Cryoport, Inc.
Form 10-K
June 27, 2011

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended March 31, 2011
OR

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: 001-34632

CRYOPORT, INC.
(Exact name of Registrant as specified in its charter)

Nevada	**88-0313393**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
20382 Barents Sea Circle, Lake Forest, California	**92630**
(Address of principal executive offices)	*(Zip Code)*

(949) 470-2300
(Registrant s telephone number, including area code)

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value	**OTC Market**

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.001
Warrants to Purchase Common Stock

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 þ

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 þ

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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) 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. þ

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 o	Non-accelerated filer o	Smaller reporting company þ

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

The aggregate market value of Common Stock held by non-affiliates as of September 30, 2010 was $9,761,382 (1)

Number of shares of Common Stock outstanding as of June 10, 2011: 27,712,101

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this report incorporates certain information by reference from the registrant s proxy statement for the annual meeting of stockholders, which proxy statement will be filed no later than 120 days after the close of the registrant s fiscal year ended March 31, 2010.

(1) Excludes 5,881 shares of common stock held by directors and officers, and any stockholder whose ownership exceeds five percent of the shares outstanding as of September 30, 2010.

CRYOPORT, INC.
Fiscal Year 2011 10-K Annual Report
Table of Contents

PART I

PART II

PART III

PART IV

NOTE REGARDING REVERSE STOCK SPLIT

On February 5, 2010, we filed a Certificate of Amendment to our Articles of Incorporation with the Secretary of State of the State of Nevada to affect a reverse split of our common stock at a ratio of ten for one. All historical share and per share amounts have been adjusted to reflect the reverse stock split.

Table of Contents

PART I

In this Annual Report, the terms we , us , our , Company and CryoPort refer to CryoPort, Inc., and our wholly subsidiary, CryoPort Systems, Inc. This Annual Report contains forward-looking statements that involve risks and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation by us or any other person that the objectives or plans will be achieved because our actual results may differ materially from any forward-looking statement. The words may, should, plans, believe, anticipate, estimate, expect, their o similar expressions are intended to identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. We caution readers that such statements are not guarantees of future performance or events and are subject to a number of factors that may tend to influence the accuracy of the statements, including but not limited to, those risk factors outlined in the section titled Risk Factors as well as those discussed elsewhere in this Annual Report. You should not unduly rely on these forward-looking statements, which speak only as of the date of this Annual Report. We undertake no obligation to publicly revise any forward-looking statement to reflect circumstances or events after the date of this Annual Report or to reflect the occurrence of unanticipated events. You should, however, review the factors and risks we describe in the reports that we file from time to time with the Securities and Exchange Commission (SEC) after the date of this Annual Report.

In addition, we own or have rights to the registered trademark CryoPort® (both alone and with a design logo) and CryoPort Express® (both alone and with a design logo). All other Company names, registered trademarks, trademarks and service marks included in this Annual Report are trademarks, registered trademarks, service marks or trade names of their respective owners.

Item 1. BUSINESS

Overview

We are a provider of an innovative cold chain frozen shipping system dedicated to providing superior, affordable cryogenic shipping solutions that ensure the safety, status and temperature, of high value, temperature sensitive materials. We have developed cost effective reusable cryogenic transport containers (referred to as shippers) capable of transporting biological, environmental and other temperature sensitive materials at temperatures below minus 150° Celsius. These dry vapor shippers and shipping system are one of the first significant alternatives to dry ice shipping and achieve 10-plus day holding times compared to one to two day holding times with dry ice.

Our value proposition comes from both providing safe transportation with an environmentally friendly, long lasting shipper, and through our value added services that offer a simple hassle-free solution for our customers. These value-added services include an internet-based web portal that enables the customer to initiate scheduling, shipping and tracking of the progress and status of a shipment, and provides in-transit temperature and custody transfer monitoring services of the shipper. The CryoPort service also provides a fully ready charged shipper containing all freight bills, customs documents and regulatory paperwork for the entire journey of the shipper to our customers at their pickup and delivery locations.

Our principal focus has been the further development and commercial launch of CryoPort Express® Portal, an innovative IT solution for shipping and tracking high-value specimens through overnight shipping companies, and our CryoPort Express® Shipper, a dry vapor cryogenic shipper for the transport of biological and pharmaceutical materials. A dry vapor cryogenic shipper is a container that uses liquid nitrogen in dry vapor form, which is suspended inside a vacuum insulated bottle as a refrigerant, to provide storage temperatures below minus 150° Celsius. The dry vapor shipper is designed using innovative, proprietary, and patented technology which prevents spillage of liquid nitrogen and pressure build up as the liquid nitrogen evaporates. A proprietary foam retention system is employed to ensure that liquid nitrogen stays inside the vacuum container, even when placed upside-down or on its side, as is often the case when in the custody of a shipping company. Biological specimens are stored in a specimen chamber, referred to as a well inside the container and refrigeration is provided by harmless cold nitrogen gas evolving from the liquid nitrogen entrapped within the foam retention system surrounding the well. Biological specimens transported using our cryogenic shipper can include clinical samples, diagnostics, live cell pharmaceutical products (such as cancer vaccines, semen and embryos, infectious substances) and other items that require and/or are protected through continuous exposure to frozen or cryogenic temperatures.

During our early years, our limited revenue was derived from the sale of our reusable product line. Our current business plan focuses on per-use leasing of the shipping container and added-value services that will be used by us to provide an end-to-end and cost-optimized shipping solution to life science companies moving pharmaceutical and biological samples in clinical trials and pharmaceutical distribution.

Table of Contents

The Company entered into its first strategic relationship with a global courier on January 13, 2010 when it signed an agreement with Federal Express Corporation (FedEx) pursuant to which the Company leases to FedEx such number of its cryogenic shippers that FedEx, from time to time, orders for FedEx s customers. Under this agreement, FedEx has the right to and shall, on a non-exclusive basis, promote market and sell transportation of the Company s shippers and its related value-added goods and services, such as its data logger, web portal and planned CryoPort Express® Smart Pak System. On January 24, 2011 we announced that FedEx had launched its deep frozen shipping solution using our CryoPort Express® Dry Shipper. On September 2, 2010, the Company entered into an agreement with DHL Express (USA), Inc. (DHL) that gives DHL life science customers direct access to the Company s web-based order entry and tracking portal to order the CryoPort Express® Shipper and receive preferred DHL shipping rates. The agreement covers DHL shipping discounts that may be used to support the Company s customers using the CryoPort Express® shipping solution. In connection with the agreement, the Company has integrated its proprietary web portal to DHL s tracking and billing systems. DHL life science customers now have a seamless way of shipping their critical biological material worldwide. The IT integration with DHL was completed during the Company s fourth quarter of fiscal year 2011.

