ANIKA THERAPEUTICS INC
Form 10-K
March 09, 2009

Use these links to rapidly review the document

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

o **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 000-21326

Anika Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Massachusetts	**04-3145961**
(State or Other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification No.)*

32 Wiggins Avenue, Bedford, Massachusetts 01730
(Address of Principal Executive Offices) (Zip Code)

(781) 457-9000
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act: Common Stock, par value $.01 per share
Preferred Stock Purchase Rights

Name of Each Exchange on Which Registered: NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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 ý No o

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. ý

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

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No ý

The aggregate market value of voting and non-voting stock held by non-affiliates of the Registrant as of June 30, 2008, the last day of the Registrant's most recently completed second fiscal quarter, was $97,648,741 based on the close price per share of Common Stock of $8.59 as of such date as reported on the NASDAQ Global Select Market. Shares of our Common Stock held by each executive officer, director and each person or entity known to the registrant to be an affiliate have been excluded in that such persons may be deemed to be affiliates; such exclusion shall not be deemed to constitute an admission that any such person is an "affiliate" of the registrant. At March 1, 2009, there were issued and outstanding 11,377,623 shares of Common Stock, par value $.01 per share.

Documents Incorporated By Reference

The registrant intends to file a proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2008. Portions of such proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

ANIKA THERAPEUTICS, INC.
TABLE OF CONTENTS

Table of Contents

FORM 10-K
ANIKA THERAPEUTICS, INC.
For Fiscal Year Ended December 31, 2008

This Annual Report on Form 10-K, including the documents incorporated by reference into this Annual Report on Form 10-K, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding:

our future sales and product revenues, including geographic expansions, possible retroactive price adjustments, and expectations of unit volumes or other offsets to price reductions;

our manufacturing capacity and efficiency gains and work-in-process manufacturing operations;

the timing, scope and rate of patient enrollment for clinical trials;

development of possible new products;

our ability to achieve or maintain compliance with laws and regulations;

the timing of and/or receipt of the Food and Drug Administration ("FDA"), foreign or other regulatory approvals and/or reimbursement approvals of current, new or potential products, and any limitations on such approvals;

our intention to seek patent protection for our products and processes, and protect our intellectual property;

our ability to effectively compete against current and future competitors;

negotiations with potential and existing partners, including our performance under any of our existing and future distribution or supply agreements or our expectations with respect to sales and sales threshold milestones pursuant to such agreements;

the level of our revenue or sales in particular geographic areas and/or for particular products, and the market share for any of our products;

our current strategy, including our corporate objectives and research and development and collaboration opportunities;

our and Bausch & Lomb's performance under the existing supply agreement for certain of our ophthalmic viscoelastic products, and our ability to remain the exclusive global supplier for AMVISC and AMVISC Plus to Bausch & Lomb;

our expectations regarding ORTHOVISC sales, including intention to increase market share for ORTHOVISC in international and domestic markets or otherwise penetrate growing markets for osteoarthritis of the knee and other joints;

our expectations regarding next generation osteoarthritis/joint health product developments, clinical trials, regulatory approvals, and commercial launches;

our expectations regarding HYVISC sales;

our ability to license ELEVESS to a new distribution partner on terms favorable to the Company, if at all, or our ability to market ELEVESS on our own;

our expectations regarding the development and commercialization of INCERT, and the market potential for INCERT;

our expectations regarding product gross margin;

our expectations regarding the commencement of our clinical trial for CINGAL;

Table of Contents

our expectation for increases in operating expenses, including research and development and selling, general and administrative expenses;

the rate at which we use cash, the amounts used and generated by operations, and our expectation regarding the adequacy of such cash;

our expectation for capital expenditures spending and decline in interest income;

our expectations regarding our existing manufacturing facility and the new Bedford, MA facility, our expectations related to costs, including financing costs, to build-out and occupy the new facility, the timing of construction, and our ability to obtain FDA licensure for the facility;

our abilities to comply with debt covenants;

our plans to address the FDA's Warning Letter and Form 483 Notice of Observations; and

our abilities to successfully defend our ELEVESS trademark.

Furthermore, additional statements identified by words such as "will," "likely," "may," "believe," "expect," "anticipate," "intend," "seek," "designed," "develop," "would," "future," "can," "could" and other expressions that are predictions of or indicate future events and trends and which do not relate to historical matters, also identify forward-looking statements.

You should not rely on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, including those factors described in the section titled "Risk Factors" in this Annual Report on Form 10-K. These risks, uncertainties and other factors may cause our actual results, performance or achievement to be materially different from the anticipated future results, performance or achievement, expressed or implied by the forward-looking statements. These forward-looking statements are based upon the current assumptions of our management and are only expectations of future results. You should carefully review all of these factors, and you should be aware that there may be other factors that could cause these differences, including those factors discussed in the sections titled "Business" and "Management's Discussions and Analysis of Financial Condition and Results of Operations" elsewhere in this Annual Report on Form 10-K. We undertake no obligation to publicly update or revise any forward-looking statement to reflect changes in underlying assumptions or factors, of new information, future events or other changes.

