Cryoport, Inc.
Form 10-K
June 28, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the fiscal year ended March 31, 2016

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

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.)**

17305 Daimler St.

Irvine, CA 92614

(Address of principal executive offices)

(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	NASDAQ

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 ¨ No x

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 x

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 x 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K ¨

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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

The aggregate market value of Common Stock held by non-affiliates of the registrant as of September 30, 2015 was $23,081,331(1) based on the closing sale price of such common equity on such date.

As of June 13, 2016 there were 14,271,910 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

(1) Excludes 2,609,861 shares of common stock held by directors and officers, and any stockholders whose ownership exceeds five percent of the shares outstanding as of September 30, 2015.

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FORWARD-LOOKING STATEMENTS

Unless the context otherwise requires, all references in this Annual Report on Form 10-K to the "Company", "we," "us," "our," or "Cryoport" refer to Cryoport, Inc. and our wholly owned subsidiary, Cryoport Systems, Inc. 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.

Cryoport, Inc.'s Annual Report on Form 10-K contains certain forward-looking statements. These forward-looking statements involve a number of risks and uncertainties. These forward-looking statements can generally be identified as such because the context of the statement will include certain words, including but not limited to, "believes," "may," "will," "expects," "intends," "estimates," "anticipates," "plans," "seeks," "continues," "predicts," "potential," "likely," or "opportunity," and also contains predictions, estimates and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on the current beliefs of the Company's management, as well as assumptions made by and information currently available to the Company's management. Readers of this Annual Report on Form 10-K should not put undue reliance on these forward-looking statements, which speak only as of the time this Annual Report on Form 10-K was filed with the Securities and Exchange Commission (the "SEC"). Reference is made in particular to forward-looking statements regarding the success of our products, product approvals, product sales, revenues, development timelines, product acquisitions, liquidity and capital resources and trends. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Cryoport Inc.'s actual results may differ materially from the results projected in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this Annual Report on Form 10-K, including the "Risk Factors" in "Item 1A — Risk Factors", and in "Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Part II. In addition, past financial or operating performance is not necessarily a reliable indicator of future performance, and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. Except as required by law, we do not undertake to update any such forward-looking statements and expressly disclaim any duty to update the information contained in this Annual Report on Form 10-K.

PART 1

Item 1. ***Business***

Overview

We provide cryogenic logistics solutions to the life sciences industry through a combination of proprietary packaging, information technology and specialized cold chain logistics knowhow. We view our solutions as disruptive to the "older technologies" of dry ice and liquid nitrogen, in that our solutions are comprehensive and combine our competencies in configurations that are customized to our client's requirements. We provide comprehensive, reliable, economic alternatives to all existing logistics solutions and services utilized for frozen shipping in the life sciences industry (e.g., personalized medicine, cell therapies, stem cells, cell lines, vaccines, diagnostic materials, semen, eggs, embryos, cord blood, bio-pharmaceuticals, infectious substances, and other commodities that require continuous exposure to cryogenic or frozen temperatures). As part of our services we provide the ability to monitor, record and archive crucial information for each shipment that can be used for scientific and regulatory purposes.

Our Cryoport Express® Solutions include a sophisticated cloud-based logistics operating platform, which is branded as the Cryoportal™. The Cryoportal™ supports the management of the entire shipment and logistics process through a single interface, including initial order input, document preparation, customs clearance, courier management, shipment tracking, issue resolution, and delivery. In addition, it provides unique and incisive information dashboards and validation documentation for every shipment. The Cryoportal™ records and retains a fully documented "chain-of-custody" and, at the client's option, "chain-of-condition" for every shipment, helping ensure that quality, safety, efficacy, and stability of shipped commodities are maintained throughout the process. This recorded and archived information allows our clients to meet exacting requirements necessary for scientific work and for proof of regulatory compliance during the logistics phase.

The branded packaging for our Cryoport Express® Solutions includes our liquid nitrogen dry vapor shippers, the Cryoport Express® Shippers. The Cryoport Express® Shippers are cost-effective and reusable cryogenic transport containers (our standard shipper is a patented vacuum flask) utilizing an innovative application of "dry vapor" liquid nitrogen ("LN2") technology. Cryoport Express® Shippers are International Air Transport Association ("IATA") certified and validated to maintain stable temperatures of minus 150° C and below for a 10-day dynamic shipment period. The Company currently features three Cryoport Express® Shippers: the Standard Dry Shipper (holding up to 75 2.0 ml vials), the High Volume Dry Shipper (holding up to 500 2.0 ml vials) and the recently introduced Cryoport Express® CXVC1 Shipper (holding up to 1,500 2.0 ml vials). In addition, we assist clients with internal secondary packaging (e.g., vials, canes, straws and plates).

