REGENERATION TECHNOLOGIES INC
Form 424B3
October 03, 2005
Table of Contents

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-128231

Prospectus

2,800,000 Shares

Common Stock

REGENERATION TECHNOLOGIES, INC.

This prospectus covers the offering and sale or other disposition of an aggregate of 2,800,000 shares of our common stock, or interests therein, by the selling stockholders listed in this prospectus. These selling stockholders acquired their common stock in a private placement transaction completed on August 29, 2005.

The selling stockholders may dispose of the common stock covered hereby, or interests therein, through public or private transactions, at prevailing market prices, at prices related to prevailing market prices, or at privately negotiated prices. We will not receive any of the proceeds from the sale or other disposition of these shares, or interests therein.

Our common stock trades on the Nasdaq National Market under the ticker symbol RTIX. On September 30, 2005, the closing sale price of our common stock was $8.17.

SEE RISK FACTORS BEGINNING ON PAGE 3 FOR A DISCUSSION OF CERTAIN RISKS AND UNCERTAINTIES THAT YOU SHOULD CONSIDER BEFORE YOU INVEST IN THE SHARES BEING SOLD WITH THIS PROSPECTUS.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this Prospectus is October 3, 2005.

Table of Contents

TABLE OF CONTENTS

	Page
Our Company	1
Risk Factors	3
Special Note Regarding Forward-Looking Statements	9
Use of Proceeds	9
Dividend Policy	9
Selling Stockholders	9
Plan of Distribution	11
Legal Matters	12
Experts	13
Where You Can Find More Information	13
Incorporation of Certain Documents by Reference	13

We have not authorized any person to make a statement that differs from what is in this prospectus. If any person does make a statement that differs from what is in this prospectus, you should not rely on it. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state in which the offer or sale is not permitted. The information in this prospectus is complete and accurate as of its date, but this information may change after that date.

Table of Contents

OUR COMPANY

This summary provides an overview of selected information and does not contain all the information you should consider. You should carefully read the entire prospectus, including the section entitled Risk Factors and the information incorporated by reference from our public filings with the Securities and Exchange Commission, before making an investment decision.

We are a leader in the use of natural tissues and innovative technologies to produce allografts that repair and promote the natural healing of human bone and other human tissues and improve surgical outcomes. We process human musculoskeletal and other tissue, including bone, cartilage, tendon, ligament, dermal and cardiovascular tissue in producing our allografts. Surgeons then use these tissues to repair and promote the healing of a wide variety of bone and other tissue defects, including spinal vertebrae repair, musculoskeletal reconstruction, fracture repair, repairs to the jaw and related tissues, and heart valve disorders, among other conditions. Our allografts are distributed in all 50 states and in ten countries.

We provide a comprehensive portfolio of natural tissue products in a broad range of markets. We separate our allografts into four primary product lines within musculoskeletal and cardiovascular surgeries: spinal, sports medicine, cardiovascular and other general orthopedic applications. The following table outlines the product lines we serve and the amount and percentage of our net revenues for the years ended December 31, 2004, 2003 and 2002:

	Year Ended December 31,					
	2004		2003		2002	
	(In thousands)					
Spinal	$ 60,611	65.4%	$ 46,159	61.1%	$ 37,971	55.0%
Sports medicine	9,002	9.7%	8,855	11.8%	10,028	14.5%
Cardiovascular	7,355	7.9%	5,141	6.8%	3,426	5.0%
General orthopedic	12,882	13.9%	13,144	17.4%	16,119	23.3%
Other non-tissue	2,853	3.1%	2,211	2.9%	1,516	2.2%
Total	$ 92,703	100.0%	$ 75,510	100.0%	$ 69,060	100.0%

We distribute our allografts both within and outside the United States. Foreign distribution, primarily in Korea and Europe, accounted for 5.7%, 7.6% and 6.5% of our net revenues during the years ended December 31, 2004, 2003 and 2002, respectively.

We pursue a market-by-market approach to the distribution of our allografts, and establish strategic distribution arrangements in order to increase our penetration in selected markets. We have exclusive distribution arrangements with Medtronic Sofamor Danek in the North American spinal market, Exactech, Inc. for our bone paste implants for general orthopedic uses, C.R. Bard, Inc. for certain urological applications for general orthopedic uses and ATS Medical, Inc. in the cardiovascular market. In other markets that our allografts serve, we use a network of our own distribution personnel and independent distributors.