Table of Contents

PART I

ITEM 1. BUSINESS

Overview

Anika Therapeutics, Inc. ("Anika," the "Company," "we," "us," or "our") was incorporated in 1992 as a Massachusetts company. Anika develops, manufactures and commercializes therapeutic products for tissue protection, healing and repair. These products are based on hyaluronic acid (HA), a naturally occurring, biocompatible polymer found throughout the body. Due to its unique biophysical and biochemical properties, HA plays an important role in a number of physiological functions such as the protection and lubrication of soft tissues and joints, the maintenance of the structural integrity of tissues, and the transport of molecules to and within cells. Our currently manufactured and marketed products consist of ORTHOVISC®, which is an HA product used in the treatment of some forms of osteoarthritis in humans; AMVISC®, AMVISC® Plus, STAARVISC -II, and ShellGel , each an injectable ophthalmic viscoelastic HA product. HYVISC®, which is an HA product used in the treatment of equine osteoarthritis, and INCERT®, an HA based anti-adhesive for surgical applications. ORTHOVISC® *mini*, a treatment for osteoarthritis targeting small joints is available in Europe. MONOVISC , a single-injection osteoarthritis product based on our proprietary cross-linking technology is available in Europe and Turkey. In the U.S., ORTHOVISC is marketed by DePuy Mitek, Inc. ("DePuy Mitek"), a subsidiary of Johnson & Johnson (collectively, "JNJ"), under the terms of a licensing, distribution, supply and marketing agreement. Outside the U.S., ORTHOVISC has been approved for sale since 1996 and is marketed by distributors in approximately 16 countries. We developed and manufacture AMVISC® and AMVISC® Plus for Bausch & Lomb Incorporated under a multiyear supply agreement. HYVISC® is marketed in the U.S. through Boehringer Ingelheim Vetmedica, Inc. INCERT® is currently marketed in three countries outside of the U.S. ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation. Our initial ELEVESS product is approved in the U.S., the European Union ("EU"), Canada and certain countries in South America, and is manufactured by Anika. We are currently seeking new distribution partners for ELEVESS both domestically and internationally. Products in development include next generation joint health related products and ELEVESS line extension products.

In 2008, revenue from the sale of our products contributed 92% of our total revenue. Licensing, milestone and contract revenue contributed 8% of our total revenue in 2008. Revenue from the sale of ophthalmic viscoelastic products was 32% of product revenue. Our joint health products contributed 57% of our product revenue, and HYVISC contributed 9% of our product revenue in 2008.

The following sections provide more specific information on our products and related activities:

Osteoarthritis Business

Osteoarthritis is a debilitating disease causing pain, swelling and restricted movement in joints. It occurs when the cartilage in a joint gradually deteriorates due to the effects of mechanical stress, which can be caused by a variety of factors including the normal aging process. In an osteoarthritic joint, particular regions of articulating surfaces are exposed to irregular forces, which result in the remodeling of tissue surfaces that disrupt the normal equilibrium or mechanical function. As osteoarthritis advances, the joint gradually loses its ability to regenerate cartilage tissue and the cartilage layer attached to the bone deteriorates to the point where eventually the bone becomes exposed. Advanced osteoarthritis often requires surgery and the possible implantation of artificial joints. The current treatment options for osteoarthritis before joint replacement surgery include viscosupplementation, analgesics, non-steroidal anti-inflammatory drugs and steroid injections.

Our joint health products include ORTHOVISC, ORTHOVISC *mini*, and MONOVISC. ORTHOVISC is available in the U.S., Canada, Turkey and some international markets for the treatment of

Table of Contents

osteoarthritis of the knee, and in Europe for the treatment of osteoarthritis in all joints. ORTHOVISC *mini* is available in Europe, and is designed for the treatment of osteoarthritis in small joints. MONOVISC is our single injection osteoarthritis treatment for all joints, and is available in Europe and Turkey. ORTHOVISC *mini* and MONOVISC are our two newest joint health products and became available during the second quarter of 2008. Our revenue from joint health products has increased 38% in 2008 from 2007.

In the U.S., ORTHOVISC is indicated for the treatment of pain caused by osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics, such as acetaminophen. ORTHOVISC has been approved for use in all joints in Europe and certain other international markets. It is a sterile, clear, viscoelastic solution of hyaluronan dissolved in physiological saline, and dispensed in a single-use syringe. A complex sugar of the glycosaminoglycan family, hyaluronan is a high molecular weight polysaccharide composed of repeating disaccharide units of sodium glucuronate and N-acetylglucosamine. ORTHOVISC is injected into joints in a series of three intra- articular injections one week apart. ORTHOVISC became available for sale in the U.S. on March 1, 2004, and is marketed by DePuy Mitek, under the terms of a ten-year licensing, distribution, supply and marketing agreement (the "JNJ Agreement").

We have a number of distribution relationships servicing international markets including Canada, Europe, Turkey, the Middle East, and Asia. We will continue to seek to establish long-term distribution relationships in other regions. See the sections captioned "*Management's Discussion and Analysis of Financial Condition and Results of Operations Management Overview*" and "*Risk Factors.*"

Ophthalmic Business

Our ophthalmic business includes HA viscoelastic products used in ophthalmic surgery. The ophthalmic products we manufacture include the AMVISC and AMVISC Plus product line, STAARVISC-II, and ShellGel. They are injectable, high molecular weight HA products used as viscoelastic agents in ophthalmic surgical procedures such as cataract extraction and intraocular lens implantation. These products coat, lubricate and protect sensitive tissue such as the endothelium, and maintain the shape of the eye, thereby facilitating ophthalmic surgical procedures.

Anika manufactures the AMVISC product line for Bausch & Lomb under the terms of a supply agreement through December 31, 2010 (the "2004 B&L Agreement") for viscoelastic products used in ophthalmic surgery. Under the 2004 B&L Agreement, we will continue to be the exclusive global supplier (other than with respect to Japan) for AMVISC and AMVISC Plus to Bausch & Lomb. The 2004 B&L Agreement also provides us with a right to negotiate to manufacture future surgical ophthalmic viscoelastic products developed by Bausch & Lomb, while Bausch & Lomb has been granted rights to commercialize certain future surgical ophthalmic viscoelastic products developed by us. Under the 2004 B&L Agreement, we are entitled to continue providing surgical viscoelastic products to our existing customers (STAAR Surgical Company and Cytosol Ophthalmics, Inc.) who currently receive such products from us. See also Item 1A. "*Risk Factors.*"

Veterinary Business

HYVISC is a high molecular weight injectable HA product for the treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis. HYVISC has viscoelastic properties that lubricate and protect the tissues in horse joints. HYVISC is distributed by Boehringer Ingelheim Vetmedica, Inc. in the United States.