Our most used solution is the "turnkey" solution, which can be accessed directly through our cloud-based Cryoportal™ or by contacting Cryoport Client Care for order entry. Once an order is placed and cleared, we ship a fully charged Cryoport Express® Shipper to the client who conveniently loads its frozen commodity into the inner chamber of the Cryoport Express® Shipper. The customer then closes the shipper package and reseals the shipping box displaying the next recipient's address ("Flap A") for pre-arranged carrier pick up. Cryoport arranges for the pick-up of the parcel by a shipping service provider, which is designated by the client or chosen by Cryoport, for delivery to the client's intended recipient. The recipient simply opens the shipper package and removes the frozen commodity that has been shipped. The recipient then reseals the package, displaying the nearest Cryoport Staging Center address, making it ready for pre-arranged carrier pick-up. When the Cryoport Staging Center receives the Cryoport Express® Shipper, it is cleaned, put through quality assurance testing, and returned to inventory for reuse.

In late 2012, we shifted our focus to become a comprehensive cryogenic logistics solutions provider. Recognizing that clients in the life sciences industry have varying requirements, we unbundled our technologies, established customer facing solutions and took a consultative approach to the market. Today, in addition to our standard "Turn-key Solution," described above, we also provide the following customer facing, value-added solutions to address our various clients' needs:

- "***Customer Staged Solution***," designed for clients making 50 or more shipments per month. Under this solution, we supply an inventory of our Cryoport Express® Shippers to our customer, in an uncharged state, enabling our customer (after training/certification) to charge them with liquid nitrogen and use our Cryoportal™ to enter orders with shipping and delivery service providers for the transportation of the package.

- "***Customer Managed Solution***," a limited customer implemented solution, whereby we supply our Cryoport Express® Shippers to clients in a fully charged state, but leaving it to the client to manage the shipping, including the selection of the shipping and delivery service provider and the return of the shipper to us.

- "***powered by Cryoport***℠," available to providers of shipping and delivery services who seek to offer a "branded" cryogenic logistics solution as part of their service offerings, with "*powered by Cryoport*℠" appearing prominently on the offering software interface and packaging. This solution can also be private labeled upon meeting certain requirements, such as minimum required shipping volumes.

- "***Integrated Solution,***" which is our total outsource solution. It is our most comprehensive solution and involves our management of the entire cryogenic logistics process for our client, including Cryoport employees at the client's site to manage the client's cryogenic logistics function in total.

- "***Regenerative Medicine Point-of-Care Repository Solution,***" designed for allogeneic therapies. In this solution we supply our Cryoport Express® Shipper to ship and store cryogenically preserved life science products for up to six days (or longer periods with supplementary shippers) at a point-of-care site, with the Cryoport Express® Shipper serving as a temporary freezer/repository enabling the efficient and effective distribution of temperature sensitive allogeneic cell-based therapies without the expense, inconvenience, and potential costly failure of an on-sight,

cryopreservation device.

- "***Personalized Medicine and Cell-based Immunotherapy Solution,***" designed for autologous therapies. In this solution our Cryoport Express® Shipper serves as an enabling technology for the safe transportation of manufactured autologous cellular-based immunotherapy market by providing a comprehensive logistics solution for the verified chain of custody and condition transport from, (a) the collection of the patient's cells in a hospital setting, to (b) a central processing facility where they are manufactured into a personalized medicine, to (c) the safe, cryogenically preserved return of these irreplaceable cells to a point-of-care treatment facility. If required, the Cryoport Express® Shipper can then serve as a temporary freezer/repository to allow the efficient distribution of this personalized medicine to the patient when and where the medical provider needs it most without the expense, inconvenience, and potential costly failure of an on-sight, cryopreservation device.

Cryoport is continuously expanding its solutions offerings in response to its customers' needs.

In April 2016, Cryoport launched its Temperature Controlled Logistics Consulting Division to assist life sciences companies in developing strategies for global cold chain logistics management and contingency options to protect their valuable, and often irreplaceable, biological commodities. The launch of Cryoport's Temperature Controlled Logistics Consulting Division addresses the demand created by the worldwide advances in cellular based therapies, including immunotherapies, stem cells and CAR T-cells. Cell-based immunotherapies are causing broad shifts and challenges for the life sciences industry, including how to obtain, properly store and transport the growing number of new, individualized, temperature sensitive therapies. Improper temperature maintenance or temperature excursions during any portion of a logistics cycle can adversely affect the viability of these biologically based commodities. Consequently, strategic, global logistics planning for cryogenic cold chain solutions has taken on a strategic importance to the life sciences industry and a rapidly growing demand for consulting expertise

In June 2016, Cryoport further broadened its capabilities and solutions offerings beyond cryogenic logistics and transportation services to include temperature-controlled storage solutions that include cGMP compliant biorepositories at controlled temperatures and climatized systems. Cryoport Biostorage services feature extensive management and monitoring, including controlled access to commodities, periodic temperature and activity reports, as well as 21 CFR, Part II compliant monitoring with 24/7/365 alarm response.