Our BioCleanse® process is a patented tissue sterilization process that is designed to add a measure of safety to our bone allografts by sterilizing the tissue and providing surgeons and patients allograft implants that are free of spores, fungi, bacteria and viruses. Before tissues are processed using the BioCleanse® process, tissue recovery agencies perform a risk assessment on every potential donor, interview family members and evaluate the donor s medical records. All collected tissue is tested for the presence of viral or bacterial diseases. Bone tissue is sterilized through the BioCleanse® process only after it has passed this screening and testing. The BioCleanse® process is an automated multi-step cleansing process which first removes blood and fats, then chemically sterilizes the tissue, while maintaining the structural integrity and biocompatibility of the tissue. We believe that BioCleanse®

Table of Contents

is the industry leading sterilization process and BioCleanse® is the only tissue sterilization process for allografts that has been reviewed by the FDA.

On July 17, 2003, we were approved for accreditation by the American Association of Tissue Banks, or AATB, a nationally recognized association of the tissue banking industry. The accreditation covers the processing, storage and distribution of musculoskeletal tissue for transplantation research and informs users of our tissue that we are in compliance with the minimum safety guidelines of the association. Accreditation is for a three-year term, after which we will apply for renewal.

On June 15, 2005, we announced that our STERLING® Interference Screw ST received clearance from the FDA. The xenograft interference screw is intended for use in an arthroscopic or open ACL and /or PCL reconstruction. The implant has a long-term absorption rate, which is intended to ensure secure graft fixation throughout the healing process, and pullout strength is comparable to metal interference screws. It also offers the benefits of our patented BioCleanse® tissue sterilization process, which enables delivery of xenograft implants that are sterile with improved biocompatibility and preserved structural integrity.

On August 17, 2005, we announced that our STERLING® Cancellous Chips and Cancellous Cubes received 510(k) clearance from the FDA. The xenograft chips and cubes are intended to be placed in bony voids or gaps of a patient s skeletal system as a void filler due to surgery or traumatic injury. They provide a scaffold for bone healing and incorporate into the patient s own bone. They also offer the benefits of our patented BioCleanse® tissue sterilization process.

We continue to seek 510(k) applications for additional xenograft implants for our product lines and expect to make STERLING® Interference Screw ST, Cancellous Chips and Cancellous Cubes available for distribution in late 2005.

RECENT EVENTS

Equity Financing

On August 29, 2005, we completed a private placement of our common stock resulting in net proceeds to us of approximately $22.4 million. We sold 2.8 million shares of common stock at $8.55 per share pursuant to a stock purchase agreement between us and the purchasers in the private placement. We used $3 million of the net proceeds from the financing to repay short-term debt outstanding under our long-term financing agreement with a major financial institution. Due in large part to this financing, as of September 8, 2005, we had approximately $21.3 million of available cash, up from $4.7 million as of June 30, 2005.

As part of this financing, we also entered into a registration rights agreement with the purchasers in the private placement. The registration rights agreement provides that we must file a registration statement covering the resale of the shares within 30 days of the closing date. In the event that the registration statement is not declared effective within 90 days after August 29, 2005, we will be liable for cash damages of 1.0% of the aggregate purchase price for each 30-day period or pro rata for any portion thereof following the date by when the registration statement should have been filed or declared effective.

We have agreed to prepare and file any amendments and supplements to the registration statement relating to these shares as may be necessary to keep the registration statement effective until the earlier of: (i) the date on which all of the shares covered by this prospectus have been sold, and (ii) the date on which all of the shares covered by this prospectus may be sold pursuant to Rule 144(k) under the Securities Act of 1933, as amended.

CORPORATE INFORMATION

We were incorporated in 1997 in Florida as a wholly-owned subsidiary of the University of Florida Tissue Bank, or UFTB. We began operations on February 12, 1998 when UFTB contributed to us its allograft manufacturing and processing operations, related equipment and technologies, distribution arrangements, research and development activities and certain other assets. At the time of our initial public offering in August 2000, we reincorporated in the State of Delaware. Our principal offices are located at 11621 Research Circle, Alachua, Florida, and our phone number is (386) 418-8888. Our Internet address is www.rtix.com. The information contained on our website is not a part of this prospectus.

Table of Contents

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 develop into actual events. You may lose all or part of the money you pay to buy our common stock.

We depend heavily upon a limited number of 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 limited 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 use for our allografts are at times in particularly short supply. Other factors, some of which are unpredictable, such as negative publicity and regulatory actions in our industry also can unexpectedly reduce the available supply of tissue.

We rely on donor recovery groups for our tissue supply. 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 groups. Our relationships with donor recovery groups, which are critical to our supply of tissue, can be affected by relationships they 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 have an impact on our ability to negotiate favorable contracts with recovery groups.

Southeast Tissue Alliance, or SETA, our largest donor recovery group, supplied us with approximately 27% of our total tissue for the year ended December 31, 2004. Our three largest recovery groups together supplied approximately 51% of our total tissue for the year ended December 31, 2004. If we were to lose any one of these three sources of tissue, the impact on our operating results would be material.

