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TICKER (EXCHANGE)	AIPT (NASDAQ)
Recent Price (07/09/2018)	\$1.20
52-week Range	\$0.81 - \$2.50
Shares Outstanding*	11.8 million
Market Capitalization	\$14.2 million
Average 3-month Volume	196,669
Insider Ownership +>5%	<1%
Institutional Ownership	3%
EPS (Qtr. ended 3/31/2018)	(0.15)
Employees	20

*As of March 31, 2018



Company Description

Precision Therapeutics Inc. (“Precision Therapeutics” or “the Company”) is a healthcare company that provides **personalized medicine†** solutions and medical devices in two main areas: (1) **precision medicine**, which aims to apply **artificial intelligence (AI)** to personalized medicine and drug discovery; and (2) Skyline Medical, which markets the FDA-cleared STREAMWAY® System for automated, direct-to-drain **medical fluid waste** collection and disposal. The Company’s precision medicine services—designed to use AI and a comprehensive disease database to improve the effectiveness of cancer therapy—were launched with Precision Therapeutics’ investment in Helomics® Corporation. The Definitive Merger Agreement was signed on June 28, 2018. Helomics’ **precision oncology** services are based on its D-CHIP™ diagnostic platform, which combines a database of **genomic** and drug response profiles from over 149,000 tumors with an AI-based searchable **bioinformatics** platform. Once a patient’s tumor is excised and analyzed, the D-CHIP™ platform compares the tumor profile with its database, and, using its extensive drug response data, provides a specific therapeutic roadmap. Additionally, through its Skyline Medical operations, the Company markets the STREAMWAY System, an environmentally conscientious system for collecting and disposing infectious waste fluids produced during medical procedures. To enhance the precision medicine foundation addressed by Helomics, the Company formed TumorGenesis Inc. (a wholly-owned subsidiary) to develop the next generation patient-derived tumor models, as well as executed a partnership with GLG Pharma. Precision Therapeutics’ growth strategy aims to generate additional income through the following three key directives: (1) boost sales of Skyline’s STREAMWAY business, (2) continue its precision medicine initiatives via Helomics and TumorGenesis; and (3) create additional strategic partnerships and acquisitions within the precision medicine space.

Key Points

- Precision Therapeutics’ Helomics investment marked a key achievement in its strategy to diversify its portfolio of products and services beyond the offerings of the Skyline Medical business.
- The STREAMWAY System is FDA-cleared in the U.S., has a medical device established license to sell in Canada, possesses a CE mark to allow for sales in Europe, and is regulatory approved in Australia and New Zealand for sales. The Company has installed over 100 units in more than 50 facilities in the U.S.
- To the Company’s knowledge, the STREAMWAY System is the only known fully automated wall-mounted direct-to-drain system that continuously collects and disposes of an unlimited amount of fluid waste, while virtually eliminating staff exposure to blood and other infectious fluids.
- In 2017, Skyline Medical implemented a refocused sales campaign, resulting in 16 systems sold in the first quarter of 2018, compared to 10 units sold throughout all of 2017. The Company has stated that it expects to sell 100 systems in 2018.
- At March 31, 2018, the Company had cash, cash equivalents, and marketable securities of \$2.2 million.

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Executive Overview

Precision Therapeutics Inc. (“Precision Therapeutics” or “the Company”) is a healthcare products and services company that provides personalized medicine solutions for the pharmaceutical, diagnostic, and biotechnology industries, and medical devices for hospitals and ambulatory surgical centers. The Company engages in the development of medical technology in two main areas: (1) precision medicine, which aims to apply artificial intelligence (AI) to personalized medicine and drug discovery; and (2) Skyline Medical, which markets the FDA-cleared STREAMWAY System for automated, direct-to-drain medical fluid waste disposal.