Also in June 2016, Cryoport announced a new Laboratory Relocation Service, for transport of complete laboratories. The Laboratory Relocation Service manages the safe, secure and proper transportation of materials that are stored in labs as well as lab equipment and instruments. Relocation projects can range in size from the relocation of a fully equipped lab to the move of a single freezer.

Competitive Advantages

With our first-to-market cryogenic logistics solutions for the life sciences industry, we have established a unique lead over potential competitors. Furthermore, we are not aware of a company that offers comparable solutions and has the same capabilities Cryoport has as a global provider of advanced, validated cryogenic logistics solutions. As a solutions company working with our tools in packaging, information technology, and cryogenic logistics, we address our growing $2.0 billion cryogenic logistics market in innovative and creative ways.

The majority of our competition utilizes “old technologies.” In fact, most of our market still uses dry ice and liquid nitrogen. In the case of dry ice the technology does not deliver cryogenic temperatures and, consequently, this medium allows cells to degrade, sometimes beyond any utility. When biology was less developed, dry ice was believed to be acceptable and was readily available.

Liquid nitrogen, on the other hand, while effective, is bulky, expensive and has special handling requirements. Both dry ice and liquid nitrogen are classified “hazardous” by shipping companies and regulatory authorities. In addition to being ineffective and/or classified as “dangerous goods,” they are inefficient when compared to Cryoport solutions. Conversely, Cryoport’s solutions are classified as non-hazardous.

Having been validated and qualified as a solutions provider for hundreds of life sciences companies and institutions, Cryoport has logged over 30,000 shipments to over 100 countries with hundreds of life sciences materials. Once life sciences companies start utilizing our advance cryogenic logistics solutions, we experience minimal client attrition.

While we look at companies such as Thermo Fisher Scientific, AmerisourceBergen Corporation and Marken as potential competitors, some of these companies are also our customers.

We think our competitive position is further enhanced by our respective “powered by Cryoport” partnership agreements with FedEx, DHL and UPS, who collectively, account for approximately 85% of world’s air freight and who, individually, have been expanding their offerings of cold chain logistics solutions to the life sciences industry. In short, we are the cryogenic solution for each of them, employing our packaging, our software and our logistics expertise.

The challenge for our seasoned, professional management team is to maintain what we believe to be a four year lead in the marketplace. In other words, we think it would take a serious potential competitor at least four years to build out the competencies that we possess and the knowledge we have of the marketplace.

In addition to our intellectual property consisting of three issued U.S. patents, one pending U.S. patent application, and one U.S. provisional patent application and our lead as the first to market mover, we think our biggest competitive advantage is our speed to market with new solutions and our sensitivity to anticipate and react to market needs. Our solutions are comprehensive and it is in our “DNA” to maintain our market lead by employing the best people in the industry as well as our current and new technologies to maintain that lead.

Given today’s environmental concerns, we also consider the fact that we are “green” to be a competitive advantage. Our packaging materials are recyclable and the key components are reusable. The fact that the inner and outer shells of our shippers are made of aircraft-grade aluminum makes these components recyclable as well. We take our responsibility toward the environment seriously.

Strategic Logistics Alliances

We have sought to establish strategic alliances as a long-term method of marketing our solutions providing minus 150° Celsius shipping condition to the life sciences industry. We have focused our efforts on leading companies in the logistics services industry as well as participants in the life sciences industry. In connection with our alliances with providers of shipping services, we refer to their offerings as “powered by Cryoport℠” to reflect our solutions being integrated into our alliance partner’s services.

Cryoport now serves and supports the three largest integrators in the world, responsible for over 85% of worldwide airfreight, with its advanced cryogenic logistics solutions for life sciences. We operate with each independently and confidentially in support of their respective market and sales strategies. We maintain our independent partnerships with strict confidentiality guidelines within the Company. These agreements represent a significant validation of our solutions and the way we conduct our business.

FedEx. In January 2013, we entered into a master agreement with Federal Express Corporation ("FedEx") (the "FedEx Agreement") renewing these services and providing FedEx with a non-exclusive license and right to use a customized version of our Cryoportal™ for the management of shipments made by FedEx customers. The FedEx Agreement became effective on January 1, 2013 and was amended in December 2015 to extend the initial term for an additional three years, expiring on December 31, 2018. FedEx has the right to terminate this agreement at any time for convenience upon 180 days' notice.

Under our FedEx Agreement, we provide frozen shipping logistics services through the combination of our purpose-built proprietary technologies and turnkey management processes. FedEx markets and sells Cryoport's services for frozen temperature-controlled cold chain transportation as its FedEx® Deep Frozen Shipping Solution on a non-exclusive basis and at its sole expense. As part of the solution, Cryoport has developed a FedEx branded version of the Cryoportal™ software platform, which is "powered by Cryoport℠" for use by FedEx and its customers, giving them access to the full capabilities of our cloud-based logistics management software platform.