Anti-adhesion Business

INCERT, approved for sale in Europe and Turkey, is designed as a family of HA based products, with chemically modified, cross-linked HA, for prevention of post-surgical adhesions. Surgical adhesions occur

Table of Contents

when fibrous bands of tissues form between adjacent tissue layers during the wound healing process. Although surgeons attempt to minimize the formation of adhesions, they nevertheless occur quite frequently after surgery. Adhesions in the abdominal and pelvic cavity can cause particularly serious problems such as intestinal blockage following abdominal surgery, and infertility following pelvic surgery. Fibrosis following spinal surgery can complicate re-operation and may cause pain. We commenced INCERT sales during the second quarter of 2006. INCERT is currently marketed in three countries. We see potential for expanded indications for the use of INCERT, but have made this a secondary goal to the successful launch and expanded distribution of our joint health and aesthetic products. There are currently no plans at this time to distribute INCERT in the U.S.

Anika co-owns issued U.S. patents covering the use of INCERT for adhesion prevention. See the section captioned "*Patent and Propriety Rights.*"

Aesthetic Dermatology Business

ELEVESS is designed as a family of aesthetic dermatology products for facial wrinkles, scar remediation and lip augmentation, and is intended to supplant collagen-based products and to compete with other HA-based products currently on the market. Our aesthetic dermatology product is a dermal filler based on our proprietary chemically modified, cross-linked HA. We received European, Canadian, and United States FDA approvals for our initial commercial product in 2007. In July 2008, we entered into a distributor agreement with Artes Medical, Inc. ("Artes") for distribution of ELEVESS in the U.S. Shipments of commercial product and sample units commenced shortly after the signing of the distribution agreement, with product launch initiated in early August 2008. Our distribution agreement with Artes was terminated in the fourth quarter of 2008 as a result of Artes' Chapter 7 bankruptcy filing. We continue to seek marketing and distribution partners to commercialize ELEVESS in key markets domestically and internationally.

See Note 15 to our consolidated financial statements, "Revenue by Product Group, by Significant Customer and by Geographic Region," for a discussion regarding our segments and geographic sales.

Research and Development of Potential Products

Our research and development efforts primarily consist of the development of new medical applications for our HA-based technology, the management of clinical trials for certain product candidates, and the preparation and processing of applications for regulatory approvals at all relevant stages of development. Our development focus includes chemically modified formulations of HA designed for longer residence time in the body. For the years ended December 31, 2008, 2007 and 2006, these expenses were $7.4 million, $4.4 million, and $3.6 million, respectively. We anticipate that we will continue to commit significant resources to research and development, including clinical trials, in the future.

Products in development include next generation joint health products. Our next generation osteoarthritis products include a single-injection treatment product that uses a non-animal source HA, and is our first osteoarthritis product based on our proprietary crosslinked HA-technology. This product has been branded as MONOVISC. We received *Conformité Européene* (CE) Mark approval for the MONOVISC product in October 2007. We launched MONOVISC in Europe during the second quarter of 2008, following a small clinical study. In the U.S., we filed an investigational device exemption, or an IDE application, with the FDA, and completed patient enrollment for our U.S. clinical trial in December of 2008. Our second single-injection osteoarthritis product is CINGAL , which is based on the same technology platform used in MONOVISC, with an added active therapeutic molecule to provide broad pain relief for a long period of time. We expect to commence a clinical trial and file an application for CE Mark for CINGAL in 2009.

There is a risk that our efforts will not be successful in (1) developing our existing product candidates, (2) expanding the therapeutic applications of our existing products, or (3) resulting in new applications for

Table of Contents

our HA technology. There is also a risk that we may choose not to pursue development of potential product candidates. We may not be able to obtain regulatory approval for any new applications we develop. Furthermore, even if all regulatory approvals are obtained, there can be no assurances that we will achieve meaningful sales of such products or applications.

Patent and Proprietary Rights

Our products and trademarks, including our Company name, product names and logos, are proprietary. We reply on a combination of patent protection, trade secrets and trademark laws, license agreements, confidentiality and other contractual provisions to protect our proprietary information.

We have a policy of seeking patent protection for patentable aspects of our proprietary technology. Our issued patents expire between 2009 and 2023. We co-own certain U.S. patents and a patent application with claims relating to the chemical modification of HA and certain adhesion prevention uses and certain drug delivery uses of HA. We also solely own patents covering composition of matter and certain manufacturing processes. We intend to seek patent protection for products and processes developed in the course of our activities when we believe such protection is in our best interest and when the cost of seeking such protection is not inordinate relative to the potential benefits. See also the section captioned "*Risk Factors We may be unable to adequately protect our intellectual property rights.*"

Other entities have filed patent applications for or have been issued patents concerning various aspects of HA-related products or processes. In addition, the products or processes we develop may infringe the patent rights of others in the future. Any such infringement may have a material adverse effect on our business, financial condition, and results of operations. See also the section captioned "*Risk Factors We may be unable to adequately protect our intellectual property rights.*"

We also rely upon trade secrets and proprietary know-how for certain non-patented aspects of our technology. To protect such information, we require certain customers and vendors, and all employees, consultants and licensees to enter into confidentiality agreements limiting the disclosure and use of such information. These agreements, however, may not provide adequate protection. See also the section captioned "*Risk Factors We may be unable to adequately protect our intellectual property rights.*"

We have granted Depuy Mitek an exclusive, non-transferable royalty bearing license to use and sell ORTHOVISC (and other products developed pursuant to the JNJ Agreement) in the U.S., as well as a license to manufacture and have manufactured such products in the event that we are unable to supply them with products in accordance with the terms of the JNJ Agreement.

Government Regulation

United States Regulation

Our research (including clinical research), development, manufacture, and marketing of products are subject to regulation by numerous governmental authorities in the U.S. and other countries. Medical devices and pharmaceuticals are subject to extensive and rigorous regulation by the FDA and by other federal, state and local authorities. The Federal Food, Drug and Cosmetic Act ("FDC Act") governs the conditions of safety, efficacy, clearance, approval, manufacture, quality system requirements, labeling, packaging, distribution, storage, record keeping, reporting, marketing, advertising, and promotion of our products. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or approval of products, withdrawal of clearances and approvals, and criminal prosecution.