We are a Nevada corporation originally incorporated under the name G.T.5-Limited (GT5) on May 25, 1990. In connection with a Share Exchange Agreement, on March 15, 2005 we changed our name to CryoPort, Inc. and acquired all of the issued and outstanding shares of common stock of CryoPort Systems, Inc., a California corporation, in exchange for 2,410,811 shares of our common stock (which represented approximately 81% of the total issued and outstanding shares of common stock following the close of the transaction). CryoPort Systems, Inc., which was originally formed in 1999 as a California limited liability company, and subsequently reorganized into a California corporation on December 11, 2000, remains the operating company under CryoPort, Inc. Our principal executive offices are located at 20382 Barents Sea Circle, Lake Forest, California 92630. The telephone number of our principal executive offices is (949) 470-2300, and our main corporate website is www.cryoport.com. The information on, or that can be accessed through, our website is not part of this Annual Report.

Our Products and Pipeline

Our product offering and service offering consists of our CryoPort Express® Shippers, reusable dry vapor shippers, the web portal allowing ease of entry and our Smart Pak data logger, a temperature monitoring system (which, together with our CryoPort Express® Shippers, comprise our new business model referred to as the CryoPort Express® System) and a containment bag which is used in connection with the shipment of infectious or dangerous goods using the CryoPort Express® Shipper.

The CryoPort Express® Shippers

Our CryoPort Express® Shippers are cryogenic dry vapor shippers capable of maintaining cryogenic temperatures of minus 150° Celsius or below for a period of 10 or more days. A dry cryogenic shipper is a device that uses liquid nitrogen contained inside a vacuum insulated bottle which serves as a refrigerant to provide storage temperatures below minus 150° Celsius. Our CryoPort Express® shipper is designed to ensure that there is no pressure build up as the liquid nitrogen evaporates or spillage of liquid nitrogen. We have developed a proprietary foam retention system to ensure that liquid nitrogen stays inside the vacuum container, which allows the shipper to be designated as a dry shipper meeting International Air Transport Association (IATA) requirements. Biological or pharmaceutical specimens are stored in a specimen chamber, referred to as a well , inside the container and refrigeration is provided by cold nitrogen gas evolving from the liquid nitrogen entrapped within the foam retention system. Specimens that may be transported using our cryogenic shipper include live cell pharmaceutical products such as cancer vaccines, diagnostic materials, semen and embryos, infectious substances and other items that require continuous exposure to frozen or cryogenic temperatures (e.g., temperatures below minus 150° Celsius).

The technology underlying the CryoPort Express® Shipper was developed by modifying and advancing technology from our first generation of reusable cryogenic dry shippers. While our CryoPort Express® Shippers share many of the characteristics and basic design details of our earlier shippers, we are manufacturing our CryoPort Express® Shippers from alternative, lower cost and lower weight materials, which will reduce overall operating costs. We maintain ongoing development efforts related to our shippers which are principally focused on material properties, particularly those properties related to the low temperature requirement, the vacuum retention characteristics, such as the

permeability of the materials, and lower cost and lower weight materials in an effort to meet the market needs for achieving a lower cost frozen and cryogenic shipping solution. Other advances additional to the development work on the cryogenic container include both an improved liquid nitrogen retention system and a secondary protective, spill proof packaging system. This secondary system, outer packaging has a low cost that lends itself to disposability, and it is made of recyclable materials. Further, it adds an additional liquid nitrogen retention capability to further assure compliance with IATA and ICAO regulations that prohibit egress of liquid nitrogen from the shipping package. IACO stands for the International Civil Aviation Organization, which is a United Nations organization that develops regulations for the safe transport of dangerous goods by air.

Our CryoPort Express® Shippers are lightweight, low-cost, re-usable dry vapor liquid nitrogen storage containers that we believe combine the best features of packaging, cryogenics and high vacuum technology. A CryoPort Express® Shipper is composed of an aluminum metallic dewar flask, with a well for holding the biological material in the inner chamber. The dewar flask, or thermos bottle, is an example of a practical device in which the conduction, convection and radiation of heat are reduced as much as possible. The inner chamber of the shipper is surrounded by a high surface, low-density open cell plastic foam material which retains the liquid nitrogen in-situ by absorption, adsorption and surface tension. Absorption is defined as the taking up of matter in bulk by other matter, as in the dissolving of a gas by a liquid, whereas adsorption is the surface retention of solid, liquid or gas molecules, atoms or ions by a solid or liquid. This material absorbs liquid nitrogen several times faster than currently used materials, while providing the shipper with a hold time and capacity to transport biological materials safely and conveniently. The annular space between the inner and outer dewar chambers is evacuated to a very high vacuum (10-6 Torr). The specimen-holding chamber has a primary cap to enclose the specimens, and a removable and replaceable secondary cap to further enclose the specimen-holding container and to contain the liquid nitrogen. The entire dewar vessel is then wrapped in a plurality of insulating and cushioning materials and placed in a disposable outer packaging made of recyclable material.

Table of Contents

We believe the CryoPort solution is the best and most cost effective solution available in the market that satisfies customer needs and regulatory requirements relating to the shipment of temperature-critical, frozen and refrigerated transport of biological materials, such as the pharmaceutical clinical trials, gene biotechnology, infectious materials handling, and animal and human reproduction markets. Due to our proprietary technology and innovative design, our shippers are less prone to losing functional hold time when not kept in an upright position than the competing products because such proprietary technology and innovative design prevent the spilling or leakage of the liquid nitrogen when the container is tipped or on its side which would adversely affect the functional hold time of the container.

An important feature of the CryoPort Express® Shippers is their compliance with the stringent packaging requirements of IATA Packing Instructions 602 and 650, respectively. These instructions include the internal pressure (hydraulic) and drop performance requirements.