We cannot be sure that our supply of tissue will continue to be available at current levels or will be sufficient to meet our needs. If we are no longer able to obtain tissue from our 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 hurt our revenues. We expect our revenues would decline in proportion to any decline in tissue supply.

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

We currently derive the majority of our revenues through our relationships with two companies, Medtronic Sofamor Danek, or MSD, and Exactech, Inc. For the year ended December 31, 2004, we derived approximately 65%, 7%, and 6% of our net revenues from distribution by MSD, Stryker Endoscopy (a former distributor), and Exactech, respectively.

MSD provides nearly all of the instrumentation, surgeon training, distribution assistance and marketing materials for our line of spinal allografts. If our relationship with MSD is terminated or materially reduced for any reason and we are unable to replace the relationship 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 products and technologies, as well as to market and distribute our existing products and technologies to new market segments or geographical areas. We may not be able to find additional distributors who will agree to and successfully market and distribute our products and technologies on commercially reasonable terms, if at all. If we are unable to establish new distribution relationships on favorable terms, our revenues may decline.

Our exploration of strategic alternatives had an adverse effect on our business, which may continue.

On February 17, 2005, we announced that we had engaged a major investment banking firm to explore strategic opportunities available to us which could include but are not limited to a possible sale or merger with a third party; new strategic alliances; or additional or alternative distribution models of our products.

Table of Contents

Since that time, we performed a thorough review of various strategic alternatives to enhance shareholder value. In May, 2005, we announced that our board of directors had determined that, the best alternative available to us, for our shareholders, employees and customers is to remain an independent company and continue to consider new strategic alliances or additional or alternative distribution models for our products.

During the period in which we were exploring strategic alternatives, we experienced shortfalls in expected orders from our key distributors. Donor recovery activities continued as planned which has resulted in an increase in inventories because customer orders have been well below our expectations. We believe that this slowdown was due at least in part to our evaluation of strategic alternatives.

During June and July of 2005, our revenues reached $7.0 million and $7.5 million, respectively, and are more representative of historical ordering patterns. However, if customer orders do not continue to improve from levels experienced during the first six months it would have a material adverse effect on our business.

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

Our products require careful calibration and precise, high-quality processing. Achieving precision and quality control requires skill and diligence by our personnel. If we fail to achieve and maintain these high processing standards, including avoiding processing errors, design defects or component failures:

- we could be forced to recall, withdraw or suspend distribution of our products;
- our products and technologies could fail quality assurance and performance tests;
- production and deliveries of our products could be delayed or cancelled; and
- our processing costs could increase.

Further, to be successful, we will need to manage our processing capacity related to tissue recovery and demand for our allografts. It may be difficult for us to match our processing capacity to demand due to problems related to yields, quality control and assurance, tissue availability, adequacy of control policies and procedures, and lack of skilled personnel. If we are unable to process and produce our allografts on a timely basis, at acceptable quality and costs, and in sufficient quantities, or if we experience unanticipated technological problems or delays in processing, it will reduce our net revenues and increase our cost per allograft processed.

Our products and technologies could become subject to significantly greater regulation by the FDA and state agencies, which could disrupt our business.

The FDA and several states have statutory authority to regulate allograft processing and allograft-based materials. The FDA could identify deficiencies in future inspections of our facilities or promulgate future regulatory rulings that could potentially disrupt our business, hurting our profitability.

For example, in mid-2001, the FDA reviewed our BioCleanse® process after the FDA raised concerns about the process. While the FDA concluded that the compliance portion of its review of our BioCleanse® process in January 2002 and determined we were in compliance with existing FDA requirements and that no regulatory action was warranted, the possibility always exists that the FDA could raise concerns with these or other aspects of our business. The FDA s decision, that no regulatory action was warranted, does not constitute a formal approval of our BioCleanse® process and the FDA is free to raise the same or similar concerns in the future.

If any of our products fall under the FDA s definitions of more than minimally manipulated or indicated for nonhomologous use, we would be required to obtain medical device approval or clearance or biologics licenses, which could require clinical testing. Disapproval of our license applications and restricted distribution of any of our products, which may become subject to pre-market approval, may result. The FDA could require post-market testing and surveillance to monitor the effects of such products, could restrict the commercial applications of these products, and could conduct periodic inspections of our facility and our suppliers facilities. Delays encountered

Table of Contents

during the FDA approval process could shorten the patent protection period during which we have the exclusive right to commercialize such technologies or could allow others to come to market with similar technologies before us.