Medical products regulated by the FDA are generally classified as drugs, biologics, and/or medical devices. Medical devices intended for human use are classified into three categories (Class I, II or III), on the basis of the controls deemed reasonably necessary by the FDA to assure their safety and efficacy.

Table of Contents

Class I devices are subject to general controls, for example, labeling and adherence to the FDA's Good Manufacturing Practices/Quality System Regulation ("GMP/QSR"). Most Class I devices are exempt from the FDA review process and some are exempt from Good Manufacturing Practice. Class II devices are subject to general and special controls (for example, performance standards, postmarket surveillance, and patient registries). Most Class II devices are subject to premarket notification and may be subject to clinical testing for purposes of premarket notification and clearance for marketing. Class III is the most stringent regulatory category for medical devices. Most Class III devices require premarket approval ("PMA") from the FDA. All of our existing products, with the exception of HYVISC, are subject to the applicable rules related to Class III devices.

AMVISC, AMVISC Plus, ShellGel and STAARVISC are approved as Class III medical devices in the U.S. for intraocular ophthalmic surgical procedures in intraocular use in humans. ORTHOVISC is approved as a Class III medical device in the U.S. for treatment of pain resulting from osteoarthritis of the knee in humans. ELEVESS is approved as a Class III medical device in the U.S. for treatment of facial wrinkles and folds, such as nasolabial folds. HYVISC is approved as an animal drug for intra- articular injection in horse joints to treat degenerative joint disease associated with synovitis. Most HA products for human use are regulated as medical devices. We believe that our INCERT product, should we decide to seek U.S. approval to market, will have to meet the regulatory requirements for Class III devices and will require clinical trials and a PMA submission.

Unless a new device is exempted from premarket notification, its manufacturer must obtain marketing clearance from the FDA through premarket notification (510(k)) or approval through PMA before the device can be introduced to the market. Product development and approval within the FDA regulatory framework takes a number of years and involves the expenditure of substantial resources. This regulatory framework may change or additional regulations may arise at any stage of our product development process and may affect approval of, or delay an application related to, a product, or require additional expenditures by us. There can be no assurance that the FDA review of marketing applications will result in product approval on a timely basis, if at all. The PMA approval process is lengthy, expensive, and typically requires, among other things, valid scientific evidence which generally includes extensive data such as pre-clinical and clinical trial data to demonstrate a reasonable assurance of safety and effectiveness.

Human clinical trials in the U.S. for significant risk devices must be conducted under a Good Clinical Practice (GCP) regulations through Investigational Device Exemption ("IDE"), which must be submitted to the FDA and either be approved or be allowed to become effective before the trials may commence. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials. In addition, the IDE approval process could result in significant delays. Even if the FDA approves an IDE or allows an IDE for a clinical investigation to become effective, clinical trials may be suspended at any time for a number of reasons. Among others, these reasons may include: a) failure to comply with applicable requirements; b) inadequacy of informed consent; and c) the data generated suggests that: the risks to clinical subjects are not outweighed by the anticipated benefits to clinical subjects and the importance of the knowledge to be gained, the investigation is scientifically unsound, or there is reason to believe that the device, as used, is ineffective. A trial may be terminated if serious unanticipated adverse events present an unreasonable risk to subjects. If clinical studies are suspended or terminated, we may be unable to continue the development of the investigational products affected.

Upon completion of required clinical trials, for Class III medical devices, results are presented to the FDA in a PMA application. In addition to the results of clinical investigations, the New Drug Application ("NDA") applicant must submit other information relevant to the safety and efficacy of the device, including, among other things, the results of non-clinical tests and clinical trials; a full description of the device and its components; a full description of the methods, facilities and controls used for manufacturing; and proposed labeling. The FDA also conducts an on-site inspection to determine whether an applicant conforms with the FDA's current Quality System Regulation ("QSR"), formerly known as GMP. FDA review of the PMA may not result in timely, or any, PMA approval, and there may be

Table of Contents

significant conditions on approval, including limitations on labeling and advertising claims and the imposition of post-market testing, tracking, or surveillance requirements.

Upon completion of required clinical trials for pharmaceuticals, results are presented to the FDA in a NDA or New Animal Drug Application ("NADA"). In addition to the results of clinical investigations, the PMA applicant must submit other information relevant to the safety and efficacy of the product, including, among other things, the results of non-clinical tests and clinical trials; a full description of the product formulation; a full description of the methods, facilities and controls used for manufacturing; and proposed labeling. The FDA also conducts an on-site inspection to determine whether an applicant conforms with the FDA's current QSR related to pharmaceuticals. FDA review of the NDA or NADA may not result in timely, or any, FDA approval, and there may be significant conditions on approval, including limitations on labeling and advertising claims and the imposition of post-market testing, tracking, or surveillance requirements.

Product or manufacturing changes after approval where such change affects safety and efficacy of the medical products as well as the use of a different facility for manufacturing, could necessitate additional review and approval by the FDA. Post approval changes in labeling, packaging or promotional materials may also necessitate further review and approval by the FDA.

Legally marketed products are subject to continuing requirements by the FDA relating to design control, manufacturing, quality control and quality assurance, maintenance of records and documentation, reporting of adverse events, and labeling and promotion. The FDC Act requires medical product manufacturers to comply with QSR for medical devices and other quality system regulations related to pharmaceuticals. The FDA enforces these requirements through periodic inspections of manufacturing facilities. To ensure full compliance with requirements set forth in the GMP/QSR regulations, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. Other federal, state, and local agencies may inspect manufacturing establishments as well.

A set of regulations known as the Medical Device Reporting regulations obligates manufacturers to inform the FDA whenever information reasonably suggests that one of their devices may have caused or contributed to a death or serious injury, or when one of their devices malfunctions and if the malfunction were to recur, the device or a similar device would be likely to cause or contribute to a death or serious injury.

