Cryoport, Inc.
Form 10-K
July 01, 2009
UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

FOR THE FISCAL YEAR ENDED MARCH 31, 2009

¨ 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: 000-51578

CRYOPORT, INC.
(Exact name of small business issuer 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
(Issuer's telephone number)

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Title of each exchange on which registered
Common Stock, $.001 par value	OTC Bulletin Board

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, $.001 par value
(Title of class)

Indicate by check mark if the registrant is well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ 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 ¨ 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 past 12 month (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 ¨

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 (§ 229.405 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 is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-K. þ

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company	Smaller reporting company þ

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

The market value of the voting stock held by non-affiliates of the issuer as of September 30, 2008 (most recently completed second fiscal quarter) was approximately $16,154,188.

As of June 27, 2009 the Company had 43,913,830 shares of its $0.001 par value common stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Inapplicable.

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PART I

In this Annual Report on Form 10-K the terms “CryoPort”, “Company” and similar terms refer to CryoPort, Inc., and its wholly owned subsidiary CryoPort Systems, Inc.

SAFE HARBOR FOR FORWARD LOOKING STATEMENTS:

THE COMPANY HAS MADE SOME STATEMENTS IN THIS ANNUAL REPORT ON FORM 10-K, INCLUDING SOME UNDER “DESCRIPTION OF BUSINESS”, “RISK FACTORS” AND “MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS,” AND ELSEWHERE, WHICH ARE FORWARD-LOOKING STATEMENTS. THESE STATEMENTS MAY DISCUSS THE COMPANY’S FUTURE EXPECTATIONS, CONTAIN PROJECTIONS OF ITS PLAN OF OPERATION OR FINANCIAL CONDITION OR STATE OTHER FORWARD-LOOKING INFORMATION. IN THIS ANNUAL REPORT ON FORM 10-K, FORWARD-LOOKING STATEMENTS ARE GENERALLY IDENTIFIED BY WORDS SUCH AS “ANTICIPATE”, “PLAN”, “BELIEVE”, “EXPECT”, “ESTIMATE”, AND THE LIK FORWARD-LOOKING STATEMENTS INVOLVE FUTURE RISKS AND UNCERTAINTIES, AND THERE ARE FACTORS THAT COULD CAUSE ACTUAL RESULTS OR PLANS TO DIFFER MATERIALLY FROM THOSE EXPRESSED OR IMPLIED BY THE STATEMENTS. THE FORWARD LOOKING INFORMATION IS BASED ON VARIOUS FACTORS AND IS DERIVED USING NUMEROUS ASSUMPTIONS. A READER, WHETHER INVESTING IN THE COMPANY’S SECURITIES OR NOT, SHOULD NOT PLACE UNDUE RELIANCE ON THESE FORWARD-LOOKING STATEMENTS, WHICH APPLY ONLY AS OF THE DATE OF THIS ANNUAL REPORT ON FORM 10-K. IMPORTANT FACTORS THAT MAY CAUSE ACTUAL RESULTS TO DIFFER FROM PROJECTIONS INCLUDE, BUT ARE NOT LIMITED TO, THE FOLLOWING:

- THE SUCCESS OR FAILURE OF MANAGEMENT’S EFFORTS TO IMPLEMENT THE COMPANY’S PLAN OF OPERATIONS;
- THE COMPANY’S ABILITY TO FUND ITS OPERATING EXPENSES;
- THE COMPANY’S ABILITY TO COMPETE WITH OTHER COMPANIES THAT HAVE A SIMILAR PLAN OF OPERATION;
- THE EFFECT OF CHANGING ECONOMIC CONDITIONS IMPACTING THE COMPANY’S PLAN OF OPERATION; AND
- THE COMPANY’S ABILITY TO MEET THE OTHER RISKS AS MAY BE DESCRIBED IN ITS FUTURE FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION.

THE COMPANY UNDERTAKES NO OBLIGATION TO PUBLICLY UPDATE OR REVISE ANY FORWARD-LOOKING STATEMENTS, WHETHER AS A RESULT OF NEW INFORMATION, FUTURE EVENTS OR OTHERWISE.