The CryoPort Express® System

The CryoPort Express® System comprises the *CryoPort Express® Shipper*, the *CryoPort Express® Smart Pak* data logger, *CryoPort Express® Portal,* which programmatically manages order entry and all aspects of shipping operations, and *CryoPort Express® Analytics,* which monitors shipment performance metrics and evaluates temperature-monitoring data collected by the data logger during shipment. The CryoPort Express® System is focused on improving the reliability of frozen shipping while reducing the customers overall operating costs. This is accomplished by providing a complete end-to-end solution for the transport and monitoring of frozen or cryogenically preserved biological or pharmaceutical materials shipped though overnight shipping companies. Certain of the intellectual property underlying the CryoPort Express® System, (other than that related to the CryoPort Express® Shipper) has been, and continues to be, developed under a contract with an outside software development company, with the underlying technology licensed to us for exclusive use in our field of use.

CryoPort Express®Portal

The CryoPort Express® Portal is used by CryoPort, our customers and our business partners to automate the entry of orders, prepare customs documentation and to facilitate status and location monitoring of shipped orders while in transit. It is used by CryoPort to manage shipping operations and to reduce administrative costs typically provisioned through manual labor relating to order-entry, order processing, preparation of shipping documents and back-office accounting. It is also used to support the high level of customer service expected by the industry. Certain features of the CryoPort Express® Portal reduce operating costs and facilitate the scaling of CryoPort s business, but more importantly they offer significant value to the customer in terms of cost avoidance and risk mitigation. Examples of these features include automation of order entry; development of Key Performance Indicators (KPI) to support our efforts for continuous process improvements in our business, and programmatic exception monitoring to detect and sometimes anticipate delays in the shipping process, often before the customer or the shipping company becomes aware of them. In the future we will add rate and mode optimization and in-transit monitoring of temperature, location and state of health (discussed below), via wireless communications.

The CryoPort Express® Portal also serves as the communications nerve center for the management, collection and analysis of Smart Pak data harvested from Smart Pak data loggers in the field. Data is converted into pre-designed reports containing valuable and often actionable information that becomes the quality control standard or pedigree of the shipment. This information can be utilized by CryoPort to provide valuable feedback to the customer relating to cryogenic shipping.

The CryoPort Express® Smart Pak

Temperature monitoring is a high value feature from our customers perspective as it is an effective and reliable method to determine that the shipment materials were not damaged or degraded during shipment due to temperature fluctuations. Phase II of our Smart Pak System which is a self-contained automated data logger capable of recording the internal and external temperatures of samples shipped in our CryoPort Express® Shipper was launched in fiscal year 2010.

Phase III of our Smart Pak System is anticipated to launch in fiscal year 2012, and consists of adding a smart chip to each shipper with wireless connectivity to enable our customers to monitor a shipper s location, specimen temperature and overall state of health via our web portal. A key feature of the Phase III product is automatic downloading of data which requires no customer intervention.

CryoPort Express® Analytics

Our continued development of the CryoPort Express® Portal is a strategic element of our business strategy and the CryoPort Express® Portal system has been designed to support planned future features with this thought in mind. Analytics is a term used by IT professionals to refer to performance benchmarks or Key Performance Indicators (KPI s) that management utilizes to measure performance against desired standards. Examples include time-based metrics for order processing time and on-time deliveries by our shipping partners, as well as profiling shipping lanes to determine average transit times and predicting an exception if a shipment is taking longer than it should based on historical metrics. The analytical results will be utilized by CryoPort to render consultative customer services.

Biological Material Holders

We have also developed a patented containment bag which is used in connection with the shipment of infectious or dangerous goods using the CryoPort Express® Shipper. Up to five vials, watertight primary receptacles are placed onto aluminum holders and up to fifteen holders (75 vials) are placed into an absorbent pouch which is designed to absorb the entire contents of all the vials in the event of leakage. This pouch containing up to 75 vials is then placed in a watertight secondary packaging Tyvek bag capable of withstanding cryogenic temperatures, and then sealed. This bag is then placed into the well of the cryogenic shipper.

Table of Contents

Other Product Candidates and Development Activities

We are continuing our research and development efforts which are expected to lead to the introduction of additional dry vapor shippers, including larger and smaller size units constructed of lower cost materials and utilizing high volume manufacturing methods. We are also exploring the use of alternative phase change materials in place of liquid nitrogen in order to seek entry into the ambient temperature and chilled (2° to 8° Celsius) shipping markets.

Government Regulation

The shipping of diagnostic specimens, infectious substances and dangerous goods, whether via air or ground, falls under the jurisdiction of many states, federal and international agencies. The quality of the containers, packaging materials and insulation that protect a specimen determine whether or not it will arrive in a usable condition. Many of the regulations for transporting dangerous goods in the United States are determined by international rules formulated under the auspices of the United Nations. For example, the ICAO is the United Nations organization that develops regulations (Technical Instructions) for the safe transport of dangerous goods by air. If shipment is by air, compliance with the rules established by IATA is required. IATA is a trade association made up of airlines and air cargo couriers that publishes annual editions of the IATA Dangerous Goods Regulations. These regulations interpret and add to the ICAO Technical Instructions to reflect industry practices. Additionally, the CDC has regulations (published in the Code of Federal Regulations) for interstate shipping of specimens, and OSHA also addresses the safe handling of Class 6.2 Substances. Our CryoPort Express® Shipper meets Packing Instructions 602 and 650 and is certified for the shipment of Class 6.2 Dangerous Goods per the requirements of the ICAO Technical Instructions for the Safe Transport of Dangerous Goods by Air and IATA. Our present and planned future versions of the CryoPort Smart Pak data logger will likely be subject to regulation by FAA, FCC, FDA, IATA and possibly other agencies which may be difficult to determine on a global basis.

We are also subject to numerous other federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Manufacturing and Raw Materials

Manufacturing. The component parts for our products are primarily manufactured at third party manufacturing facilities. We also have a warehouse at our corporate offices in Lake Forest, California, where we are capable of manufacturing certain parts and fully assemble our products. Most of the components that we use in the manufacture of our products are available from more than one qualified supplier. For some components, however, there are relatively few alternate sources of supply and the establishment of additional or replacement suppliers may not be accomplished immediately, however, we have identified alternate qualified suppliers which we believe could replace existing suppliers. Should this occur, we believe that with our current level of dewars and production rate we have enough to cover a four to six week gap in maximum disruption of production. There are no specific agreements with any manufacturer nor are there any long term commitments to any manufacturer. We believe that most of the manufactures currently used by us could be replaced within a short period of time as none have a proprietary component or a substantial capital investment specific to our products.