The process of obtaining approvals from the FDA and foreign regulatory authorities can be costly, time consuming, and subject to unanticipated delays. Approvals of our products, processes or facilities may not be granted on a timely basis or at all, and we may not have available resources or be able to obtain the financing needed to develop certain of such products. Any failure or delay in obtaining such approvals could adversely affect our ability to market our products in the U.S. and in other countries.

In addition to regulations enforced by the FDA, we are subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other existing and future federal, state and local laws and regulations as well as those of foreign governments. Federal, state and foreign regulations regarding the manufacture and sale of medical products are subject to change. We cannot predict what impact, if any, such changes might have on our business.

FDA Warning Letter

In July 2008, we received a Warning Letter (the "Warning Letter") from the FDA in response to an earlier FDA Form 483 Notice of Observations issued to us following an inspection at our current manufacturing facility in Woburn, Massachusetts. We have fully cooperated with the FDA to address the issues in the Form 483 filing and have issued a response to the FDA's Warning Letter. We have developed a

Table of Contents

corrective action plan and we have provided the FDA with progress reports. On September 15, 2008, the FDA issued a letter to us indicating that the responses submitted by us were sufficient. We have no major disagreements with the FDA, and expect to have a successful re-inspection and clearance of the Warning Letter by early 2009. Product quality is the highest concern to us and we are committed to the continual improvement of our quality systems. Failure to comply with applicable regulatory requirements and to address the issues raised by the FDA in the Warning Letter could result in regulatory action. Any such regulatory action would be expected to have a material adverse effect on our business and operations.

Foreign Regulation

In addition to regulations enforced by the FDA, we and our products are subject to certain foreign regulations. International regulatory bodies often establish regulations governing product standards, packing requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. ORTHOVISC is approved for sale and is marketed in Canada, Europe, Turkey, and parts of the Middle East. In the European Union ("EU"), ORTHOVISC is sold under *Conformité Européene* (CE mark) authorization, a certification required under European Union medical device regulations. The CE mark, achieved in 1996, allows ORTHOVISC to be marketed without further approvals in most of the EU nations as well as other countries that recognize EU device regulations. ORTHOVISC® *mini*, a treatment for osteoarthritis targeting small joints is available in Europe under CE mark authorization received in 2008. In August 2004, we received an EC Design Examination Certificate which entitled us to affix a CE mark to INCERT-S as a barrier to adhesion formation following surgery. AMVISC® and AMVISC® Plus are CE marked, and in May 2005, we received an EC Design Examination Certificate which entitled us to affix a CE mark to ShellGel as an ophthalmic viscoelastic surgical device. Staarvisc, an ophthalmic viscoelastic surgical device is licensed in Canada from May 2002. We received EU CE Mark approval for ELEVESS during the second quarter of 2007. Monovisc, a medical device for treatment of pain associated with osteoarthritis, was approved in the EU in October 2007. We may not be able to achieve and/or maintain compliance required for CE marking or other foreign regulatory approvals for any or all of our products. The requirements relating to the conduct of clinical trials, product licensing, marketing, pricing, advertising, promotion and reimbursement also vary widely from country to country. In the third quarter of 2006, the government of Turkey eliminated reimbursement for over 100 drugs including ORTHOVISC, designated as a drug in Turkey, and its competing products. International sales declined in 2007 compared to 2006 due to the reimbursement change in Turkey. We did not ship product to our Turkish distributor during the 10 months ended May 2007. Starting in June 2007, sales to Turkey have been at a lower level reflective of a private pay business.

Competition

We compete with many companies, including, among others, large pharmaceutical firms and specialized medical products companies across all of our product lines. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing and manufacturing organizations and more experience in the regulatory process than us. We also compete with academic institutions, governmental agencies and other research organizations, which may be involved in research, development and commercialization of products. Many of our competitors also compete against us in securing relationships with collaborators for their research and development and commercialization programs.

Competition in our industry is based primarily on product efficacy, safety, timing and scope of regulatory approvals, availability of supply, marketing and sales capability, reimbursement coverage, product pricing and patent protection. Some of the principal factors that may affect our ability to compete in our HA development and commercialization markets include:

the quality and breadth of our technology and technological advances;

Table of Contents

our ability to complete successful clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors;

our ability to recruit and retain skilled employees; and

the availability of substantial capital resources to fund discovery, development and commercialization activities or the ability to defray such costs through securing relationships with collaborators for our research and development and commercialization programs.

We are aware of several companies that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have already obtained product approvals, submitted applications for approval or have commenced human clinical studies, either in the U.S. or in certain foreign countries. All of the Company's products face substantial competition. There exist major worldwide competing HA-based products for use in ophthalmic surgery, orthopedics, surgical adhesion prevention, and cosmetic dermal fillers. There is a risk that we will be unable to compete effectively against our current or future competitors.

Employees

As of December 31, 2008, we had 84 employees. We consider our relations with our employees to be good. None of our employees are represented by labor unions.

Environmental Laws

We believe that we are in compliance with all federal, state and local environmental regulations with respect to our manufacturing facilities and that the cost of ongoing compliance with such regulations does not have a material effect on our operations. Our leased manufacturing facility is located within the Wells G&H Superfund site in Woburn, Massachusetts. We have not been named and are not a party to any legal proceedings regarding the Wells G&H Superfund site.

Product Liability

The testing, marketing and sale of human health care products entail an inherent risk of allegations of product liability, and we cannot assure you that substantial product liability claims will not be asserted against us. Although we have not received any material product liability claims to date and have coverage under our insurance policy of $5,000,000 per occurrence and $5,000,000 in the aggregate, we cannot assure you that if material claims arise in the future, our insurance will be adequate to cover all situations. Moreover, we cannot assure you that such insurance, or additional insurance, if required, will be available in the future or, if available, will be available on commercially reasonable terms. Any product liability claim, if successful, could have a material adverse effect on our business, financial condition, and results of operation.