DHL. In June 2014, we entered into a master agreement with LifeConEx, a part of DHL Global Forwarding ("DHL"). DHL has enhanced its cold chain logistics offerings to its life sciences and healthcare customers with Cryoport's validated cryogenic solutions. DHL offers Cryoport's cryogenic solutions through its worldwide Thermonet network of Certified Life Sciences Stations under the DHL brands as "*powered by Cryoport℠*". In addition, DHL's customers have direct access to our cloud-based order entry and tracking portal to order Cryoport Express® Solutions and receive preferred DHL shipping rates and discounts. Our proprietary logistics management operating platform, the Cryoportal™, is integrated with DHL's tracking and billing systems to provide DHL life sciences and healthcare customers with a seamless way of accessing critical information regarding shipments of biological material worldwide.

UPS. In October 2014, we added United Parcel Services, Inc. ("UPS") as our third major distributor by entering into an agreement with UPS Oasis Supply Corporation, a part of UPS, whereby UPS offers our validated and comprehensive cryogenic solutions to its life sciences and healthcare customers on a global basis. Over the course of rolling out our new relationship with UPS, UPS customers will have direct access to our cloud-based order entry and tracking portal to order Cryoport Express® Solutions and gain access to UPS's broad array of domestic and international shipping and logistics solutions at competitive prices. Our proprietary logistics management operating platform, the Cryoportal™, is integrated with UPS's tracking and billing systems to provide UPS life sciences and healthcare customers with a seamless way of accessing critical information regarding shipments of biological material worldwide.

Worthington Industries. In April 2016, we signed a strategic partnership with Worthington Industries, a maker of cryogenic storage vessels and equipment. Through this partnership, Worthington's CryoScience by Taylor Wharton business will design and manufacture biostorage and logistics equipment for use in Cryoport's life sciences cryogenic logistics solutions. With the added competencies Worthington's CryoScience by Taylor Wharton brings to Cryoport, we can concentrate on further advancing and expanding our cold chain solutions to meet the growing and varied demands for validated cryogenic logistics solutions in the life sciences market. Working in tandem with Worthington allows Cryoport to meet the demands of a more diverse clientele through a broader offering, which in turn increases our revenue opportunity as well as provides us the opportunity to rapidly scale to support our clients commercialization activities.

Pacific Bio-Material Management. Through a strategic partnership with Pacific Bio-Material Management, Inc. ("PBMMI") entered into in May 2016, Cryoport now offers storage solutions that include cGMP compliant biorepositories at controlled temperatures and climatized systems with effective redundancies such as back-up freezers and power. Cryoport Biostorage services features extensive management and monitoring, including controlled access to commodities, periodic temperature and activity reports, as well as 21 CFR, Part 11 compliant monitoring with 24/7/365 alarm response.

Cryoport's Positioning in the Life Sciences Industry

Life sciences technologies are expected to have a significant impact on global society over the next 25 years. In the United States alone, the life sciences industry is made up of 6,000 identifiable establishments. However, the industry is growing globally in a way where research and manufacturing pipelines span across the globe, which increases the need to mitigate logistics risk.

The total cold chain logistics market has historically grown 70% faster per annum than the total logistics market. For 2011, global cold chain logistics transportation costs were reported to be $7.2 billion; about $1.5 billion within the cryogenic range of requirements. By 2017, transportation cost alone, for global life sciences cold chain logistics, is forecasted to grow to $9.3 billion, a 41% increase, and twice the growth of the overall market.

In addition, with the recent advancements in the development of biologics and cell-based therapies, scientists, intermediaries, and manufacturers require the means for cryogenically transporting their work. Temperatures must be maintained below the “glass point” (generally, minus 136ºC) while shipping these therapies to ensure that the shipped specimens are not subject to degradation that could impact the characteristics and efficacy of those specimens.

While we estimate that our solutions currently offer comprehensive and technology-based monitoring and tracking for a potential of six to seven million deep frozen shipments globally on an annual basis, we also believe that with investment in our services, adaptations of our solutions can be applied to a large portion of an additional fifty-five to sixty million annual shipments requiring ambient (between 20° and 25°C), chilled (between 2° and 8°C) or frozen (minus 10°C or less) temperatures.

Cryoport’s clients include companies and institutions that require reliable cryogenic logistics solutions such as therapy developers for personalized medicine, bio-pharmaceuticals, research, contract research organizations, diagnostic laboratories, contract manufacturers, cord blood repositories, vaccine manufacturers, animal husbandry related companies, and in-vitro fertilization clinics.