The Company’s precision medicine services, designed to use AI and a comprehensive disease database to improve the effectiveness of cancer therapy, were launched with Precision Therapeutics’ investment in Helomics Corporation, a precision diagnostic company and integrated clinical **contract research organization (CRO)**. The Definitive Merger Agreement was signed on June 28, 2018. Precision Therapeutics’ investment in Helomics marked a key point in the Company’s strategy to diversify its portfolio of products beyond the offerings of its Skyline Medical business and into the precision medicine space.

The Company’s precision medicine operations center around the AI-based bioinformatics diagnostic platform of Helomics—Dynamic Clinical Health Insight Platform or D-CHIP—that includes a database containing the molecular, genomic, and drug response profiles of over 149,000 cancer cases performed in Helomics’ clinical laboratory. The combination of using this data, as well as the molecular and drug response profiling of the patient tumor, allows the D-CHIP to provide a personalized therapeutic roadmap for that patient. To enhance the precision medicine foundation provided by Helomics, the Company intends to add additional strategic partnerships and acquisitions. One example of this is the formation of a wholly-owned subsidiary, TumorGenesis Inc., to develop the next generation of patient-derived tumor models for precision cancer therapy and drug development.

The Company is also involved in commercializing the STREAMWAY System for automated and direct-to-drain medical fluid waste disposal. Sold through its Skyline Medical business, the STREAMWAY System is designed to replace the manual process of collecting fluids in canisters and transporting and dumping in sinks outside of the procedure rooms, which can result in the medical staff’s exposure to **bloodborne** pathogens. To the Company’s knowledge, the STREAMWAY System is the only known fully automated direct-to-drain system that is wall-mounted and designed to collect, measure, and dispose an unlimited amount of fluid waste without interruption.

Through the operation of its Skyline Medical and Helomics businesses, Precision Therapeutics has an established revenue stream, while positioning itself for additional revenue sources through the expansion of its precision medicine initiatives.

PRECISION MEDICINE DIVISION

The Company’s precision medicine services business, which is committed to improving the effectiveness of cancer therapy using the power of AI, is conducted through the operations of two entities: Helomics Corporation and TumorGenesis Inc. This business was launched with Precision Therapeutics’ partnership investment in Helomics on January 2018, purchasing preferred stock in Helomics convertible into a 20% stake, followed by an additional 5% equity stake acquisition. In April 2018, the Company announced a letter of intent (LOI) to acquire the remaining equity in Helomics. A definitive merger agreement was signed on June 28, 2018. Once the merger is complete, TumorGenesis’ operations (currently a subsidiary of Precision Therapeutics), would become integrated with Helomics.

Background

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, disease, environment, and lifestyle for each case to develop effective therapies. This approach allows doctors and researchers to predict more accurately which treatment, dose, and therapeutic regimen could provide the best possible outcome. The global precision medicine market is estimated to reach \$141.7 billion by 2026, up from \$43.6 billion in 2016. This growth is supported by the industry's investment in precision medicine, with leading biopharmaceutical companies doubling their investments in the technology over the last five years, with the potential to increase by an additional 33% over the next five years (Source: BIS Research's *Global Precision Medicine Market to Reach \$141.70 Billion by 2026*, December 2017).

Precision oncology, or precision cancer medicine, focuses on matching the most accurate and effective treatment to each individual cancer patient based on the genetic understanding of the patient's disease and the tumor biology of each patient. Over the past several decades, researchers have identified molecular patterns that are useful in defining the prognosis of a given cancer, determining the appropriate treatments, and designing targeted treatments to address specific molecular alterations. The objective of precision oncology is to develop treatments tailored to the genetic changes in each person's cancer, intended to improve the effectiveness of the therapeutic regimen and minimize the treatment's effects on healthy cells.

Helomics Corporation

Precision Therapeutics plans to capitalize on Helomics' D-CHIP AI-based bioinformatics platform to develop and market new approaches for personalized cancer prognosis and therapy, with an initial focus on ovarian and breast cancers. Helomics offers a portfolio of products aimed at delivering tumor and cellular profiling services as well as precision oncology services for gynecologic, lung, colon, and solid tumors. In addition, Helomics offers boutique CRO services, clinical, diagnostics, and research tests, and tissue and **biorepository** services.