Available Information

Our Annual Reports on Form 10-K, including our consolidated financial statements, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other information, including amendments and exhibits to such reports, filed or furnished pursuant to the Securities Exchange Act of 1934, are available free of charge in the "SEC Filings" section of our website located at http://www.anikatherapeutics.com, as soon as reasonably practicable after the reports are filed with or furnished to the Securities and Exchange Commission. The information on our website is not part of this Annual Report on Form 10-K. Reports filed with the SEC may be viewed at www.sec.gov or obtained at the SEC Public Reference Room at 100F Street NE, Washington, D.C. Information regarding the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

Table of Contents

ITEM 1A. RISK FACTORS

Our operating results and financial condition have varied in the past and could in the future vary significantly depending on a number of factors. From time to time, information provided by us or statements made by our employees contain "forward-looking" information that involves risks and uncertainties. In particular, statements contained in this Annual Report on Form 10-K, and in the documents incorporated by reference into this Annual Report on Form 10-K, that are not historical facts, including, but not limited to statements concerning new products, product development and offerings, product and price competition, competition and strategy, customer diversification, product price and inventory, contingent consideration payments, deferred revenues, economic and market conditions, potential government regulation, seasonal factors, international expansion, revenue recognition, profits, growth of revenues, composition of revenues, cost of revenues, operating expenses, sales, marketing and support expenses, general and administrative expenses, product gross profit, interest income, interest expense, anticipated operating and capital expenditure requirements, cash inflows, contractual obligations, tax rates, SFAS 123R, leasing and subleasing activities, acquisitions, liquidity, litigation matters, intellectual property matters, distribution channels, stock price, third party licenses and potential debt or equity financings constitute forward-looking statements and are made under the safe harbor provisions of Section 27 of the Securities Act of 1933 as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are neither promises nor guarantees. Our actual results of operations and financial condition have varied and could in the future vary significantly from those stated in any forward-looking statements. The following factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this Form 10-K, in the documents incorporated by reference into this Form 10-K or presented elsewhere by our management from time to time. Such factors, among others, could have a material adverse effect upon our business, results of operations and financial condition.

Our business is subject to comprehensive and varied government regulation and, as a result, failure to obtain FDA or other U.S. and foreign governmental approvals for our products may materially adversely affect our business, results of operations and financial condition.

Product development and approval within the FDA framework takes a number of years and involves the expenditure of substantial resources. There can be no assurance that the FDA will grant approval for our new products on a timely basis if at all, or that FDA review will not involve delays that will adversely affect our ability to commercialize additional products or expand permitted uses of existing products, or that the regulatory framework will not change, or that additional regulation will not arise at any stage of our product development process which may adversely affect approval of or delay an application or require additional expenditures by us. In the event our future products are regulated as human drugs or biologics, the FDA's review process of such products typically would be substantially longer and more expensive than the review process to which they are currently subject as devices.

Products in development include next generation joint health related products. Monovisc is a single-injection treatment product that uses a non-animal source HA, and is our first osteoarthritis product based on our proprietary crosslinked HA- technology. We received CE Mark approval for the Monovisc product in October 2007. We are conducting a pivotal trial in the U.S. for a PMA application. Our second single-injection osteoarthritis product is Cingal, which is based on the same technology platform used in MONOVISC, with an added active therapeutic molecule to provide broad pain relief for a long period of time. We expect to commence a clinical trial and file an application for CE Mark for CINGAL in 2009.

We cannot assure you that:

- we will begin or successfully complete U.S. clinical trials for next generation products;
- the clinical data will support the efficacy of these products;

Table of Contents

- we will be able to successfully complete the FDA or foreign regulatory approval process, where required; or

- additional clinical trials will support a PMA application and/or FDA approval or other foreign regulatory approvals, where required, in a timely manner or at all.

We also cannot assure you that any delay in receiving FDA approvals will not adversely affect our competitive position. Furthermore, even if we do receive FDA approval:

- the approval may include significant limitations on the indications and other claims sought for use for which the products may be marketed;

- the approval may include other significant conditions of approval such as post-market testing, tracking, or surveillance requirements; and

- meaningful sales may never be achieved.

Once obtained, marketing approval can be withdrawn by the FDA for a number of reasons, including, among others, the failure to comply with regulatory requirements, or the occurrence of unforeseen problems following initial approval. We may be required to make further filings with the FDA under certain circumstances. The FDA's regulations require a PMA supplement for certain changes if they affect the safety and effectiveness of an approved device, including, but not limited to, new indications for use, labeling changes, process or manufacturing changes, the use of a different facility to manufacture, process or package the device, and changes in performance or design specifications. Our failure to receive approval of a PMA supplement regarding the use of a different manufacturing facility or any other change affecting the safety or effectiveness of an approved device on a timely basis, or at all, may have a material adverse effect on our business, financial condition, and results of operations. The FDA could also limit or prevent the manufacture or distribution of our products and has the power to require the recall of such products. It also might be necessary for us, in applicable circumstances, to initiate a voluntary recall per FDA regulations of one or several of our products. Significant delay or cost in obtaining, or failure to obtain FDA approval to market products, any FDA limitations on the use of our products, or any withdrawal or suspension of approval or rescission of approval by the FDA could have a material adverse effect on our business, financial condition, and results of operations.

In addition, all FDA approved or cleared products manufactured by us must be manufactured in compliance with the FDA's Good Manufacturing Practices ("GMP") regulations and, for medical devices, the FDA's Quality System Regulations ("QSR"). Ongoing compliance with QSR and other applicable regulatory requirements is enforced through periodic inspection by state and federal agencies, including the FDA. The FDA may inspect our facilities, from time to time, to determine whether we are in compliance with regulations relating to medical device and pharmaceutical companies, including regulations concerning manufacturing, testing, quality control and product labeling practices. We cannot assure you that we will be able to comply with current or future FDA requirements applicable to the manufacture of our products.

FDA regulations depend heavily on administrative interpretation and we cannot assure you that the future interpretations made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect us. In addition, changes in the existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of our products.