Our production and manufacturing process incorporates innovative technologies developed for aerospace and other industries which are cost effective, easier to use and more functional than the traditional dry ice devices and other methods currently used for the shipment of temperature-sensitive materials. Our manufacturing process uses non-hazardous cleaning solutions which are provided and disposed of by a supplier approved by the Environmental Protection Agency (the EPA). EPA compliance costs for us are therefore negligible.

Raw Materials. Various common raw materials are used in the manufacture of our products and in the development of our technologies. These raw materials are generally available from several alternate distributors and manufactures. We have not experienced any significant difficulty in obtaining these raw materials and we do not consider raw material availability to be a significant factor in our business.

Patents and Proprietary Rights

In order to remain competitive, we must develop and maintain protection on the proprietary aspects of our technologies. We rely on a combination of patents, copyrights, trademarks, trade secret laws and confidentiality agreements to protect our intellectual property rights. We currently own four registered United States trademarks and

three issued United States patents primarily covering various aspects of our products. In addition, we have filed a patent application for various aspects of our shipper and web-portal, which includes, in part, various aspects of our business model referred to as the CryoPort Express® System, and we intend to file additional patent applications to strengthen our intellectual property rights. The technology covered by the above indicated issued patents relates to matters specific to the use of liquid nitrogen dewars in connection with the shipment of biological materials. The concepts include those of disposability, package configuration details, liquid nitrogen retention systems, systems related to thermal performance, systems related to packaging integrity, and matters generally relevant to the containment of liquid nitrogen. Similarly, the trademarks mentioned relate to the cryogenic temperature shipping activity. Issued patents and trademarks currently owned by us include:

Type:	No.	Issued	Expiration
Patent	6,467,642	Oct. 22, 2002	Oct. 21, 2022
Patent	6,119,465	Sep. 19, 2000	Sep. 18, 2020
Patent	6,539,726	Apr. 1, 2003	Mar 31, 2023
Trademark	7,583,478,7	Oct. 9, 2002	N/A
Trademark	7,586,797,8	Apr. 16, 2002	N/A
Trademark	7,748,667,3	Feb. 3, 2009	N/A
Trademark	7,737,451,1	Mar. 17, 2009	N/A

Table of Contents

Our success depends to a significant degree upon our ability to develop proprietary products and technologies and to obtain patent coverage for these products and technologies. We intend to file trademark and patent applications covering any newly developed products, methods and technologies. However, there can be no guarantee that any of our pending or future filed applications will be issued as patents. There can be no guarantee that the U.S. Patent and Trademark Office or some third party will not initiate an interference proceeding involving any of our pending applications or issued patents. Finally, there can be no guarantee that our issued patents or future issued patents, if any, will provide adequate protection from competition.

Patents provide some degree of protection for our proprietary technology. However, the pursuit and assertion of patent rights involve complex legal and factual determinations and, therefore, are characterized by significant uncertainty. In addition, the laws governing patent issuance and the scope of patent coverage continue to evolve. Moreover, the patent rights we possess or are pursuing generally cover our technologies to varying degrees. As a result, we cannot ensure that patents will issue from any of our patent applications, or that any of its issued patents will offer meaningful protection. In addition, our issued patents may be successfully challenged, invalidated, circumvented or rendered unenforceable so that our patent rights may not create an effective barrier to competition. Moreover, the laws of some foreign countries may not protect our proprietary rights to the same extent, as do the laws of the United States. There can be no assurance that any patents issued to us will provide a legal basis for establishing an exclusive market for our products or provide us with any competitive advantages, or that patents of others will not have an adverse effect on our ability to do business or to continue to use our technologies freely.

We may be subject to third parties filing claims that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or whether those claims will hurt our business. If we are forced to defend against such claims, regardless of their merit, we may face costly litigation and diversion of management s attention and resources. As a result of any such disputes, we may have to develop, at a substantial cost, non-infringing technology or enter into licensing agreements. These agreements may be unavailable on terms acceptable to it, or at all, which could seriously harm our business or financial condition.

We also rely on trade secret protection of our intellectual property. We attempt to protect trade secrets by entering into confidentiality agreements with third parties, employees and consultants, although, in the past, we have not always obtained such agreements. It is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, our trade secrets could be disclosed to our competitors. Despite the measures we have taken to protect our intellectual property, parties to such agreements may breach confidentiality provisions in our contracts or infringe or misappropriate our patents, copyrights, trademarks, trade secrets and other proprietary rights. In addition, third parties may independently discover or invent competitive technologies, or reverse engineer our trade secrets or other technology. Therefore, the measures we are taking to protect our proprietary technology may not be adequate.

Customers and Distribution

As a result of growing globalization, including with respect to such areas as life science clinical trials and distribution of pharmaceutical products, the requirement for effective solutions for keeping certain clinical samples and pharmaceutical products at frozen temperatures takes on added significance due to extended shipping times, custom delays and logistics challenges. Today, such goods are traditionally shipped in styrofoam cardboard insulated containers packed with dry ice, gel/freezer packs or a combination thereof. The current dry ice solutions have limitations that severely limit their effective and efficient use for both short and long-distances (e.g., international). Conventional dry ice shipments often require labor intensive re-icing operations resulting in higher labor and shipping costs.

We believe our patented cryogenic shippers make us well positioned to take advantage of the growing demand for effective and efficient international transport of temperature sensitive materials resulting from continued globalization. Of particular significance is the trend within the pharmaceutical and biotechnology industries toward globalization. We believe this presents a new and unique opportunity for pharmaceutical companies, particularly early or developmental stage companies, to conduct some of their clinical trials in foreign countries where the cost may be cheaper and/or because the foreign countries significantly larger population provides a larger pool of potential patients suffering from the indication that the drug candidate is being designed to treat. We also plan to provide domestic

shipping solutions in situations and regions where there is a high priority placed on maintaining the integrity of materials shipped at cryogenic temperatures and where we can be cost effective.

To date, most of our customers have been in the pharmaceutical or medical industries. As we initially focus our efforts to increase revenues, we believe that the primary target customers for our CryoPort Express® System are concentrated in the following markets, for the following reasons:

Pharmaceutical clinical trials / contract research organizations;

Gene biotechnology;

Transport of infectious materials and dangerous goods;

Pharmaceutical distribution; and

Fertility clinics/artificial insemination.