PART I

ITEM 1. BUSINESS.

Cryoport, Inc. (the"Company") is a frozen shipping container company, involved in the global movement of biological specimens for the life science industry at temperatures below zero centigrade. During the early years of the Company our limited revenue were derived from the sale of our reusable product line. The Company's current business plan focuses on a shipping container that will used by the Company to provide a simple shipping solution to life science companies moving pharmaceutical and biological samples in clinical trials and pharmaceutical distribution.

Overview:

The Company is focused on providing a solution for the frozen shipping market in the growing global biotechnology and pharmaceutical industries. The Company's business model includes delivering a reliable and cost effective frozen shipping solution, the CryoPort Express™ System, utilizing the Company's newly developed product line, the CryoPort Express™ Shippers, for the frozen or cryogenic transport of biological materials. These materials include live cell pharmaceutical products; e.g., cancer vaccines, diagnostic materials, reproductive tissues, infectious substances and other items that require continuous exposure to frozen or cryogenic temperatures (less than -150°C). The Company's mission is to provide a reliable and cost effective transport and packaging solutions for the transportation of biological or pharmaceutical materials requiring, or benefiting from, frozen or cryogenic temperatures.

The Company currently occupies approximately 12,000 square feet of manufacturing and office space in Lake Forest, California and has eight full-time employees and consultants and four part-time consultants.

History:

The Company was originally incorporated under the name G.T.5-Limited ("GT5") on May 25, 1990 as a Nevada Corporation. Upon completion of a Share Exchange Agreement, on March 15, 2005 the Company changed its name to Cryoport, Inc. and acquired all of the issued and outstanding shares of Cryoport Systems, Inc. in exchange for 24,108,105 shares of its 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, originally formed in 1999 as a California limited liability company and reorganized into a California corporation on December 11, 2000, remains the operating company under Cryoport, Inc.

Our Products

The Company's Current Product Line:

The CryoPort Express™ System.

The Company is commencing the full commercialization of the CryoPort Express™ System which is focused on improving the reliability of frozen shipping while reducing the customers' overall operating costs. The CryoPort Express™ System provides a simple, effective solution for the frozen or cryogenic transport of biological or pharmaceutical materials using a web-based order-entry system, which manages the scheduling and shipping of the CryoPort Express™ Shippers, a line of multiple size, cryogenic dry vapor shippers. This line of shippers is capable of maintaining cryogenic temperatures of minus 150 centigrade or less, for 10+ days.

A dry cryogenic shipper is a device that uses liquid nitrogen which is contained inside a vacuum insulated bottle as a refrigerant to provide storage temperatures below minus 150° centigrade. The CryoPort dry shipper is designed such

that there can be no pressure build up as the liquid nitrogen evaporates, or spillage of liquid nitrogen. A proprietary foam retention system is employed to ensure that liquid nitrogen stays inside the vacuum container, allowing the shipper to be designated as a dry shipper which meets the International Air Transport Association, ("IATA") requirements. Biological or pharmaceutical specimens are stored in 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 transported using the cryogenic shipper can include live cell pharmaceutical products; e.g., cancer vaccines, diagnostic materials, semen and embryos, infectious substances and other items that require continuous exposure to frozen or cryogenic temperatures (lower than -150°C).

The technology underlying the CryoPort Express™ Shipper was developed by modifying and advancing technology from the Company's previous line of reusable cryogenic dry shippers, which the Company historically developed, manufactured and sold to customers. In order to focus resources on the development of the new CryoPort Express™ Shippers, the Company discontinued actively selling the reusable shippers in fiscal 2007, although minimal sales continued until the line was discontinued this past fiscal year. The new CryoPort Express™ Shippers are manufactured from alternative, lower cost materials, which will reduce overall operating costs and we have developed a new business model that simplifies the shipping process for our potential customer companies that does not require the purchase of the expensive containers.

The Company's production and manufacturing incorporates innovative technologies developed for aerospace and other industries to develop products that are more 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.