The key offering of Helomics is its Precision Oncology Insights service, which combines comprehensive molecular profiling of the patient's tumor and the use of its D-CHIP bioinformatics platform to determine which therapeutic option is likely to work best for a particular patient. Helomics' approach to precision oncology is based on the following steps: (1) obtain a sample of the tumor, along with the patient's detailed medical history; (2) test to determine the genetic profile of the patient's tumor; (3) test to determine the drug response profile of the patient's tumor (unique to Helomics) (4) analyze the results utilizing D-CHIP to determine the best therapeutic options for that particular tumor profile; and (5) provide an actionable roadmap for patient therapy to the oncologist to positively impact patient outcomes.

The competitive advantage of Helomics lies in its extensive actionable big data repository, derived from its ability to work on live tumor cells, and its D-CHIP platform. The company's proprietary TruTumor™ patient-derived tumor model provides Helomics with the ability to work with actual live tumor cells (not modified **cell lines**) to study the unique biology of a patient's tumor in order to understand how a patient's cancer cells grow and respond to treatments. Helomics has over 15 years of experience in growing, collecting, and analyzing human tumor cells in multiple cancers, resulting in a data repository that contains the molecular, genomic, and drug response profiles of more than 149,000 cancer cases. This information provides understanding of each cancer by sub-type and the cancer's response to different therapeutic options—resulting in the ability to generate treatment protocols personalized by the specific tumor type on a patient-by-patient basis.

Once a tumor sample is received by the Company, the tumor's molecular and drug response profile is analyzed and compared to Helomics' database using D-CHIP's proprietary AI-powered bioinformatics engine. The D-CHIP platform can generate actionable insights that delivers a link between the specific tumor profile and those therapies to which the tumor is sensitive, resulting in a specific therapy roadmap. Once a therapeutic option is implemented, outcome data from the patient's progression flows back to the D-CHIP platform, allowing it to continually learn the association between a tumor's genetic alterations and its response to a specific therapeutic option—expanding its knowledge base. The D-CHIP technology can also be used by pharmaceutical, medical, and diagnostic companies in the research and development of targeted cancer treatments and diagnosis, for drug repurposing initiatives, and to perform better clinical trials by improving patient recruitment and selection.

In addition to the revenue generated by Helomics through its wide range of CRO services—including tumor and cellular profiling services, biorepository services, and clinical and diagnostics tests—the D-CHIP platform generates subscription revenues from pharmaceutical, biopharmaceutical, and diagnostic companies that require access to its database and analytics engine to support their internal product development efforts.

TumorGenesis Inc.

In February 2018, Precision Therapeutics announced the formation of TumorGenesis to develop the next generation of **patient derived (PDX) tumor** models for precision cancer therapy and drug development. TumorGenesis is developing a new approach to growing tumor models in the laboratory that display *in vivo* like growth characteristics and response to therapeutics. TumorGenesis offers an external 3-D structured environment combining chemistry, biology, mechanics, and cell nutrients to allow the cancer cells to grow as closely as possible to the environment inside the human body. The Company believes that the TumorGenesis approach is quicker, less costly, and more closely mimics the characteristics of the patient's tumor inside the body, compared to testing with traditional animal or cell culture models that are currently used in the clinical development of cancer therapies. The Company plans to initially develop the TumorGenesis PDX model for three orphan cancers that have a high unmet need for new and effective treatments that are tailored to the patient's unique tumor profiles: **multiple myeloma, triple-negative breast cancer (TNBC), and ovarian cancer.**

In March 2018, the Company secured licenses with three medical technology companies—SyntArray LLC., 48Hour Discovery, and CellBridge Incorporated—providing TumorGenesis with access to medical technology to advance the development of its tumor models. Once Precision Therapeutics completes its acquisition of Helomics, TumorGenesis' operations (currently a wholly-owned subsidiary), would become integrated with Helomics, allowing it to leverage Helomics' complementary offering in the precision oncology market.