Failure to comply with applicable regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the FDA to grant pre-market clearance or pre-market approval for devices or drugs, withdrawal of approvals and criminal prosecution. In July 2008, we received a Warning Letter (the "Warning Letter") from the FDA in response to an earlier FDA Form 483 Notice of Observations issued to us following an inspection at our Woburn facility. We have fully cooperated with the FDA to address the

Table of Contents

issues in the Form 483 filing and have issued a response to the FDA's Warning Letter. We have developed a corrective action plan and we have provided the FDA with progress reports. On September 15, 2008, the FDA issued a letter to us indicating that the responses submitted by us were sufficient. We have no major disagreements with the FDA, and expect to have a successful re-inspection and clearance of the Warning Letter by early 2009. Product quality is the highest concern to us and we are committed to the continual improvement of our quality systems. Failure to comply with applicable regulatory requirements and to address the issues raised by the FDA in the Warning Letter could result in regulatory action. Any such regulatory action would be expected to have a material adverse effect on our business and operations.

In addition to regulations enforced by the FDA, we are subject to other existing and future federal, state, local and foreign regulations. International regulatory bodies often establish regulations governing product standards, packing requirements, labeling requirements, quality system and manufacturing requirements, import restrictions, tariff regulations, duties and tax requirements. We cannot assure you that we will be able to achieve and/or maintain compliance required for CE marking or other foreign regulatory approvals for any or all of our products or that we will be able to produce our products in a timely and profitable manner while complying with applicable requirements. Federal, state, local and foreign regulations regarding the manufacture and sale of medical products are subject to change. We cannot predict what impact, if any, such changes might have on our business.

The process of obtaining approvals from the FDA and other regulatory authorities can be costly, time consuming, and subject to unanticipated delays. We cannot assure you that approvals or clearances of our products will be granted or that we will have the necessary funds to develop certain of our products. Any failure to obtain, or delay in obtaining such approvals or clearances, could adversely affect our ability to market our products.

Current economic conditions, including the credit crisis affecting the financial markets and global recession, could adversely affect our business, results of operations and financial condition.

The worldwide financial markets are currently experiencing turmoil, characterized by volatility in security prices, rating downgrades of investments, and reductions in available credit. These events have materially and adversely impacted the availability of financing to a wide variety of businesses, and the resulting uncertainty has led to reductions in capital investments, overall spending levels, future product plans, and sales projections across industries and markets. These trends could have a material adverse impact on our business, our ability to achieve planned results of operations and our financial condition as a result of:

- reduced demand for our products;
- increased risk of order cancellations or delays;
- increased pressure on the prices for our products;
- greater difficulty in collecting accounts receivable; and
- risks to our liquidity, including the possibility that we might not have sufficient access to cash when needed.

We are unable to predict the likely duration and severity of the current disruption in financial markets and adverse economic conditions in the U.S. and other countries, but the longer the duration the greater the risks we face in operating our business.

Substantial competition could materially affect our financial performance.

We compete with many companies, including, among others, large pharmaceutical companies, specialized medical products companies and healthcare companies. Many of these companies have substantially greater financial resources, larger research and development staffs, more extensive marketing

Table of Contents

and manufacturing organizations and more experience in the regulatory process than us. We also compete with academic institutions, governmental agencies and other research organizations that may be involved in research, development and commercialization of products. Because a number of companies are developing or have developed HA products for similar applications and have received FDA approval, the successful commercialization of a particular product will depend in part upon our ability to complete clinical studies and obtain FDA marketing and foreign regulatory approvals prior to our competitors, or, if regulatory approval is not obtained prior to our competitors, to identify markets for our products that may be sufficient to permit meaningful sales of our products. For example, we are aware of several companies that are developing and/or marketing products utilizing HA for a variety of human applications. In some cases, competitors have already obtained product approvals, submitted applications for approval or have commenced human clinical studies, either in the U.S. or in certain foreign countries. There exist major competing products for the use of HA in ophthalmic surgery. In addition, certain HA products made by our competitors for the treatment of osteoarthritis in the knee have received FDA approval before ours and have been marketed in the U.S. since 1997, as well as select markets in Canada, Europe and other countries. To date, the FDA approved seven HA products for the treatment of facial wrinkles which have been marketed internationally for a number of years. There can be no assurance that we will be able to compete against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations.

We are uncertain regarding the success of our clinical trials.

Several of our products do require clinical trials to determine their safety and efficacy for U.S. and international marketing approval by regulatory bodies, including the FDA. There can be no assurance that we will be able to successfully complete the U.S. or international regulatory approval process for products in development. In addition, there can be no assurance that we will not encounter additional problems that will cause us to delay, suspend or terminate our clinical trials. In addition, we cannot make any assurance that clinical trials, if completed, will ultimately demonstrate these products to be safe and efficacious. Our current products in clinical trial include MONOVISC.

We are dependent upon marketing and distribution partners and the failure to maintain strategic alliances on acceptable terms will have a material adverse effect on our business, financial condition and results of operations.

Our success will be dependent, in part, upon the efforts of our marketing and distribution partners and the terms and conditions of our relationships with such partners. We cannot assure you that such partners will not seek to renegotiate their current agreements on terms less favorable to us or terminate such agreements. We are continuing to seek to establish long-term distribution relationships in regions not covered by existing agreements, but can make no assurances that we will be successful in doing so. There can be no assurance that we will be able to identify or engage appropriate distribution or collaboration partners or effectively transition to any such partners. There can be no assurance that we will obtain European or other reimbursement approvals or, if such approvals are obtained, they will be obtained on a timely basis or at a satisfactory level of reimbursement.

We may need to obtain the assistance of additional marketing partners to bring new and existing products to market and to replace certain marketing partners. The failure to establish strategic partnerships for the marketing and distribution of our products on acceptable terms will have a material adverse effect on our business, financial condition, and results of operations.

Our future success depends upon market acceptance of our existing and future products.