Life Sciences Agreements

Zoetis. In December 2012, we signed an agreement with Pfizer Inc. relating to Zoetis Inc. (formerly the animal health business unit of Pfizer Inc.) pursuant to which we were engaged to manage frozen shipments of a key poultry vaccine. Under this arrangement, Cryoport provides on-site logistics personnel and its logistics management operating platform, the Cryoportal™ to manage shipments from the Zoetis manufacturing site in the United States to domestic customers as well as various international distribution centers. As part of our logistics management services, Cryoport is constantly analyzing logistics data and processes to further introduce economies and reliability throughout the network, ensuring products arrive at their destinations in specified conditions, on-time and with the optimum utilization of resources. The Company manages Zoetis’ total fleet of dewar flask shippers used for this purpose, including liquid nitrogen shippers. In July 2013 the agreement was amended to expand Cryoport’s scope to manage all logistics of Zoetis’ key frozen poultry vaccine to all Zoetis’ international distribution centers as well as all domestic shipments. In October 2013, the agreement was further amended to further expand Cryoport’s role to include the logistics management for a second poultry vaccine. In September 2015, the agreement was further amended and extended through September 2018, subject to certain termination and extension provisions.

In summary, we serve the life sciences industry with cryogenic logistics solutions that are advanced, comprehensive, reliable, validated, and efficient. Our clients include those companies and institutions that have logistics requirements for personalized medicine, immunotherapies, stem cells, cell lines, tissue, vaccines, in-vitro fertilization, cord blood and other temperature sensitive commodities of life sciences.

Corporate History and Structure

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 200,901 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 17305 Daimler Street, Irvine, CA 92614. 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 prospectus.

The Company became public by a reverse merger with a shell company in May 2005. Over time the Company has transitioned from being a development company to a fully operational public company, providing cold chain logistics solutions to the life sciences industry globally.

Cryoport Express® Solutions

Our Cryoport Express® Solutions are currently made up primarily of the Cryoportal™ software platform, Cryoport Express® Shippers, Cryoport Express® SmartPak condition monitoring systems and our life sciences cold chain logistics expertise. Cryoport Express® Solutions are focused on improving the reliability of frozen shipping while reducing our clients' overall operating costs. This is accomplished by providing complete end-to-end solutions for the transport and monitoring of frozen or cryogenically preserved biological or other materials shipped primarily through distribution partners, such as FedEx, UPS, and DHL, and specialty couriers.

The information technology is centered on a cryogenic logistics operating platform called the Cryoportal™. The Cryoportal™ is a cloud-based cryogenic logistics operating platform. Among its functions, the Cryoportal™ programmatically assists in the management of all aspects of the logistics operations beginning with order entry and continuing to monitor, log data, track shipments and store vital information. The Cryoportal™ is capable of producing a variety of Cryoport Express® Analytics which report shipment performance metrics and evaluates temperature-monitoring and other data collected by the Cryoport Express® SmartPak during shipment.

Cryoport Express® Solutions are focused on improving the reliability of cryogenic logistics while reducing our clients' overall operating costs. This is accomplished by providing tailored and complete end-to-end solutions for cryogenic logistics requirements including management, transport, monitoring and data collection regarding frozen/cryogenically preserved biological commodities or pharmaceutical materials shipped primarily though integrators and Cryoport's logistics network which includes specialty couriers, brokers and other intermediaries. Certain of the intellectual property underlying our Cryoport Express® Solutions, other than that related to the Cryoport Express® Shippers, have been, and continue to be, developed under a contract with an outside software development company, with the underlying technology licensed to Cryoport for exclusive use in our field of use.

Cryoportal™

The Cryoportal™ is used by Cryoport, our clients and 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 assist in managing logistics 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 Cryoportal™ 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's") 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.

The Cryoportal™ also serves as the communications center for the management, collection and analysis of SmartPak data collected from SmartPak condition monitoring system 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 our clients relating to their shipments.

The Cryoportal™ software platform has been developed as a "carrier-agnostic" system, allowing the client and the Cryoport Client Care team to work with a single or multiple integrators, freight forwarders, couriers and/or brokers depending on the specific requirements and client preferences. To increase operational efficiencies, Cryoportal™ has

already been integrated with the tracking systems of FedEx, DHL and UPS and we plan to integrate it with other key logistics providers.

The Cryoportal™ was developed for time- and temperature-sensitive shipments that are required to be maintained at specific temperatures, such as ambient (between 20° and 25° Celsius), chilled (between 2° and 8° Celsius) or frozen (minus 10° Celsius or less all the way down to cryogenic temperatures (minus 150°C) to ensure that the shipped specimen is not subject to degradation or out of its designated "safe" range. While our current focus is on cryogenic logistics within the life sciences industry using the logistics solutions described herein, the use of the Cryoportal™ can and may be extended into other temperature ranges of the cold chain.

To our knowledge, the Cryoportal™ software platform is unique to cold chain logistics in the life sciences industry. It is robust and has considerable capabilities. We frequently are complimented about the Cryoportal™ and our strategic alliance partners chose to license the Cryoportal™ rather than attempt to duplicate its features in their logistics management software. We have engineered in a way that gives us the ability to offer the "powered by Cryoport℠" strategy to our strategic alliance partners.