SKYLINE MEDICAL DIVISION

The Company's Skyline Medical division develops and markets the STREAMWAY System, an environmentally conscientious system for the collection and disposal of infectious waste fluids resulting from surgical procedures and post-operative care. The STREAMWAY System is FDA-cleared in the U.S., has a medical device established license to sell in Canada, possesses a CE mark allowing sales in Europe, and is regulatory approved in Australia and New Zealand for sales. The Company has installed over 100 units in more than 50 facilities in the U.S., covering 19 states. The STREAMWAY System is a wall-mounted fully-automated system that disposes of an unlimited amount of potentially infectious fluids collected during surgical procedures, providing uninterrupted performance while virtually eliminating healthcare workers' exposure to these fluids. The System is intended to replace the manual process of collecting fluids in canisters, which is still being used by many hospitals and surgical centers.

Skyline believes that the STREAMWAY System is unique to the industry in that it not only allows continuous suction but also provides for unlimited capacity, eliminating the need to interrupt a procedure to change canisters. In addition, the System's operation can be accomplished without significant changes to established operative processes, a major roadblock that prevents physicians and medical establishments from adopting innovative technologies. To the Company's knowledge, the STREAMWAY System is the only known fully automated direct-to-drain system that is wall-mounted and able to collect, measure, and dispose of an unlimited amount of waste fluid without interruption.

Infectious and Bio-Hazardous Medical Waste Overview

Medical waste is any kind of waste generated by healthcare facilities like physician's offices, hospitals, dental practices, laboratories, medical research facilities, and veterinary clinics. The global medical waste management market was estimated at \$21 billion in 2016 and is expected to reach \$33.4 billion by 2025 (Source: Grand View Research's *Medical Waste Management Market Analysis By Services, By Treatment, And Segment Forecasts, 2018 – 2025, 2017*). Among the different categories of medical waste, infectious liquid waste (such as blood and body fluids) presents one of the most serious threats to human health and the environment due to the proliferation of bloodborne diseases. The presence of infectious liquid materials is most prevalent in the surgical suite where often large amounts of bodily fluids are removed from the patient during the surgical procedure. The most common medical fluid waste disposal method used in hospitals and surgical centers is with suction canisters, where following the procedure, the fluids in the canisters are measured to estimate patient blood loss. These canisters and their contents are then disposed. This is typically done by directly pouring the material into a sink that drains to a sanitary sewer, where it is subsequently treated by the local waste management facility. The manual process requires that healthcare personnel open and empty the canisters in the hospital drain system. The issue with this process, however, is the increased potential for contact with the waste fluid as a result of leakage, breakage, spills, or splash exposure. Another method that hospitals use to dispose of fluid waste is to pull the top off a canister and pour a solidifier into it, which causes the fluid to turn into a gel. The canister is then red bagged and sent to either be incinerated or disposed of in a landfill.

Healthcare workers that come in contact with these fluids face a potential infection from bloodborne pathogens, such as Hepatitis B and C, HIV/AIDS, human papillomavirus (HPV) infection, and other infectious agents. Despite the risks, healthcare worker exposures and/or potential exposures to these pathogens are widespread. An estimated 400,000 U.S. healthcare workers are exposed to blood-borne pathogens every year (Source: *The Journal of the American Medical Association [JAMA]*, Vol. 307(1):75-84, 2012) and approximately 1 out of 10 healthcare workers in the U.S. suffers a splash exposure or a needle stick injury every year (Source: *American Journal of Infection Control*, Vol. 41(2), 185-186, 2013). Another study found that up to 50% of operating procedures resulted in at least one person becoming contaminated with blood (Source: *Annals of Surgery*, Vol. 214(5): 614–620, 1991).

