at the current levels.

***If we fail to maintain the high processing standards that implants require or if we are unable to develop processing capacity as required, our commercial opportunity will be reduced or eliminated.***