The CryoPort Express™ Shippers share many of the characteristics and basic design details of the currently available reusable products. The expected shared characteristics include general geometry and shape, similar liquid capacities and similar thermal performance characteristics. As a result, much of the market experience gained from the sale of these products is directly relevant to the usage characteristics of the CryoPort Express™ System and the CryoPort Express™ Shippers. The CryoPort Express System offers two sizes of shippers based on the market requirements. The Company maintains ongoing development related to the shippers and is principally focused on material properties, particularly those properties related to the low temperature requirement, the vacuum retention characteristics; i.e., permeability of the materials and lower cost materials based on meeting 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.

The CryoPort Express™ Shippers are currently being manufactured at the Company's Lake Forest, California facility. This shipper is IATA certified for the shipment of Class 6.2 Dangerous Goods. This shipper may be used where packaging of the biological material need not comply with IATA Packing Instructions 602 or 650. The shipper may be utilized for the shipment of specimens for diagnosis, treatment or evaluation of disease that must conform to the IATA 650 packaging standards.

These shippers are lightweight, low-cost, re-usable vapor phase liquid nitrogen storage containers that combine the best features of packaging, cryogenics and high vacuum technology. The shipper is composed of an aluminum metallic dewar flask, with a well for holding the biological material in the inner chamber. A 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. A high surface, low density open cell plastic foam material surrounds the inner chamber for retaining 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 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 LN2 up 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 LN2. The entire Dewar vessel is then wrapped in a plurality of insulating and cushioning materials and placed either in a disposable outer packaging made of recyclable material.

The Company believes the above product configuration satisfies the needs of the markets that require the temperature-critical, frozen and refrigerated transport of biological materials, such as pharmaceutical clinical trials,

gene biotechnology, infectious materials handling, and animal and human reproduction. Due to the Company's unique proprietary technology and innovative design, its shippers are less prone to losing functional hold time when not kept in an upright position than the competing products.

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.

Biological Material Holders for Infectious and Dangerous Goods. The Company has 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, 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 plastic bag capable of withstanding cryogenic temperatures, and then sealed. This entire package is then placed in a unique, patented, secondary containment bag, which is a plastic film based material, critical to the function of the overall cryogenic package. These bags use a pressure-sensitive adhesive closure much like a common overnight courier envelope. As a result, these bags are inherently disposable, one-use-only. This bag is then placed into the well of the cryogenic shipper.

The Company's Future Products:

The Company's continuing R&D efforts are expected to lead to the introduction of additional units including larger and smaller size units 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.

The Company plans further research and development efforts to continually improve the features of the CryoPort Express™ System and the CryoPort Express™ Shippers and to further enable both higher mass manufacturing and additional cost reduction opportunities.

Our Strategy:

The Company's present objective is to leverage its proprietary technology and developmental expertise to design, develop, manufacture and sell frozen shipping devices. The key elements of its strategy include::

- To provide a simple, one-call solution for customers that manages the scheduling and shipping for frozen or cryogenic transport of biological or pharmaceutical sample and drug materials

- To make the use of the frozen shipping solution cost effective

- To provide a "green" solution that eliminates the greenhouse gases from dry ice (solid carbon dioxide) and eliminates the need for Syrofoam lined boxes which cannot go in landfills in many states

Expand the Company's product offerings to address growing markets. Given the need for a temperature-sensitive shipping device that can cost effectively be used, the Company is continuing the development of the CryoPort Express™ System, which utilizes a shipping device that meets the temperature requirements during the transit time, eliminates the customer's need to dispose of the shipper, and eliminates the costs associated with retrieving, disposing of or re-icing the package while in transit, plus the costs associated with maintaining and managing an inventory of shippers, as well as significantly minimizes loss of specimen viability during the shipping process. The Company continues to develop the CryoPort Express™ System , specifically the web-based order placement system and the sizes and features of the CryoPort Express Shippers™ based on market needs.

Expand the Company's marketing and distribution channels. The Company's products serve the shipping needs of companies across a broad spectrum of industries on a growing international level. It is the Company's goal to establish those contacts necessary to achieve a broader distribution of its products.