FDA regulations of human cellular and tissue-based products, titled Good Tissue Practices, went into full force as of May 2005, and regulate all stages of allograft processing, from procurement of tissue to distribution of final allografts. These regulations will potentially increase regulatory scrutiny within our industry and this could lead to increased enforcement action affecting the conduct of our business. In addition, the effect of these regulations on recovery agencies which supply us with tissue may be significant and lead to additional costs of recovery activities. These costs may translate into increased costs to us, as we compensate the recovery agencies based on their cost of recovery.

Other regulatory entities include state agencies with statutes covering tissue banking. Of particular relevance to our business are regulations issued by Florida, New York, California and Maryland. Most states do not currently have tissue banking regulations. However, recent incidents of allograft related infections in the industry may stimulate the development of regulation in other states. It is possible that others may make allegations against us or against donor recovery groups or tissue banks, including those with which we have a relationship, about non-compliance with applicable FDA regulations or other relevant statutes and regulations. Allegations of this nature could cause regulators or other authorities to take investigative or other action, or could cause negative publicity for our business and our industry.

Our industry is subject to additional local, state, federal and international government regulations and any increased regulations of our current or future activities could significantly increase the cost of doing business, thereby reducing our profitability.

Some aspects of our business are subject to additional local, state, federal or international regulation. Changes in the laws or new interpretations of existing laws could negatively affect our business, revenues or prospects, and increase the costs associated with conducting our business. In particular, the procurement and transplantation of allograft tissue is subject to federal regulation under the National Organ Transplant Act, or NOTA, a criminal statute that prohibits the purchase and sale of human organs, including bone and other tissue. NOTA permits the payment of reasonable expenses associated with the transportation, processing, preservation, quality control and storage of human tissue, which are the types of services we perform. If in the future NOTA were amended or interpreted in a way that made us unable to include some of these costs in the amounts we charge our customers, it could reduce our revenues and therefore hurt our business. It is possible that more restrictive interpretations or expansions of NOTA could be adopted in the future which could require us to change one or more aspects of our business, at a substantial cost, in order to continue to comply with this statute.

A variety of additional local, state, federal and international government laws and regulations govern our business, including those relating to the storage, handling, generation, manufacture and disposal of medical wastes from the processing of tissue. If we fail to conduct our business in compliance with these laws and regulations, we could be subject to significant liabilities. We could be subject to significant liabilities arising from hazardous biological materials for which our insurance may not be adequate. Moreover, such insurance may not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so, which could harm our financial condition and liquidity.

Our success will depend on the continued acceptance of our products and technologies by the medical community.

Our new products, technologies or enhancements to existing products may never achieve broad market acceptance, which can be affected by numerous factors, including:

lack of clinical acceptance of our products and technologies;

introduction of competitive tissue repair treatment options which render our products and technologies too expensive or obsolete;

lack of availability of third-party reimbursement; and

difficulty training surgeons in the use of our products and technologies.

Table of Contents

Market acceptance will also depend on our ability to demonstrate that our existing and new products and technologies are an attractive alternative to existing tissue repair treatment options. Our ability to do so will depend on surgeons evaluations of the clinical safety, efficacy, ease of use, reliability and cost-effectiveness of these tissue repair options and technologies. For example, we believe that some in the medical community have lingering concerns over the risk of disease transmission through the use of tissue products.

Furthermore, we believe that even if the medical community generally accepts our products and technologies, recommendations and endorsements by influential surgeons will be important to the commercial success of our products and technologies. If our products and technologies are not broadly accepted in the marketplace, we may not achieve a competitive position in the market.

Rapid technological changes will affect us and our customers, which could result in reduced demand for our products.

Technologies change rapidly in our industry and there are frequent introductions of new technologies. For example, steady improvements have been made in synthetic human tissue substitutes which compete with our allografts. Unlike allografts, synthetic tissue technologies are not dependent on the availability of human tissue. If one of our competitors successfully introduces synthetic technologies using recombinant technologies, which stimulate the growth of tissue surrounding an implant, it could result in a decline in demand for allografts. Although our growth strategy contemplates introducing new products and technologies, the development of these new products and technologies is a complex and uncertain process, requiring a high level of innovation, as well as the ability to accurately predict future technology and market trends. The products we currently have in development will require significant additional development, investment and testing. We may need to undertake costly and time-consuming efforts to achieve these objectives. We may not be able to respond effectively to technological changes and emerging industry standards, or to successfully identify, develop or support new technologies or enhancements to existing products in a timely and cost-effective manner, if at all. If we are unable to achieve the improvements in our products necessary for their successful commercialization, the demand for our products will decline.

We face intense competition, which could result in reduced acceptance and demand for our products and technologies.

The medical technology/biotechnology industry is intensely competitive. We compete with companies in the United States and internationally that engage in the development and production of medical technologies and processes including:

- biotechnology, orthopedic, cardiovascular, pharmaceutical, biomaterial and other companies;
- academic and scientific institutions; and
- public and private research organizations.