Skyline Medical's STREAMWAY System

Skyline Medical's STREAMWAY System suctions waste fluid from the patient using standard surgical tubing, where the waste fluid passes through the Company's proprietary disposable filters and into the STREAMWAY device. The STREAMWAY System constantly updates and displays the fluid volume removed during the procedure, allowing the surgical team to assess the total amount of fluid removed from the patient at any point. The waste liquid then gets disposed of directly from the device to the sanitary sewer through the plumbing of the hospital, significantly reducing the risk to the healthcare worker of exposure to these infectious fluids. A simple, easy-to-use human interface display screen guides the user through the set-up process, and subsequently guides the user through the cleaning process post-procedure.

Skyline Medical believes that the STREAMWAY System is unique to the industry in that it allows continuous suction to the procedural field with unlimited capacity, eliminating the need to interrupt a procedure to change canisters. In addition, the System can be put into operation without significant changes to established operative procedures—a benefit the Company believes is likely to facilitate market adoption as it eliminates a key roadblock that prevents physicians and medical establishments from adopting innovative technologies. The System is fully-automated, does not require transport to and from the operating room (OR), and eliminates the use of canisters (including their cleaning, transport, and disposal steps) as it collects the waste fluid in the internal collection chamber and automatically disposes of the fluid with no handling by personnel.

The Company also manufactures and sells two disposable products required for the System's operation: a bifurcated dual port procedure filter with tissue trap, and a bottle of cleaning solution—both used on a single procedure basis. Each procedure requires the use of a disposable filter that is designed specifically for use only with the STREAMWAY System. In addition, at the end of each procedure, a proprietary pre-measured amount of cleaning solution in a plastic bottle is attached to the STREAMWAY System and an automatic cleaning cycle takes place, making the device ready for the next procedure.

The disposables are a critical component of the Company's business model, providing it with a profitable Razor/Razorblade type business model and an ongoing revenue stream for every unit installed, with the Company expecting revenues from the sale of the disposables to be significantly higher over time than the revenues from the sale of the unit.

STREAMWAY Benefits

The Company believes that its STREAMWAY System provides substantial benefits across three key areas: (1) increased safety; (2) reduced cost; and (3) improved efficiency.

The STREAMWAY System is designed to replace the antiquated manual fluid handling methods that require hand carrying and the manual emptying of fluid-filled canisters, significantly reducing the risk to healthcare workers who may be exposed to these infectious fluids. The STREAMWAY System's internal surgical waste reservoir is isolated from medical personnel and disposes the medical waste directly into the hospital sanitary sewer, with no direct handling of the waste by healthcare workers. In addition, its automated cleaning feature creates another layer of safety, as the cleaning and preparation of the machine for the next procedure requires minimal medical personnel interaction.

In addition to simplifying the handling of medical waste fluids and improving the safety for healthcare workers, the technology further provides cost savings (in terms of overhead costs and labor cost) to facilities over the traditional methods used for collecting, neutralizing, and disposing of biohazard fluids. In addition to eliminating the manual process of medical fluid waste and canister disposal, the STREAMWAY System saves medical personnel time before, during, and after the surgical procedure. Specifically, the use of the System eliminates the need for: (1) a suction canister set-up, (2) healthcare workers to swap out full canisters during the procedure, and (3) significant post-operative clean-up (as STREAMWAY cleanup is unattended and takes approximately five minutes).

STREAMWAY Sales and Marketing Efforts

In 2017, the Company implemented a refocused sales and marketing campaign, which included the hiring of key sales personnel and increased participation at major industry conferences. These efforts resulted in an acceleration of STREAMWAY System's sales. As a result, in the first three months of 2018, the Company sold 16 STREAMWAY Systems (10 systems in March 2018 alone), compared with the 10 units sold throughout all of 2017. The Company has stated that it expects to sell 100 STREAMWAY Systems in 2018.

Part of the refocused efforts is the expansion of its international presence through direct sales and independent distribution agreements. In the first quarter of 2018, the Company hired a new International Vice President of Sales and Marketing who is incorporating Skyline Medical Europe with an office in Belgium, and has also hired a direct sales representative to handle Germany and France. In addition to its direct sales efforts, Skyline has executed contracts with three international distributors: (1) Quadromed, a Canadian distributor; (2) MediBridge Sarl, a Swiss distributor representing the Company in Switzerland; and (3) Device Technologies Australia PTY LTD, an Australian distributor whose territories include Australia, New Zealand, Fiji, and the Pacific Islands.