Establish strategic partnerships. In order to expedite the Company's time to market and increase its market presence, the Company is currently negotiating to establish strategic alliances to facilitate the manufacture, promotion and distribution of its products, including plans to establish alliances with shipping container manufacturers (both cryogenic and dry ice), integrated express companies, and freight forwarding companies.

Sales and Marketing:

The Company currently has an internal sales person who manages both its direct sales efforts and its limited third party resellers, which include Miller Supply, Air Liquide and Tegrant. The Company's current distribution channels cover the Americas, Europe and Asia. During the year ended March 31, 2009 the distributor, Miller Supply, accounted for 18% of the Company's overall sales volumes. These sales were in the Company's shipping accessories and the reusable shippers that were discontinued during the past fiscal year.

The Company's geographical sales for the year ended March 31, 2009 were as follows:

USA	81.4%
Europe	17.8%
Canada	0.8%

Customer Base:

The Company believes that the primary customers for the CryoPort Express™ System are concentrated in the following markets for the following reasons:

- Pharmaceutical clinical trials
- Gene biotechnology
- Transport of infectious materials and dangerous goods
- Diagnostics
- Government laboratories
- Pharmaceutical distribution
- Human assisted reproduction/artificial insemination

Pharmaceutical Clinical Trials. Every pharmaceutical company developing a new drug that must be approved by the Food and Drug Administration conducts clinical trials to, among other things, test the safety and efficacy of the potential new drug. In connection with the clinical trials, 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 the specified testing laboratory, 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 up to 36 hours, in the absence of re-icing (which is quite costly). Because shipments of packages internationally can be delayed for more than 36 hours due to flight cancellations, incorrect destinations, labor problems, ground logistics, customs and safety reasons, dry ice is not always a reliable and cost effective option. Clinical trial specimens are often irreplaceable because each one represents 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. The Company's shippers are ideally suited for this market, as the hold time provided by its shipper 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 650 or 602 certified packaging. The Company has developed and obtained IATA certification of the CryoPort Express™ System, it is ideally suited for this market, in particular due to the elimination of the cost to return the reusable shipper.

Transport of Infectious Materials and Dangerous Goods. The transport of potentially infectious materials demands strict adherence to regulations that protect public safety while maintaining the viability of the material being shipped. All blood products are considered to be potentially 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 frozen environment. The Company has developed the CryoPort Express™ Shipper 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. The Company's CryoPort Express™ Shipper is 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 distribution, 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, there are a substantial 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. The Company anticipates being in a position to service that need.

Assisted Human Reproduction. According to The Wall Street Journal, January 6, 2000 issue, 30,000 infants are born annually in the United States through artificial insemination and according to Department of Health statistics, 10 million Americans annually are affected by infertility problems. It is estimated that this represents at least 50,000 doses of semen. 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, to stabilize the cells and to ensure reproducible results. This can only be accomplished with the use of liquid nitrogen or LN2 dry vapor shippers. The Company anticipates that this market will continue to increase as this practice gains acceptance in new areas of the world.

Competition:

Within the Company's intended markets for the CryoPort Express™ System, there is limited known competition. The Company intends to become competitive by reason of improved technological in its products and through the use of its business model facilitating simple one-call by customers process to achieve effective frozen shipping compared to today's complicated and expensive use of dry ice. The traditional suppliers, Chart Industries, Taylor Wharton, and Air Liquide have various models of dry shippers available that sell at prices that preclude a reasonable concept of disposability. 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 the Company does. Competitive factor advantages include the technology that allows the ability of the shipper to retain liquid nitrogen when placed in non-upright positions, the overall "leak-proofness" of the package which determines compliance with shipping regulations and the overall weight and volume of the package which determines shipping costs.

Industry Overview:

The Company's products 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 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. This will require a greater dependence on passively controlled temperature transport systems (i.e., systems having no external power source). [References: Cryopak Industries – Investment

Package/Annual Report and US Department of Commerce - US Industrial Outlook.]

The Company believes 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., -150°C) 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, -196°C.

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 carbon dioxide (dry ice). Dry ice is used in shipping extensively 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 biologicals 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°C, while the refrigerated compartment at 8°C 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 one and one-half 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.

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;