Many of our competitors have much greater financial, technical, research, marketing, distribution, service and other resources than we have. Moreover, our competitors may offer a broader array of tissue repair treatment products and technologies or may have greater name recognition than we do in the marketplace. For example, we compete with a number of divisions of Johnson & Johnson, a company with significantly greater resources and brand recognition than we have. Our competitors, including several development stage companies, may develop or market technologies that are more effective or commercially attractive than ours, or that may render our technologies obsolete. For example, the successful development of a synthetic tissue product that permits remodeling of bones could result in a decline in the demand for allograft-based

products and technologies.

If we do not manage the medical release of donor tissue into processing in an efficient manner, it could affect our profitability.

There are many factors which affect the level and timing of donor medical releases, such as effectiveness of donor screening performed by our donor recovery groups, the timely receipt, recording and review of required medical documentation, and employee loss and turnover in our medical records department. Some of our donor

Table of Contents

recovery groups are also processors who provide us with partially processed tissues which they have already determined to be medically suitable for processing. Therefore, these sources provide a higher level of documentation than those that perform donor recovery alone. Although we strive for the timely medical release of tissue, while at the same time maximizing safety for our employees and for tissue recipients, our internal policies may sacrifice timely release of tissue in favor of safety. We continue to review our internal policies in order to provide the best framework for medical releases, however we can provide no assurance that releases will occur at levels which maximize our processing efficiency and minimize our cost per allograft processed.

Negative publicity concerning methods of tissue recovery and screening of donor tissue in our industry could reduce demand for our allografts and impact the supply of available donor tissue.

Media reports or other negative publicity concerning both improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of our allografts. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft technologies.

Potential patients may not distinguish our allografts, technologies and the tissue recovery and the processing procedures we have in place, from those of our competitors or others engaged in tissue recovery. In addition, families of potential donors may become reluctant to agree to donate tissue to for-profit tissue processors.

If our patents and the other means we use to protect our intellectual property prove to be inadequate, our competitors could exploit our intellectual property to compete more effectively against us.

The law of patents and trade secrets is constantly evolving and often involves complex legal and factual questions. The U.S. government may deny or significantly reduce the coverage we seek in our patent applications before or after a patent is issued. We therefore cannot be sure that any particular patent we apply for will be issued, that the scope of the patent protection will be comprehensive enough to provide adequate protection from similar technologies which may compete with ours, that interference proceedings regarding any of our patent applications will not be filed, or that we will achieve any other competitive advantage from a patent. In addition, it is possible that one or more of our patents will be held invalid if challenged or that others will claim rights in or ownership of our patents and other proprietary rights. If any of these events occur, our competitors may be able to use our intellectual property to compete more effectively against us.

Because patent applications are secret until patents are actually issued (or until 18 months after a patent application has been filed) and the publication of discoveries in the scientific or patent literature lags behind actual discoveries, we cannot be certain that our patent application was the first application filed covering a particular invention. If another party s rights to an invention are superior to ours, we may not be able to obtain a license to use that party s invention on commercially reasonable terms, if at all. In addition, our competitors, many of which have greater resources than we do, could obtain patents that will prevent, limit or interfere with our ability to make use of our inventions either in the United States or in international markets. Further, the laws of some foreign countries do not always protect our intellectual property rights to the same extent as the laws of the United States. Litigation or regulatory proceedings in the United States or foreign countries also may be necessary to enforce our patent or other intellectual property rights or to determine the scope and validity of our competitors proprietary rights. These proceedings can be costly, result in development delays, and divert our management s attention from our business.

We also rely upon unpatented proprietary techniques and processes in tissue recovery, research and development, tissue processing and quality assurance. It is possible that others will independently develop technology similar to ours or otherwise gain access to or disclose our proprietary

technologies. We may not be able to meaningfully protect our rights in these proprietary technologies, which would reduce our ability to compete.

In 1996, a law was passed in the United States that limits the enforcement of patents covering the performance of surgical or medical procedures on a human body. This law prevents medical practitioners and health care entities who practice these procedures, not otherwise covered by a patented procedure, from being sued for patent infringement. Therefore, depending upon how these limitations are interpreted by the courts, they could have a material adverse effect on our ability to enforce any of our proprietary methods or procedures deemed to be surgical or medical procedures.

Table of Contents

Our success will depend in part on our ability to operate without infringing on or misappropriating the proprietary rights of others, and if we are unable to do so we may be liable for damages.