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 dynamic shipping period of 10 or more days. A dry vapor cryogenic shipper is a device that uses liquid nitrogen contained inside a vacuum insulated vessel which serves as a refrigerant to provide stable storage temperatures below minus 150° Celsius. Our Cryoport Express® Shippers are designed to ensure that there is no pressure build up as the liquid nitrogen evaporates. We have developed a proprietary retention system to ensure that liquid nitrogen stays inside the vacuum container, which allows the shipper to be designated as a dry vapor shipper meeting 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 gas evolving from the liquid nitrogen entrapped within the proprietary retention system. Specimens that may be transported using our cryogenic shipper include: live cells, scientific or pharmaceutical commodities such as cancer vaccines, diagnostic materials, semen, eggs, embryos, infectious substances, and other commodities that require continuous exposure to frozen/cryogenic temperatures, i.e., temperatures below minus 150° Celsius.

An important feature of our Cryoport Express® Shippers, except for the newly introduced Cryoport Express® CXVC1 Shipper, is their compliance with the stringent packaging requirements of IATA Packing Instructions 602 and 650, respectively. These specifications include meeting internal pressure (hydraulic) and drop performance requirements. Under IATA guidelines, Cryoport Express® Shippers are classified as "Non-hazardous." Dry ice and liquid nitrogen are classified as "Dangerous Goods." Our shippers are also in compliance with International Civil Aviation Organization ("ICAO") regulations that prohibit egress of liquid nitrogen residue from the shipping packages. The ICAO is a United Nations organization that develops regulations for the safe transport of dangerous goods by air.

We currently offer three sizes of dry vapor shippers, the Cryoport Express® Standard Shipper with a storage capacity of up to 75 2.0 ml vials, the Cryoport Express® High Volume Shipper, which has a storage capacity of up to 500 2.0 ml vials, and the Cryoport Express® CXVC1 Shipper, introduced in August 2014, which has a storage capacity of up to 1,500 2.0 ml vials. Our Cryoport Express® Shippers are composed of an aluminum (aircraft-grade) dewar flask, containing a well for holding the high value biological or other materials in its inner chamber and our proprietary retention foam that absorbs the liquid nitrogen placed in the shipper to provide it with its extreme cold temperature. The dewar flask is vacuum insulated to limit the transmission of heat from outside the flask to the liquid nitrogen captured within the absorption foam and the well.

Cryoport Express® Standard Shippers

The Cryoport Express® Standard Shippers are lightweight, low-cost, re-usable dry vapor liquid nitrogen storage containers that, we believe, combine the best features of life sciences packaging, cryogenics science and vacuum insulation technology. A Cryoport Express® Standard Shipper is composed of an aluminum metallic dewar flask, with a well for holding the biological material in the inner chamber. The dewar vessel is a device in which the conduction, convection and radiation of heat are reduced as much as possible giving it the capability of maintaining its contents at a near-constant temperature over relatively long periods of time. The inner chamber of the shipper is surrounded by a high surface, low-density 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 walls is evacuated to a very high vacuum (10-6 Torr). The specimen-holding chamber has a primary cap to enclose the specimens/commodities, and a removable and replaceable secondary cap to further enclose the specimen/commodity-holding container and to contain the liquid nitrogen dry vapor. 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. The Cryoport Express® Standard Shippers has a storage capacity of up to 75 2.0 ml vials.

Cryoport Express® High Volume Shippers

The Cryoport Express® High Volume Shipper also uses a dry vapor liquid nitrogen (LN2) technology to maintain minus 150°C temperatures with a dynamic shipping endurance of 10 days. The Cryoport Express® High Volume Shipper is based on the same dry vapor technology as Cryoport's original standard dry shipper and utilizes an absorbent material to hold LN2, thus providing the extended endurance time and IATA validation as a non-hazardous shipping container. The high volume dry shipper is reusable and recyclable, making it a highly sustainable and cost effective method of transporting life science materials. The Cryoport Express® High Volume Shipper has a storage capacity of up to 500 2.0 ml vials.

Cryoport Express® CXVC1 Shippers

The Cryoport Express® CXVC1 Shipper is our largest shipper and can be used either as a dry vapor shipper or a liquid shipper. It is designed to focus on vaccine ampoules or cryovial shipments in canisters. In the case of dry vapor liquid nitrogen (LN2), it maintains minus 150°C temperatures with a dynamic shipping endurance of 20 days. In the case of liquid nitrogen (LN2), it maintains minus 150°C temperatures with a shipping endurance of 72 days. The Cryoport Express® CXVC1 Shipper, in dry vapor form, is based on the same technology as Cryoport's original standard dry shipper and utilizes an absorbent material to hold LN2, thus providing the extended endurance time and IATA validation as a non-hazardous shipping container. The Cryoport Express® CXVC1 Shipper, in liquid form, is a 'wet' dewar with all the characteristics attendant to a wet dewar and with a holding time of 72 days. The Cryoport Express® CXVC1 Shipper is reusable and recyclable, making it a highly sustainable and cost effective method of transporting life science materials. As a point of reference, the Cryoport Express® CXVC1 Shipper has a storage capacity of up to 1,500 0.2 ml vials.