Our success will depend in part upon the acceptance of our existing and future products by the medical community, hospitals and physicians and other health care providers, third-party payers, and end-users. Such acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective or cost-competitive than other similar products. Ultimately,

Table of Contents

for our new products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our new products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

We may be unable to adequately protect our intellectual property rights.

Our efforts to enforce our intellectual property rights may not be successful. We reply on a combination of copy right, trademark, patent and trade secret laws, confidentiality procedures and contractual provisions to protect our proprietary rights. Our success will depend, in part, on our ability to obtain and enforce patents, protect trade secrets, obtain licenses to technology owned by third parties when necessary, and conduct our business without infringing on the proprietary rights of others. The patent positions of pharmaceutical, medical products and biotechnology firms, including ours, can be uncertain and involve complex legal and factual questions. There can be no assurance that any patent applications will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or commercial advantage, or will not be circumvented by others. In the event a third party has also filed one or more patent applications for any of its inventions, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office ("PTO") to determine priority of invention, which could result in failure to obtain, or the loss of, patent protection for the inventions and the loss of any right to use the inventions. Even if the eventual outcome is favorable to us, such interference proceedings could result in substantial cost to us, and diversion of management's attention away from our operations. Filing and prosecution of patent applications, litigation to establish the validity and scope of patents, assertion of patent infringement claims against others and the defense of patent infringement claims by others can be expensive and time consuming. There can be no assurance that in the event that any claims with respect to any of our patents, if issued, are challenged by one or more third parties, that any court or patent authority ruling on such challenge will determine that such patent claims are valid and enforceable. An adverse outcome in such litigation could cause us to lose exclusivity covered by the disputed rights. If a third party is found to have rights covering products or processes used by us, we could be forced to cease using the technologies or marketing the products covered by such rights, could be subject to significant liabilities to such third party, and could be required to license technologies from such third party. Furthermore, even if our patents are determined to be valid, enforceable, and broad in scope, there can be no assurance that competitors will not be able to design around such patents and compete with us using the resulting alternative technology. We have a policy of seeking patent protection for patentable aspects of our proprietary technology. We intend to seek patent protection with respect to products and processes developed in the course of our activities when we believe such protection is in our best interest and when the cost of seeking such protection is not inordinate. However, no assurance can be given that any patent application will be filed, that any filed applications will result in issued patents or that any issued patents will provide us with a competitive advantage or will not be successfully challenged by third parties. The protections afforded by patents will depend upon their scope and validity, and others may be able to design around our patents.

Other entities have filed patent applications for or have been issued patents concerning various aspects of HA-related products or processes. There can be no assurance that the products or processes developed by us will not infringe on the patent rights of others in the future. Any such infringement may have a material adverse effect on our business, financial condition, and results of operations.

We also rely upon trade secrets and proprietary know-how for certain non-patented aspects of our technology. To protect such information, we require all employees, consultants and licensees to enter into confidentiality agreements limiting the disclosure and use of such information. There can be no assurance that these agreements provide meaningful protection or that they will not be breached, that we would have adequate remedies for any such breach, or that our trade secrets, proprietary know-how, and our

Table of Contents

technological advances will not otherwise become known to others. In addition, there can be no assurance that, despite precautions taken by us, others have not and will not obtain access to our proprietary technology. Further, there can be no assurance that third parties will not independently develop substantially equivalent or better technology.

Pursuant to the 2004 B&L Agreement, we have agreed to transfer to Bausch & Lomb, upon expiration of the term of the 2004 B&L Agreement on December 31, 2010, or in connection with earlier termination in certain circumstances, our manufacturing process, know-how and technical information, which relate to only AMVISC products. Upon expiration of the 2004 B&L Agreement, there can be no assurance that Bausch & Lomb will continue to use us to manufacture AMVISC and AMVISC Plus. If Bausch & Lomb discontinues the use of us as a manufacturer after such time, our business, financial condition, and results of operations would likely be materially and adversely affected.

Our manufacturing processes involve inherent risks and disruption could materially adversely affect our business, financial condition and results of operations.

The operation of biomedical manufacturing plants involves many risks, including the risks of breakdown, failure or substandard performance of equipment, the occurrence of natural and other disasters, and the need to comply with the requirements of directives of government agencies, including the FDA. In addition, we rely on a single supplier for certain key raw materials and a small number of suppliers for a number of other materials required for the manufacturing and delivery of our HA products. Although we believe that alternative sources for many of these and other components and raw materials that we use in our manufacturing processes are available, any supply interruption could harm our ability to manufacture our products until a new source of supply is identified and qualified. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired.

Furthermore, our manufacturing processes and research and development efforts involve animals and products derived from animals. We procure our animal-derived raw materials from qualified vendors, control for contamination and have processes that effectively inactivate infectious agents; however, we cannot assure you that we can completely eliminate the risk of transmission of infectious agents. Furthermore, regulatory authorities could in the future impose restrictions on the use of animal-derived raw materials that could impact our business.

The utilization of animals in research and development and product commercialization is subject to increasing focus by animal rights activists. The activities of animal rights groups and other organizations that have protested animal based research and development programs or boycotted the products resulting from such programs could cause an interruption in our manufacturing processes and research and development efforts. The occurrence of material operational problems, including but not limited to the events described above, could have a material adverse effect on our business, financial condition, and results of operations during the period of such operational difficulties.

Our new facility construction and validation processes could materially adversely affect our operations.

We entered into a new lease on January 4, 2007, for a new headquarters facility consisting of approximately 134,000 square feet of general office, research and development and manufacturing space located in Bedford, Massachusetts. The lease has an initial term of ten and a half years, and commenced on approximately May 1, 2007 when certain agreed upon landlord improvements were completed. We commenced the buildout of the new facility during the second quarter of 2007. Our administrative, marketing, regulatory, and research and development personnel moved into the Bedford facility in November 2007. The remaining buildout was completed in mid-2008 and validation for the new manufacturing space is expected to be completed in 2009. We provide no assurance that the validation and approval processes will be completed on time, if at all. Furthermore, we cannot assure you that the