Pharmaceutical Clinical Trials. Every pharmaceutical company developing a new drug must be approved by the FDA who conducts clinical trials to, among other things, test the safety and efficacy of the potential new drug. Presently, a significant amount of clinical trial activity is managed by a number of large Clinical Research Organizations (CROs). Due to the growing downsizing trend in the pharmaceutical industry, CROs are going to obtain an increasing share of the clinical trial market.

Table of Contents

In connection with the clinical trials, due to globalization the companies may enroll patients from all over the world who regularly submit a blood or other specimen at the local hospital, doctor s office or laboratory. These samples are then sent to specified testing laboratories, which may be local or in another country. The testing laboratories will typically set the requirements for the storage and shipment of blood specimens. In addition, several of the drugs used by the patients require frozen shipping to the sites of the clinical trials. While both domestic and international shipping of these specimens is accomplished using dry ice today, international shipments especially present several problems, as dry ice, under the best of circumstances, can only provide freezing for one to two days, in the absence of re-icing (which is quite costly). Because shipments of packages internationally can take longer than one to two days or be delayed due to flight cancellations, incorrect destinations, labor problems, ground logistics, customs delays and safety reasons, dry ice is not always a reliable and cost effective option. Clinical trial specimens are often irreplaceable because each one represents clinical data at a prescribed point in time, in a series of specimens on a given patient, who may be participating in a trial for years. Sample integrity during the shipping process is vital to retaining the maximum number of patients in each trial. Our shippers are ideally suited for this market, as our longer hold time ensures that specimens can be sent over long distances with minimal concern that they will arrive in a condition that will cause their exclusion from the trial. There are also many instances in domestic shipments where the CryoPort Express® Shipper will provide higher reliability and be cost effective.

Furthermore, the IATA requires that all airborne shipments of laboratory specimens be transmitted in either IATA Instruction 650 or 602 certified packaging. We have developed and obtained IATA certification of the CryoPort Express® System, which is ideally suited for this market, in particular due to the elimination of the cost to return the reusable shipper.

Gene Biotechnology. The gene biotechnology market includes basic and applied research and development in diverse areas such as stem cells, cloning, gene therapy, DNA tumor vaccines, tissue engineering, genomics, and blood products. Companies participating in the foregoing fields rely on the frozen transport of specimens in connection with their research and development efforts, for which our CryoPort Express® Shippers are ideally suited.

Transport of Infectious Materials and Dangerous Goods. The transport of infectious materials must be classified as such and must maintain strict adherence to regulations that protect public safety while maintaining the viability of the material being shipped. Some blood products are considered infective and must be treated as such. Pharmaceutical companies, private research laboratories and hospitals ship tissue cultures and microbiology specimens, which are also potentially infectious materials, between a variety of entities, including private and public health reference laboratories. Almost all specimens in this infectious materials category require either a refrigerated or a frozen environment. We believe our CryoPort Express® Shipper is ideally suited to meet the shipping requirements of this market.

Partly in response to the attack on the World Trade Center and the anthrax scare, government officials and health care professionals are focusing renewed attention on the possibility of attacks involving biological and chemical weapons such as anthrax, smallpox and sarin gas. Efforts expended on research and development to counteract biowarfare agents requires the frozen transport of these agents to and from facilities conducting the research and development. Vaccine research, including methods of vaccine delivery, also requires frozen transport. We believe our CryoPort Express® Shipper is ideally suited to this type of research and development.

Pharmaceutical Distribution. The current focus for the CryoPort Express® System also includes the area of pharmaceutical distribution. There are a significant number of therapeutic drugs and vaccines currently or soon to be, undergoing clinical trials. After the FDA approves them for commercial marketing, it will be necessary for the manufacturers to have a reliable and economical method of distribution to the physician who will administer the product to the patient. Although there are not now a large number of drugs requiring cryogenic transport, there are a number in the development pipeline. It is likely that the most efficient and reliable method of distribution will be to ship a single dosage to the administering physician. These drugs are typically identified to individual patients and therefore will require a complete tracking history from the manufacturer to the patient. The most reliable method of doing this is to ship a unit dosage specifically for each patient. Because the drugs require maintenance at frozen or cryogenic temperatures, each such shipment will require a frozen or cryogenic shipping package. CryoPort anticipates being in a position to service that need.

Fertility Clinics. We estimate that artificial insemination procedures in the United States account for at least 50,000 doses of semen annually. Since relatively few sperm banks provide donor semen, frozen shipping is almost always involved. As with animal semen, human semen must be stored and shipped at cryogenic temperatures to retain viability, stabilize the cells, and ensure reproducible results. This can only be accomplished with the use of liquid nitrogen or LN2 dry vapor shippers. CryoPort anticipates that this market will continue to increase as this practice gains acceptance in new areas of the world.

In addition to the above markets, our longer-term plans include expanding into new markets including, the diagnostics, food, environmental, semiconductor and petroleum industries.

Sales and Marketing

During the fiscal year ended March 31, 2011, annual net revenues from three customers, B-D Biosciences, CDx Holdings and Life Technologies accounted for 19%, 38% and 11% of our total revenues, respectively. During the fiscal year ended March 31, 2010, annual net revenue from two customers, B-D Biosciences and CDx Holdings accounted for 32% and 19% of our total revenues, respectively.

Table of Contents

Our geographical sales for the year ended March 31, 2011 were as follows:

USA and Canada	50%
Europe	20%
Asia and Rest of World	30%

We recently entered into agreements with FedEx and DHL and we plan to further expand our sales and marketing efforts through the establishment of additional strategic relationships with global couriers and, subject to available financial resources, the hiring of additional sales and marketing personnel.

During the year ended March 31, 2011, we had one internal sales person who manages our direct sales. In April 2011 the Company hired a Chief Commercial Officer and added three members to the direct sales force, of whom have backgrounds in the cold-chain shipping industry.

Industry and Competition

Our products and services are sold into a rapidly growing niche of the packaging industry focused on the temperature sensitive packaging and shipping of biological materials. Expenditures for value added packaging for frozen transport have been increasing for the past several years and, due in part to continued globalization, are expected to continue to increase even more in the future as more domestic and international biotechnology firms introduce pharmaceutical products that require continuous refrigeration at cryogenic temperatures. We believe this will require a greater dependence on passively controlled temperature transport systems (i.e., systems having no external power source).