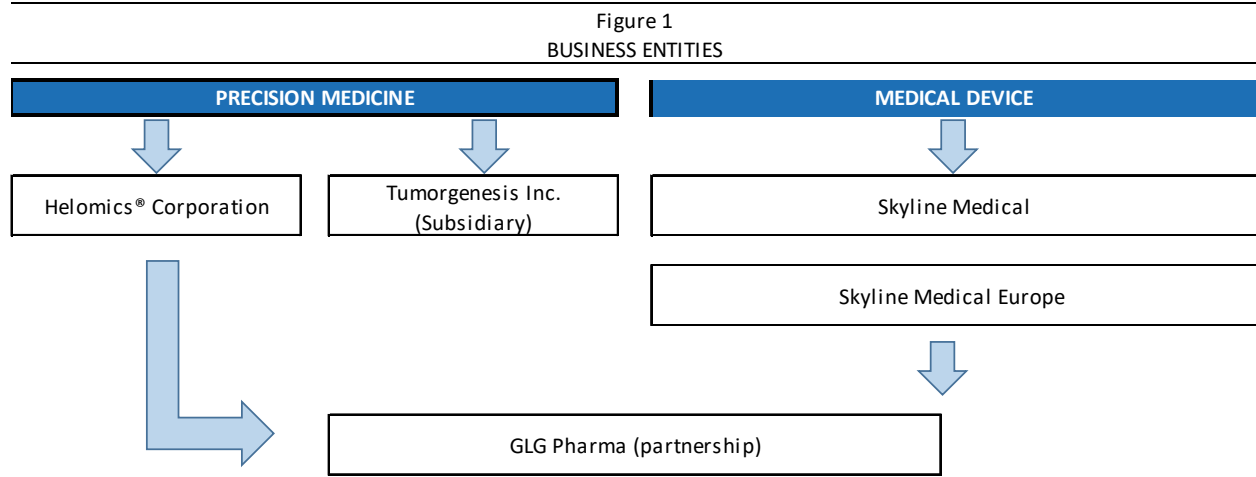
GLG Pharma

In November 2017, Precision Therapeutics and Helomics announced a collaborative partnership with GLG Pharma, focused on using their combined technologies to bring a personalized, precision medicine approach to ovarian and breast cancer patients. The Precision Therapeutic and Helomics proposed joint venture owns 50%, with the remaining 50% owned by GLG Pharma. The partnership plans to add a collection and analysis system for **ascites fluids** to the STREAMWAY System to bring personalized medicines and testing to ovarian and breast cancer patients. The STREAMWAY System would be used to drain the ascites fluids from the patient during the operation. Following the procedure, pathologists can then process and send the fluid sample and analysis results to Helomics for further evaluation using Helomics' precision oncology insights platform. The partnership is expected to create new revenue streams to be shared between Precision Therapeutics, Helomics, and GLG Pharma.

The Company views its GLG Pharma partnership as a first step in its long-term strategy of turning its STREAMWAY System into a diagnostic tool, with the System able to perform tests- and run-test **assays** on the waste fluid that the STREAMWAY Systems collects and disposes of during all surgical procedures. This could allow for the detection of previously unknown medical conditions unrelated to the surgical procedure being conducted.

Corporate Information (Headquarters, Employees, and History)

Figure 1 provides an overview of the Company’s current areas of operation.



Source: Precision Therapeutics Inc.

The Company was originally incorporated on April 23, 2002 in Minnesota as BioDrain Medical, Inc. Effective August 6, 2013, the Company changed its name to Skyline Medical, Inc. On August 31, 2015, the Company completed a successful offering and concurrent uplisting to the NASDAQ Capital Market. On February 1, 2018, the Company changed its corporate name from Skyline Medical Inc. to Precision Therapeutics Inc., and changed its ticker symbol to AIPT. Skyline Medical remains as an incorporated division of Precision Therapeutics Inc. The Company is headquartered in Eagan, Minnesota, and currently has 20 employees, 19 of whom are full-time.