We cannot be certain that U.S. or foreign patents or patent applications of other companies do not exist or will not be issued that would prevent us from commercializing our products and technologies. Third parties may demand license fees or sue us for infringing or misappropriating their patent or other intellectual property rights. Intellectual property litigation is costly. If we do not prevail in litigation, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license requiring us to make royalty payments. It is possible that a required license will not be available to us on commercially acceptable terms, if at all. In addition, a required license may be non-exclusive, and therefore our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around another company s patent, we may be unable to make use of some of the affected technologies or distribute the affected products which would negatively impact our revenues.

We or our competitors may be exposed to product liability claims which could cause us to be liable for damages or cause investors to think we will be liable for similar claims in the future.

The development of allografts and technologies for human tissue repair and treatment entails an inherent risk of product liability claims, and substantial product liability claims may be asserted against us. We may not have adequate insurance coverage for any future claims that arise. Moreover, insurance covering our business may not always be available in the future on commercially reasonable terms, if at all. If our insurance proves to be inadequate to pay a damage award, we may not have sufficient funds to do so, which would harm our financial condition and liquidity. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. In addition, claims against us, regardless of their merit or potential outcome, may also hurt our ability to obtain surgeon endorsement of our allografts or to expand our business.

If we are not successful in expanding our distribution activities into international markets, we will not be able to pursue one of our strategies for increasing our revenues.

Our current and planned international distribution strategies vary by market, as well as within each country in which we operate. For example, we distribute only a portion of our line of allografts within each country. Our international operations will be subject to a number of risks which may vary from the risks we face in the United States, including:

- the need to obtain regulatory approvals in additional foreign countries before we can offer our grafts and technologies for use;
- longer distribution-to-collection cycles, as well as difficulty in collecting amounts owed to us;
- dependence on local distributors;
- limited protection of intellectual property rights;
- fluctuations in the values of foreign currencies; and

political and economic instability.

Table of Contents

The value of our investment in Organ Recovery Systems, Inc. is dependent on the financial success of this venture.

We own 1,285,347 shares of convertible preferred stock issued by Organ Recovery Systems, Inc., or ORS, a privately held company, for which the purchase price was $5.25 million. ORS is organized for the purpose of advancing organ transplantation technology. Realization of our investment in ORS is dependent upon ORS s successful execution of its operational strategies and the continued industry acceptance of its current and future product developments. If ORS does not successfully execute its operational strategies and recognize long-term profitability, the value of our investment could be impaired which could have a negative effect on our financial statements for the period in which the impairment occurs.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains some forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995 and information relating to us that are based on the beliefs of our management, as well as assumptions made by and the information currently available to our management. When used in this prospectus, the words estimate, project, believe, anticipate, intend, expect, continue and similar expres intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in these forward-looking statements, including those risks discussed in this prospectus.

You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. Except for special circumstances in which a duty to update arises when prior disclosure becomes materially misleading in light of subsequent events, we do not intend to update any of these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

USE OF PROCEEDS

We will not receive any proceeds from the sale or other disposition by the selling stockholders of the shares of common stock covered hereby, or interests therein.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our stock. We do not expect to declare or pay any dividends on our common stock in the foreseeable future. In addition, our existing bank credit facility restricts our ability to pay dividends. The payment of future dividends is within the discretion of our board of directors and will depend on our future earnings, if any, our capital requirements, financial condition and other relevant factors.

SELLING STOCKHOLDERS

The following table sets forth information regarding the number of shares of our common stock beneficially owned by each of the selling stockholders as of October 3, 2005. The selling stockholders received their shares of common stock being registered in this registration statement in a private placement transaction completed on August 29, 2005. Except as set forth below, no selling stockholder has held any position or office or had any material relationship with us or any of our predecessors or affiliates within the past three years. No estimate can be given as to the amount of our common stock that will be beneficially owned by the selling stockholders after completion of this offering because the selling stockholders may offer all, some or none of the shares of our common stock covered hereby.

Table of Contents

Selling Stockholder	Shares of Common Stock Beneficially Owned Prior to Offering	Number of Shares of Common Stock Registered Herein	Shares of Common Stock Beneficially Owned After Offering (1)	
			Number	Percent
Kane & Co. (2)	7,300	7,300	0	*
Booth & Co. (3)	96,400	96,400	0	*
Gerlach & Co. (4)	666,900	666,900	0	*
Gerlach & Co. (5)	79,400	79,400	0	*
Henry C. Beinstein	37,497	23,392	14,015	*
Upland Associates L.P.	106,783	46,783	60,000	*
Neil J. Gagnon (6)	2,736,310	152,047	2,266,485	7.7
Lois E. Gagnon	340,495	101,403	239,092	*
The Lois E. and Neil J. Gagnon Foundation	134,640	40,935	93,705	*
Gagnon Family Partnership	109,931	29,240	80,691	*
Gagnon Investment Associates	407,770	116,960	290,810	1.0
Gagnon 1999 Grandchildren s Trust STS 2/1/99 Maureen Drew, TTEE	99,178	29,240	69,938	*
Zeke L.P.	300,000	300,000	0	*
MedCap Partners L.P.	300,000	300,000	0	*
MedCap Master Fund L.P.	50,000	50,000	0	*
Capital Ventures International	160,000	160,000	0	*
Special Situation Cayman Fund L.P. (7)	224,100	120,000	104,100	*
Special Situation Fund III L.P. (7)	857,784	480,000	377,784	1.3

* Represents less than 1%

(1) Assumes all shares registered pursuant to this prospectus will be sold.