We believe that growth in the following markets has resulted in the need for increased efficiencies and greater flexibility in the temperature sensitive packaging market:

Pharmaceutical clinical trials, including transport of tissue culture samples;

Pharmaceutical commercial product distribution;

Transportation of diagnostic specimens;

Transportation of infectious materials;

Intra laboratory diagnostic testing;

Transport of temperature-sensitive specimens by courier;

Analysis of biological samples;

Environmental sampling;

Gene and stem cell biotechnology and vaccine production; and

Food engineering.

Many of the biological products in these above markets require transport in a frozen state as well as the need for shipping containers which have the ability to maintain a frozen, cryogenic environment (e.g., minus 150° Celsius) for a period ranging from two to ten days (depending on the distance and mode of shipment). These products include semen, embryo, tissue, tissue cultures, cultures of viruses and bacteria, enzymes, DNA materials, vaccines and certain pharmaceutical products. In some instances, transport of these products requires temperatures at, or approaching,

minus 196° Celsius.

One problem faced by many companies operating in these specialized markets is the limited number of cryogenic shipping systems serving their needs, particularly in the areas of pharmaceutical companies conducting clinical trials. The currently adopted protocol and the most common method for packaging frozen transport in these industries is the use of solid state carbon dioxide (dry ice). Dry ice is used extensively in shipping to maintain a frozen state for a period of one to four days. Dry ice is used in the transport of many biological products, such as pharmaceuticals, laboratory specimens and certain infectious materials that do not require true cryogenic temperatures. The common approach to shipping these items via ground freight is to pack the product in a container, such as an expanded polystyrene (styrofoam) box or a molded polyurethane box, with a variable quantity of dry ice. The box is taped or strapped shut and shipped to its destination with freight charges based on its initial shipping weight.

With respect to shipments via specialized courier services, there is no standardized method or device currently in use for the purpose of transporting temperature-sensitive frozen biological specimens. One common method for courier transport of biological materials is to place frozen specimens, refrigerated specimens, and ambient specimens into a compartmentalized container, similar in size to a 55 quart Coleman or Igloo cooler. The freezer compartment in the container is loaded with a quantity of dry ice at minus 78° Celsius, while the refrigerated compartment at 8° Celsius utilizes ice substitutes.

Two manufacturers of the polystyrene and polyurethane containers frequently used in the shipping and courier transport of dry ice frozen specimens are Insulated Shipping Containers, Inc. and Tegrant (formerly SCA Thermosafe). When these containers are used with dry ice, the average sublimation rate (e.g., the rate at which dry ice turns from a solid to a gaseous state) in a container with a 11/2 inch wall thickness is slightly less than three pounds per 24 hours. Other existing refrigerant systems employ the use of gel packs and ice substitutes for temperature maintenance. Gels and eutectic solutions (phase changing materials) with a wide range of phasing temperatures have been developed in recent years to meet the needs of products with varying specific temperature control requirements.

Table of Contents

The use of dry ice and ice substitutes, however, regardless of external packaging used, are frequently inadequate because they do not provide low enough storage temperatures and, in the case of dry ice, last for only a few days without re-icing. As a result, companies run the risk of increased costs due to lost specimens and additional shipping charges due to the need to re-ice.

Some of the other disadvantages to using dry ice for shipping or transporting temperature sensitive products are as follows:

- Availability of a dry ice source;
- Handling and storage of the dry ice;
- Cost of the dry ice;
- Compliance with local, state and federal regulations relating to the storage and use of dry ice;
- Weight of containers when packed with dry ice;
- Securing a shipping container with a high enough R-value (which is a measure of thermal resistance) to hold the dry ice and product for the required time period;
- Securing a shipping container that meets the requirements of IATA, the DOT, the CDC, and other regulatory agencies; and
- The emission of green house gases into the environment.

Due to the limitations of dry ice, shipment of specimens at true cryogenic temperatures can only be accomplished using liquid nitrogen dry vapor shippers, or by shipping over actual liquid nitrogen. While such shippers provide solutions to the issues encountered when shipping with dry ice, they too are experiencing some criticisms by users or potential users. For example, the cost for these products typically can range from $650 to $3,000 per unit, which can substantially limit their use for the transport of many common biologics, particularly with respect to small quantities such as, is the case with direct to the physician drug delivery. Because of the initial cost and limited production of these containers, they are designed to be reusable. However, the cost of returning these heavy containers can be significant, particularly in international markets, because most applications require only one-way shipping. We expect to provide a cost effective solution compared to dry ice. We believe we will provide an overall cost savings of 10% to 20% for international and specialty shipments compared to dry ice, while at the same time providing a higher level of support and related services.

Another problem with these existing systems relates to the hold time of the unit in a normal, upright position versus the hold time when the unit is placed on its side or inverted. If a container is laying on its side or is inverted the liquid nitrogen is prone to leaking out of the container due to a combination of factors, including a shift in the equilibrium height of the liquid nitrogen in the absorbent material and the relocation of the point of gravity, which affects the hold time and compromises the dependability of the dry shipper, particularly when used in circumstances requiring lengthy shipping times. Due to the use of our proprietary technology, our CryoPort Express® Shippers are not prone to leakage when on their side or inverted, thereby protecting the integrity of our shipper s hold time.

Within our intended markets for our CryoPort Express® Shippers, there is limited known competition. We intend to become competitive by reason of our improved technology in our products and through the use of our service enabled business model. The CryoPort Express® System provides a simple and cost effective solution for the frozen or cryogenic transport of biological or pharmaceutical materials. This solution uses our innovative dewar and is supported by the CryoPort Express® Portal, our web-based order-entry system, which manages the scheduling and shipping of the CryoPort Express® Shippers. In addition, the traditional dry ice shippers and suppliers, such as MVE/Chart Industries, Taylor Wharton and Air Liquide, offer various models of dry vapor liquid nitrogen shippers that are not cost efficient for multi-use and multi-shipment purposes due to their significantly greater unit costs and