Cryoport Express® Shipper Summary

We believe Cryoport Express® Solutions are the best and most cost effective solution available in the biotechnology and life sciences markets and satisfy customer needs and scientific and regulatory requirements relating to the shipment of time- and temperature-critical, frozen and refrigerated transport of biological materials, such as stem cells, cell lines, pharmaceutical clinical trial samples, gene biotechnology, infectious materials handling, 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 our proprietary dry vapor technology and innovative design prevent the spilling or leakage of the liquid nitrogen when the container is tipped or on its side which would otherwise adversely affect the functional hold time of the shipper.

The Cryoport Express® SmartPak Condition Monitoring System

Condition monitoring is a high-value feature from our client's perspective as it is an effective and reliable method to determine that the shipment materials were not damaged and did not experience degradation during shipment due to temperature fluctuations. Our current standard SmartPak System consists of a self-contained automated data logger and thermocouple capable of recording cryogenic temperatures of samples shipped in our Cryoport Express® Shippers. The data-logging temperature probe is positioned within the shipper to record the most accurate reading. The resultant temperature mapping includes both the temperature inside the chamber (which is closest to the actual biomaterial) and the external temperature. This reading, combined with the mapping of shipment check-in points, can provide a holistic view of the complete shipping process.

We recently developed the SmartPak II™ Condition Monitoring System, which is currently in beta testing and is scheduled to be launched during the second quarter of fiscal year 2017. The SmartPak II™ Condition Monitoring System tracks the key aspects of each shipment that could affect the quality and/or timing of delivery of the material to its intended destination. This includes real-time tracking using GPS, cellular and Wi-Fi triangulation, monitoring of internal and external temperatures, pressure, shock, orientation of the shipper, as well as light, as a measure of security breaches, compromised packaging or shipper openings during transit. This advanced condition monitoring system is engineered to work in tandem with Cryoport's logistics management platform, the Cryoportal™, enabling predictive and proactive monitoring of materials shipped. At the client's election, shipments can have a full chain-of-custody and chain-of- condition with data monitoring, analysis, archival storage available for every shipment.

Chain-of-Condition

Chain-of-Condition information is essential for many life sciences materials. Monitoring starts with our custom-built condition monitoring systems (the Cryoport Express® SmartPak I and II). The Cryoport Express® SmartPak provides

data on the condition of the shipper and material shipped, which is critical for temperature-sensitive biologics. The Cryoportal™ acts as the data repository for all shipment and condition information, which the customer can access through the Internet. Chain–of-condition service provided via Cryoport Express® SmartPak Condition Monitoring Systems is available at the client's election.

Chain-of-Custody

When overlaid with the carrier check-ins, the data monitor and analysis also provides a chain-of-custody. The report from the data monitor serves as analysis for temperature monitoring of the entire shipment as well as a tampering warning. If the client has elected to have chain–of-condition monitoring, each time the shipper is opened there is a temperature record. The report identifies outlier temperature excursions such as opening the shipment in customs or tampering and thus will allow for more conclusive investigations to ensure that specimens were not adversely impacted during shipment.

Cryoport Express® Analytics

Cryoport Express® Analytics information is captured by the Cryoportal™ to provide us and our customers access to important information from the shipments recorded in the Cryoportal™ to assist in management of our customers' shipping. For us, we use the information to support planned future features to allow for an expansion of our solutions offering. 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 for analytics tracked through the Cryoportal™ 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 potential shipping exceptions based on historical metrics. The analytical results are being utilized by Cryoport to render consultative and proactive client services.

Biological Material Holders

A containment bag is used in connection with the shipment of infectious or dangerous goods using the Cryoport Express® Shippers. Up to 75 cryovials (polypropylene vials with high-density polyethylene closures), set on aluminum canes, are placed into an absorbent pouch, which is designed to contain the entire contents of all the vials in the event of leakage. This pouch is then placed in a watertight Tyvek bag (secondary packaging) capable of withstanding cryogenic temperatures, and then sealed. This bag is then placed into the well of the Cryoport Express® Shipper.

Logistics Expertise, Consulting and Support

Cryoport's client services professionals provide 24/7/365 live logistics and monitoring services with specialized knowledge in the domestic and global logistics of life sciences material requiring cryogenic temperatures. The Cryoport logistics professionals have validated shipping lanes in and out of more than 80 countries to date to ensure shipments maintain cryogenic temperatures and arrive securely and on time.