(2) The shares purchased by OFIL PLC U.S. Emerging Growth Fund in the private placement completed on August 29, 2005 are registered in this nominee name.

(3) The shares purchased by USAZ Oppenheimer Emerging Growth Fund in the private placement completed on August 29, 2005 are registered in this nominee name.

(4) The shares purchased by Oppenheimer Discovery Fund in the private placement completed on August 29, 2005 are registered in this nominee name.

(5) The shares purchased by Oppenheimer Emerging Growth Fund in the private placement completed on August 29, 2005 are registered in this nominee name.

(6) Neil Gagnon beneficially owned 2,736,310 shares of Common Stock of Regeneration Technologies, Inc., which amount included (i) 619,127 shares beneficially owned by Mr. Gagnon over which he had sole voting and sole dispositive power; (ii) 49,765* shares beneficially owned by Mr. Gagnon over which he had sole voting power and shared dispositive power; (iii) 340,495 shares beneficially owned by Lois Gagnon, Mr. Gagnon s wife, over which he had shared voting and shared dispositive power; (iv) 4,255* shares beneficially owed by Mr. Gagnon and Mrs.

10

Table of Contents

Gagnon as Joint Tenants with Rights of Survivorship, over which he had shared voting and shared dispositive power; (v) 134,640 shares held by the Lois E. and Neil E. Gagnon Foundation, of which Mr. Gagnon was a trustee and over which he had shared voting and shared dispositive power; (vi) 109,931 shares held by the Gagnon Family Limited Partnership of which Mr. Gagnon was a partner and over which he had shared voting and shared dispositive power; (vii) 99,178 shares held by the Gagnon Grandchildren Trust over which Mr. Gagnon had shared dispositive but no voting power; (viii) 407,770 shares held by a hedge fund (of which Mr. Gagnon was a general partner) over which Mr. Gagnon had sole dispositive and sole voting power; (ix) 3,082* shares held by the Gagnon Securities LLC P/S Plan (the Plan) (of which Mr. Gagnon was a Trustee) over which Mr. Gagnon had sole dispositive and sole voting power; (x) 2,445* shares held by the Plan, over which Mr. Gagnon had shared dispositive and sole voting power; and (xi) 965,622* shares held for certain customers of Gagnon Securities LLC (of which Mr. Gagnon was the Managing Member and the principal owner) over which Mr. Gagnon had shared dispositive but no voting power. Share information above followed by * was derived from Amendment No. 2 to Schedule 13G filed by Neil Gagnon dated December 31, 2004.

(7) MGP Advisors Limited, or MGP, is the general partner of Special Situations Fund III, L.P. AWM Investment Company, Inc., or AWM, is the general partner of MGP and the general partner of and investment adviser to the Special Situations Cayman Fund, L.P. Austin W. Marxe and David M. Greenhouse are the principal owners of MGP and AWM. Through their control of MGP and AWM, Messrs. Marxe and Greenhouse share voting and investment control over the portfolio securities of each of the funds listed above.

PLAN OF DISTRIBUTION

We are registering the shares of our common stock on behalf of the selling stockholders, which as used herein, includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer. We are paying all costs, expenses and fees in connection with the registration of the shares offered by this prospectus. Brokerage commissions, if any, attributable to the sale of shares will be borne by the selling stockholders.

The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale or other disposition. These transactions may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and under terms then prevailing or at prices related to the then current market price or in negotiated transactions. The selling stockholders may sell their shares by one or more of, or a combination of, the following methods:

- distributions by one or more underwriters on a firm commitment or best efforts basis;
- purchases by a broker-dealer as principal and resale by that broker-dealer for its own account pursuant to this prospectus;
- ordinary brokerage transactions and transactions in which the broker solicits purchasers;
- block trades in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- crosses in which the same broker acts as an agent on both sides of the trade;
- an exchange distribution in accordance with the rules of the applicable exchange;

in privately negotiated transactions;

in transactions other than on exchanges or services;

in connection with transactions to cover short sales made after the effective date of the registration statement of which this prospectus is a part;

by pledge or by grant of a security interest in the shares to secure debts and other obligations;

Table of Contents

through the writing of options, whether the options are listed on an option exchange or otherwise;

in connection with the writing of non-traded and exchange-traded call options or put options, in hedge transactions and in settlement of other transactions in standardized over-the-counter options;

through the distribution of the shares by any selling stockholder to its partners, members or stockholders; and

any other method permitted pursuant to applicable law.