unit weight (which may substantially increase the shipping cost). On the other hand, they are more established and have larger organizations and have greater financial, operational, sales and marketing resources and experience in research and development than we do. Factors that we believe give us a competitive advantage are attributable to our shipping container which allows our shipper to retain liquid nitrogen when placed in non-upright positions, the overall leak-proofness of the our package which determines compliance with shipping regulations and the overall weight and volume of the package which determines shipping costs, and our business model represented by the merged integration of our shipper with CryoPort Express® Portal and Smart Pak data logger into a seamless shipping, tracking and monitoring solution. Other companies that offer potentially competitive products include Industrial Insulation Systems, which offers cryogenic transport units and has partnered with Marathon Products Inc., a manufacturer and global supplier of wireless temperature data collecting devices used for documenting environmentally sensitive products through the cold chain and Kodiak Thermal Technologies, Inc. which offers, among other containers, a repeat use active-cool container that uses free piston stirling cycle technology. While not having their own shipping devices, BioStorage Technologies is potentially a competitive company through their management services offered for cold-chain logistics and long term biomaterial storage. Cryogena offers a single use disposable LN2 shipper with better performance than dry-ice, but it does not perform as well and is not as cost-effective as the CryoPort solution when all costs are considered. In addition, BioMatrica, Inc. is developing and offering technology that stabilizes biological samples and research materials at room temperature. They presently offer these technologies primarily to research and academic institutions; however, their technology may eventually enter the broader cold-chain market.

Table of Contents

Research and Development

Our research and development efforts are focused on continually improving the features of the CryoPort Express® System including the web based customer service portal and the CryoPort Express® Shippers. Further these efforts are expected to lead to the introduction of shippers of varying sizes based on market requirements, constructed of lower cost materials and utilizing high volume manufacturing methods that will make it practical to provide the cryogenic packages offered by the CryoPort Express® System. Other research and development effort has been directed toward improvements to the liquid nitrogen retention system to render it more reliable in the general shipping environment and to the design of the outer packaging. Alternative phase change materials in place of liquid nitrogen may be used to increase the potential markets these shippers can serve such as ambient and 2-8°C markets. Our research and development expenditures during for the fiscal years ended March 31, 2011 and 2010 were $449,129 and $284,847, respectively.

Corporate Governance

Our Board is committed to legal and ethical conduct in fulfilling its responsibilities. The Board expects all directors, as well as officers and employees, to act ethically at all times and to adhere to the policies comprising the Company s Code of Business Conduct and Ethics. The Board of Directors (the Board) of the Company adopted the corporate governance policies and charters. Copies of the following corporate governance documents are posted on our website, and are available free of charge, at www.cryoport.com: (1) Code of Business Conduct and Ethics (2) Charter of the Nominating and Governance Committee of the Board of Directors, (3) Charter of the Audit Committee of the Board of Directors, and (4) Charter of the Compensation Committee of the Board of Directors. If you would like a printed copy of any of these corporate governance documents, please send your request to CryoPort, Inc., Attention: Corporate Secretary, 20382 Barents Sea Circle, Lake Forest CA 92630.

Human Resources

As of March 31, 2011, we had 13 full-time employees and 9 consultants; 3 of the consultants work for us on a full-time basis. Each of our employees has signed a confidentiality agreement and none are covered by a collective bargaining agreement. We have never experienced employment-related work stoppages and consider our employee relations to be good.

Table of Contents

ITEM 1A. RISK FACTORS

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of CryoPort, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our potential product and service revenues, acceptance of our products and services, expenses, net income(loss) and earnings(loss) per common share.

Risks Related to Our Business

We have incurred significant losses to date and may continue to incur losses.

We have incurred net losses in each fiscal year since we commenced operations. The following table represents net losses incurred for the years ended March 31, 2011 and 2010:

	Net Loss
Fiscal Year Ended March 31, 2011	$ 6,152,278
Fiscal Year Ended March 31, 2010	$ 5,651,561

As of March 31, 2011, we had an accumulated deficit of $52,096,087. While we expect to continue to derive revenues from our current products and services, in order to achieve and sustain profitable operations, we must successfully commercialize and launch our CryoPort Express® System, significantly expand our market presence and increase revenues. We may continue to incur losses in the future and may never generate revenues sufficient to become profitable or to sustain profitability. Continuing losses may impair our ability to raise the additional capital required to continue and expand our operations.

If we are unable to obtain additional funding, we may have to reduce or discontinue our business operations.

As of March 31, 2011, we had cash and cash equivalents of $9,278,443. We have expended substantial funds on the research and development of our products and IT systems. As a result, we have historically experienced negative cash flows from operations and we expect to continue to experience negative cash flows from operations in the future. Therefore, our ability to continue and expand our operations is highly dependent on the amount of cash and cash equivalents on hand combined with our ability to raise additional capital to fund our future operations.

We anticipate, based on currently proposed plans and assumptions relating to our ability to market and sell our products (but not including any additional strategic relationships with global couriers), that our cash on hand, together with projected cash flows, will satisfy our operational and capital requirements at least through the fourth quarter of our fiscal year 2012. There are a number of uncertainties associated with our financial projections that could reduce or delay our future projected revenues and cash-inflows, including, but not limited to, our ability to complete the commercialization and launch of our CryoPort Express® System, launch our relationship with FedEx, increase our customer base and revenues and enter into strategic relationships with additional global couriers. If our projected revenues and cash-inflows are reduced or delayed, we may not have sufficient capital to operate through the fourth quarter of our fiscal year 2012 unless we raise more capital. Additionally, if we are unable to realize satisfactory revenue in the near future, we will be required to seek additional financing to continue our operations beyond that period. We will also require additional financing to expand into other markets and further develop and market our products. We have no current arrangements with respect to any additional financing. Consequently, there can be no assurance that any additional financing on commercially reasonable terms, or at all, will be available when needed. The inability to obtain additional capital may reduce our ability to continue to conduct business operations. Any additional equity financing may involve substantial dilution to our then existing stockholders. In addition, raising additional funding may be complicated by certain provisions in the securities purchase agreements and related transaction documents, as amended, entered into in connection with our prior convertible debenture financings.

If we are not successful in establishing strategic relationships with global couriers, we may not be able to successfully increase revenues and cash flow which could adversely affect our operations.

We believe that our near term success is best achieved by establishing strategic relationships with global couriers, such as our recent agreements with FedEx and DHL. Such relationships will enable us to provide a seamless,

end-to-end shipping solution to customers and allow us to leverage the couriers established express, ground and freight infrastructures and penetrate new markets with minimal investment. Further, we expect that the global couriers will utilize their sales forces to promote and sell our frozen shipping services. If we are not successful in launching our relationship with FedEx or DHL or establishing additional relationships with global couriers, our sales and marketing efforts will be significantly impacted and anticipated revenue growth will be substantially delayed which could have an adverse affect on our operations.