Milestones

Recent Milestones

In the past six months, the Company has achieved significant milestones, as highlighted below, with additional potential milestones outlined thereafter.

- Changed its name from Skyline Medical to Precision Therapeutics Inc. and its NASDAQ ticker symbol to AIPT, effective February 1, 2018, to better reflect the Company's new strategic focus on precision medicine.
- Purchased preferred stock in Helomics Corporation, convertible into a 20% stake, followed by an additional 5% equity stake acquisition.
- Signed an LOI to acquire the remaining equity in Helomics, increasing the Company's stake from 25% to 100%.
- Formed a wholly-owned subsidiary, TumorGenesis Inc., to develop the next generation of patient-derived (PDx) tumor models for precision cancer therapy and drug development.
 - TumorGenesis secured three license agreements providing access to technology in support of its operations: CellBridge Incorporated, SyntArray, LLC, and 48Hour Discovery.
- Executed a license agreement with Illumina, Inc. for its Next Generation Sequencing (NGS) platform, MiSeqDx, to support its continued development of the D-CHIP AI-based bioinformatics platform.
- Implemented a refocused sales and marketing campaign for its Skyline Medical business, which included the hiring of key sales personnel and increased participation at major industry conferences, resulting in an acceleration of STREAMWAY System sales.
- Executed an expansion of its Skyline Medical international presence through direct sales efforts and independent distribution agreements:
 - Hired a new International Vice President of Sales and Marketing, who is incorporating Skyline Medical Europe with an office in Belgium; also, hired a Direct Sales Representative to handle Germany and France.
 - Executed contracts with three international distributors. (1) Quadromed (Canada); (2) MediBridge Sarl (Switzerland); and (3) Device Technologies Australia PTY LTD (Australia and the Pacific).
- Entered into a strategic partnership with GLG Pharma to bring a personalized, precision medicine approach to ovarian and breast cancer patients.
- Signed a definitive merger agreement with Helomics Corporation on June 28, 2018.

Potential Milestones (2018)

- Complete the merger with Helomics Corporation.
- Execute additional strategic partnerships and acquisitions in the precision medicine space to enhance the foundation provided by Helomics.
- Continue its enhanced sales efforts for the Skyline Medical business in order to achieve projected sales goals of 100 STREAMWAY Systems sales in 2018 (a tenfold increase over the Company's 2017 sales figures).
- Secure first European sale of the STREAMWAY System in the second half of 2018.

Intellectual Property

Precision Therapeutics believes that to maintain a competitive advantage in the marketplace, it must develop and maintain protection of the proprietary aspects of its technology. The Company relies on a combination of patents, trade secrets, continuing technological innovations, licensing opportunities, and other intellectual property rights and measures to protect its intellectual property and maintain a competitive position.

The Company holds the following granted patents in the U.S., and a pending application on its earlier models: US7469727, US8123731, and US Publication No. US20090216205. In general, the patents are related to its STREAMWAY System and are directed to a system and method for collecting waste fluid from a surgical procedure while ensuring there is no interruption of suction during the surgical procedure and no limit on the volume of waste fluid which can be collected.

In addition, Precision Therapeutics employs The Patent Cooperation Treaty (PCT) applications, which allows an applicant to file a single patent application to seek patent protection for an invention simultaneously in each of the 148-member countries of the PCT, including the U.S. By filing this single international patent application through the PCT system, it is easier and more cost effective than filing separate applications directly with each national or regional patent office in the various countries in which patent protection is desired.