In addition, the selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, if available, rather than pursuant to this prospectus.

To the extent required, we may amend or supplement this prospectus from time to time to describe a specific plan of distribution. In connection with distributions of the shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with those transactions, broker-dealers or other financial institutions may engage in short sales of the common stock in the course of hedging the positions they assume with the selling stockholders. The selling stockholders also may sell the common stock short after the effective date of the registration statement of which this prospectus is a part and re-deliver the shares to close out those short positions. The selling stockholders also may enter into option or other transactions or the creation of one or more derivative securities with broker-dealers or other financial institutions that require the delivery to the broker-dealer or other financial institution of shares offered by this prospectus, which shares the broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect those transactions). The selling stockholders also may pledge or hypothecate shares to a broker-dealer or other financial institution, and, upon a default, that broker-dealer or other financial institution may effect sales of the pledged shares pursuant to this prospectus (as supplemented or amended to reflect that transaction). In effecting sales, broker-dealers or agents engaged by the selling stockholders may arrange for other broker-dealers to participate. Broker-dealers or agents may receive commissions, discounts or concessions from the selling stockholders in amounts to be negotiated immediately prior to the sale.

The selling stockholders and any broker-dealers that act in connection with the sale of the common stock may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act of 1933, and any commission received by them and any profit on the resale of the shares of common stock as principal might be deemed to be underwriting discounts and commissions under the Securities Act of 1933. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against some liabilities, including liabilities arising under the Securities Act of 1933. Liabilities under the federal securities laws cannot be waived.

The selling stockholders will be subject to prospectus delivery requirements under the Securities Act of 1933. In the event of a distribution of shares by a selling stockholder, the selling stockholder, any selling broker or dealer and any affiliated purchasers may be subject to Regulation M under the Securities Exchange Act of 1934, which would generally prohibit these persons from bidding for or purchasing any security that is the subject of the distribution until his or her participation in that distribution is completed. In addition, Regulation M generally prohibits any stabilizing bid or stabilizing purchase for the purpose of pegging, fixing or stabilizing the price of common stock in connection with this offering.

The securities were originally sold by us to the selling stockholders on August 29, 2005 in a private placement transaction. As part of that transaction, we agree to indemnify and hold the selling stockholders harmless against certain liabilities under the Securities Act that could arise in connection with the sale of the securities by the selling stockholder. We and the selling stockholders have also agreed that we will indemnify each other against certain liabilities arising under the Securities Act.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Fulbright & Jaworski L.L.P. New York, New York.

Table of Contents

EXPERTS

The financial statements, the related financial statement schedule, and management s report on the effectiveness of internal control over financial reporting, incorporated in this prospectus by reference from the Company s Annual Report on Form 10-K of Regeneration Technologies, Inc. for the year ended December 31, 2004 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their reports, which are incorporated herein by reference, and have been so incorporated in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any materials filed by us at the SEC s Public Reference Room at 100 F Street, N.E. You may obtain information on the operation on the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. Copies of such information may also be inspected at the reading room of the library of the National Association of Securities Dealers, Inc., 1735 K Street, N.W., Washington, D.C. 20006. The SEC maintains an Internet site http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Securities and Exchange Commission.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until the selling stockholders sell all their shares of our common stock offered by this prospectus:

(i) our annual report on Form 10-K as amended by Amendment No. 1 and Amendment No. 2 on Form 10-K/A for the fiscal year ended December 31, 2004;

(ii) our proxy statement for our 2005 Annual Meeting of Stockholders filed on June 28, 2005;

(iii) our quarterly reports on Form 10-Q for the quarterly periods ended March 31, 2005 and June 30, 2005;

(iv) our current reports on Form 8-K, filed on January 25, 2005, February 22, 2005, August 1, 2005, and August 29, 2005; and

(v) the description of our common stock contained in our registration statement on Form 8-A, dated August 9, 2000.

We will furnish without charge to you, upon written or oral request, a copy of any or all of the documents described above, except for exhibits to such documents, unless such exhibits are specifically incorporated by reference into such documents. Requests should be addressed to: Regeneration Technologies, Inc., 11621 Research Circle, Alachua, FL 32615, (386) 418-8888, Attention: Investor Relations.

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The selling stockholders will not make an offer of these shares in any state where the offer is not permitted. You should not assume that information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.