Our agreements with FedEx and DHL may not result in a significant increase in our revenues or cash flow.

On January 13, 2010, we entered into an agreement with FedEx pursuant to which we lease to FedEx such number of our cryogenic shippers that FedEx, from time to time, orders for its customers. FedEx has the right to and shall, on a non-exclusive basis, promote, market and sell transportation of our shippers and our related value-added goods and services, such as our data logger, web portal and planned CryoPort Express® Smart Pak System. Because our agreement with FedEx does not contain any requirement that FedEx lease a minimum number of shippers from us during the term of the agreement, we may not experience a significant increase in our revenues or cash flows as a result of this agreement. On September 2, 2010, we entered into an agreement with DHL that gives DHL life sciences customers direct access to our web-based order entry and tracking portal to order our CryoPort Express® Shipper and preferred DHL shipping rates. Although the agreement provides shipping discounts that may be used to support our customers using our CryoPort Express® shipping solution, DHL will not be promoting, marketing or selling transportation of our shippers or services, which may not lead to any increase in our revenues.

Table of Contents

Current economic conditions and capital markets are in a period of disruption and instability which could adversely affect our ability to access the capital markets, and thus adversely affect our business and liquidity.

The current economic conditions and financial crisis have had, and will continue to have, a negative impact on our ability to access the capital markets, and thus have a negative impact on our business and liquidity. The shortage of liquidity and credit combined with substantial losses in worldwide equity markets could lead to an extended worldwide recession. We may face significant challenges if conditions in the capital markets do not improve and we do not achieve positive cash flow from operations. Our ability to access the capital markets may be severely restricted at a time when we need to access such markets, which could have a negative impact on our business plans, including the commercialization and launch of our CryoPort Express® System and other research and development activities. Even if we are able to raise capital, it may not be at a price or on terms that are favorable to us. We cannot predict the occurrence of future financial disruptions or how long the current market conditions may continue.

The sale of substantial shares of our common stock may depress our stock price.

As of March 31, 2011, there were 27,504,583 shares of our common stock issued and outstanding. Substantially all of these shares of common stock are eligible for trading in the public market. The market price of our common stock may decline if our stockholders sell a large number of shares of our common stock in the public market, or the market perceives that such sales may occur.

We could also issue up to 30,332,635 additional shares of our common stock including shares to be issued upon conversion of the outstanding balance of our convertible debentures and upon the exercise of outstanding warrants and options or reserved for future issuance under our stock incentive plans, as further described in the following table:

	Number of Shares of Common Stock Issuable or Reserved For Issuance
Common stock issuable upon conversion of the outstanding balance of our convertible debentures	869,065
Common stock issuable upon exercise of outstanding warrants	27,822,669
Common stock issuable upon exercise of outstanding options or reserved for future incentive awards under our stock incentive plans	1,640,901
Total	30,332,635

Of the total options and warrants outstanding as of March 31, 2011, options and warrants exercisable for an aggregate of 23,849,159 shares of common stock would be considered dilutive to the value of our stockholders interest in CryoPort because we would receive upon exercise of such options and warrants an amount per share that is less than the market price of our common stock on March 31, 2011.

We will have difficulty increasing our revenues if we experience delays, difficulties or unanticipated costs in establishing the sales, distribution and marketing capabilities necessary to successfully commercialize our products.

We are continuing to develop sales, distribution and marketing capabilities in the Americas, Europe and Asia. It will be expensive and time-consuming for us to develop a global marketing and sales network. Moreover, we may choose, or find it necessary, to enter into additional strategic collaborations to sell, market and distribute our products. We may not be able to provide adequate incentive to our sales force or to establish and maintain favorable distribution and marketing collaborations with other companies to promote our products. In addition, any third party with whom we have established a marketing and distribution relationship may not devote sufficient time to the marketing and sales of our products thereby exposing us to potential expenses in exiting such distribution agreements. We, and any of our

third party collaborators, must also market our products in compliance with federal, state, local and international laws relating to the provision of incentives and inducements. Violation of these laws can result in substantial penalties. Therefore, if we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, or if our distributors fail to promote our products, we will have difficulty increasing our revenues.

Our ability to grow and compete in our industry will be hampered if we are unable to retain the continued service of our key professionals or to identify, hire and retain additional qualified professionals.

A critical factor to our business is our ability to attract and retain qualified professionals including key employees and consultants. We are continually at risk of losing current professionals or being unable to hire additional professionals as needed. If we are unable to attract new qualified employees, our ability to grow will be adversely affected. If we are unable to retain current employees or strategic consultants, our financial condition and ability to maintain operations may be adversely affected.

Table of Contents

We are dependent on new products and services, the lack of which would harm our competitive position.

Our future revenue stream depends to a large degree on our ability to bring new products and services to market on a timely basis. We must continue to make significant investments in research and development in order to continue to develop new products and services, enhance existing products and services, and achieve market acceptance of such products and services. We may incur problems in the future in innovating and introducing new products and services. Our development stage products and services may not be successfully completed or, if developed, may not achieve significant customer acceptance. If we are unable to successfully define, develop and introduce new, competitive products and services and enhance existing products and services, our future results of operations would be adversely affected. Development and manufacturing schedules for technology products and services are difficult to predict, and we might not achieve timely initial customer shipments of new products or launch of services. The timely availability of these products and services and their acceptance by customers are important to our future success. A delay in new or enhanced product or service introductions could have a significant impact on our results of operations.

Because of these risks, our research and development efforts may not result in any commercially viable products or services. If significant portions of these development efforts are not successfully completed, or any new or enhanced products or services are not commercially successful, our business, financial condition and results of operations may be materially harmed.

If we successfully develop products and/or services, but those products and/or services do not achieve and maintain market acceptance, our business will not be profitable.

The degree of acceptance of our CryoPort Express® Shipper and/or CryoPort Express® System, or any future product or services, by our current target markets, and any other markets to which we attempt to sell our products and services, and our profitability and growth will depend on a number of factors including, among others:

- our shippers ability to perform and preserve the integrity of the materials shipped;
- relative convenience and ease of use of our shipper and/or web portal;
- availability of alternative products;