In April 2016, Cryoport announced the launch of a new Temperature Controlled Logistics Consulting Division to assist life sciences companies in developing strategies for global cold chain logistics management and contingency options to protect their valuable, and often irreplaceable, biological commodities. The launch of Cryoport's Temperature Controlled Logistics Consulting Division addresses the demand created by the worldwide advances in cellular based therapies, including immunotherapies, stem cells and CAR T-cells. Cell-based immunotherapies are causing broad shifts and challenges for the life sciences industry, including how to obtain, properly store and transport the growing number of new, individualized, temperature sensitive therapies. Improper temperature maintenance or temperature excursions during any portion of a logistics cycle can adversely affect the viability of these biologically based commodities. Consequently, strategic, global logistics planning for cryogenic cold chain solutions has taken on a strategic importance to the life sciences industry and a rapidly growing demand for consulting expertise.

Other Development Activities

We are continuing our research and development efforts to further refine our current technology as well as explore opportunities with partners to offer complementary packaging solutions for frozen temperature (minus 10° Celsius or less), chilled temperature (2° and 8° Celsius) and ambient temperature (between 20° and 25° Celsius) shipping markets.

We also continue to further expand the functionality of our Cryoportal™ to ensure a high level of effectiveness and efficiency in the cold chain logistics process and to allow for intelligent and easy data monitoring and analysis.

Government Regulation

The shipping of diagnostic specimens, infectious substances and dangerous goods, whether via air or ground, falls under the jurisdiction of many state, 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.

The International Civil Aviation Organization ("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 International Air Transport Association ("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 Centers for Disease Control ("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® Shippers meet Packing Instructions 602 and 650 and are 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 SmartPak condition monitoring systems will likely be subject to regulation by the 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. In April 2016 we signed a strategic partnership with Worthington Industries, a maker of cryogenic storage vessels and equipment. Through this partnership, Worthington's CryoScience by Taylor Wharton business will design and manufacture biostorage and logistics equipment for use in Cryoport's life sciences cryogenic logistics solutions. With the added competencies Worthington's CryoScience by Taylor Wharton brings to Cryoport, we can concentrate on further advancing and expanding our cold chain solutions to meet the growing and varied demands for validated cryogenic logistics solutions in the life sciences market. Working in tandem with Worthington allows Cryoport to meet the demands of a more diverse clientele through a broader offering which in turn, increases our revenue opportunity as well as provides us the opportunity to rapidly scale to support our clients commercialization activities. Our current fleet of cryogenic shippers consists of shippers that were manufactured in-house as well as shippers purchased from third parties that are modified to meet our specifications using our proprietary technology and know-how. In general, cryogenic shippers are available from more than one qualified manufacturer. 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. Should this occur, we believe that with our current level of shippers, we have enough inventory to cover our forecasted demand.

Our data loggers used in our condition monitoring systems, the SmartPak I and II, have been acquired from single sources with the calibration done by an independent third party.

Raw Materials. Various common raw materials are used in the manufacture of our shippers 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 three registered U.S. trademarks and three issued U.S. patents primarily covering various aspects of our Cryoport Express® Shippers.

We have also filed a U.S. provisional patent application for a smart label which will communicate electronically with our data logger. 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 shippers 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 and a patent application include:

Type:	**No.**	**Issued**	**Expiration**
Patent	6,467,642	Oct. 22, 2002	Jan. 2, 2021
Patent	6,119,465	Sep. 19, 2000	Feb. 10, 2019
Patent	6,539,726	Apr. 1, 2003	May 8, 2021
Patent Application	12/656,641		
Trademark	3,569,471	Feb. 3, 2009	Feb. 3, 2019
Trademark	3,589,928	Mar. 17, 2009	Mar. 17, 2019
Trademark	2,632,328	Oct. 8, 2002	Oct. 8, 2022

Our success depends in part 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 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 such third parties, 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 such areas as biotechnology, clinical trials, distribution of pharmaceutical products and reproductive medicine, the requirement for effective and reliable solutions for keeping clinical samples, pharmaceutical products and other specimen at frozen temperatures takes on added significance due to more complex shipping routes, extended shipping times, custom delays and logistics challenges. Today, such specimens 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 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 Cryoport Express® Shippers, the Cryoportal™ and our logistics expertise 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 life sciences and biotechnology industries toward globalization.

We provide domestic shipping solutions in situations where specimens must be kept at frozen temperatures and in regions where there is a high priority placed on maintaining the integrity of materials shipped at these temperatures.

Pharmaceutical Clinical Trials. Every United States based pharmaceutical company developing a new drug must seek drug development protocol approval by the FDA. These clinical trials are to test the safety and efficacy of the potential new drug among other things. A significant amount of clinical trial activity is managed by a number of large Clinical Research Organizations (“CROs”).

In connection with the clinical trials, due to globalization, companies can be enrolled from all over the world and may need to 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, drugs used by the patients may require frozen shipping to the sites of