On January 25, 2014, the Company filed a non-provisional PCT Application No. PCT/US2014/013081 claiming priority from the U.S. Provisional Patent Application number 61756763, which was filed one year earlier on January 25, 2013. In July 2015, Skyline Medical filed an international (PCT) patent application for its fluid waste collection system and received a favorable determination by the International Searching Authority finding that all of the claims satisfy the requirements for novelty, inventive step, and industrial applicability. Skyline anticipates that the favorable International Search Report will result in allowance of its various national applications.

The U.S. Patent Office has assigned application #14/763,459 to the Company's previously filed PCT application. As of November 22, 2017, the Company was informed that the European Patent Office has allowed all its claims for application #14743665.3-1651, and has sent a Notice of Intent. Skyline is now in the process of identifying the key European countries that the Company plans to validate the patent in. Figure 2 (page 11) provides a summary of the Company's current intellectual property portfolio, which is further described below.

Patent # US7469727

PCT/US2003/25018 (also listed as PCT/US03/25018) was filed on 8/8/2003.

The U.S. Patent Application (US2005/0209585 A1) was filed on September 22, 2005 and claimed the above PCT as prior art. The named inventor was Marshall Ryan. The Patent was issued on 12/30/2008.

Patent #US8123731

The U.S. Patent Application (US2009/0076470) was filed on March 19, 2009 and claimed Biodrain's previous patent US7469727 and PCT/US2003/25018 as priority. Once again, the named inventor was Marshall Ryan. The patent was issued on 2/28/2012.

European Patent # EP1539580

The application was published from the PCT/US2003/25018 application on 3/4/2004 and listed the PCT application and earlier provisional as priority. The inventors were listed as Nord, Drogue, and Ryan. The patent was issued on 4/4/2007 and includes Spain, France, UK, Netherlands, Germany, and Italy.

Canadian Patent # CA2495747

The Canadian application was made on 2/16/2005 and claimed PCT/US2003/25018 as prior art. The inventors were listed as Nord and Drogue with Biodrain Medical as owner. The patent was issued on 4/12/2011.

National Stage Filing PCT/US2014/013081

Applications for U.S. and Canada were made in July 2015.

U.S. Publication date: December 17, 2015. Publication # US2015/036200 A1

Application for Europe made in August 2015. Application 14743665.3 will be granted (Notice of Intent to Grant received 11/22/17).

Power of Attorney applications began in May 2018 for selected European countries.

Inventors listed: Schmidt, Johnson, and Dauwalter.

Figure 2
 SKYLINE IP STATUS (MAY 2018)

Country	Patent / Publication No.	Issue Date	Status
United States	US7469727	12/30/2008	Granted
United States	US8123731	2/28/2012	Granted
United States	US2009/0216205	8/27/2009	Pending
Europe (Spain, France, UK, Netherlands)	EP1539580	4/4/2007	Granted
Also Including Germany	603130000.3	4/4/2007	Granted
Also Including Italy	M12007B027210	4/4/2007	Granted
Canada	CA2495747	4/12/2011	Granted
United States International Application	PCT/US2014/013081 International Publication No: WO 2014/117043	1/25/2014	Favorable International Search Report & Written Opinion from U.S. Patent Office received on 4/30/2014. All 23 claims allowed.
United States	14/763,459 US2015/0362000 A1	7/24/2015 12/17/2015	National Stage Filing Application-numerous office actions received regarding claims-Tom Oppold addressing.
Canada	2899208	8/10/2015	National Stage Filing Application-typically rubberstamps after either Europe or U.S. issues patents. Will go forward after Europe issues patent approval.
Europe	14743665.3	8/22/2015 11/22/2017 5/30/2018	National Stage Filing Application. Received Notice of Intent to Grant on 11/22/2017. Identified 11 European States that want the European Patent validated in-power of Attorney filings started May 2018.

Source: Precision Therapeutics Inc.

Company Leadership

MANAGEMENT

Figure 3 provides an overview of the key individuals that are a part of Precision Therapeutics' management team, followed by respective biographies.

Figure 3
MANAGEMENT

Carl Schwartz	Chief Executive Officer (CEO), Director
David Johnson	Chief Operating Officer (COO)
Bob Myers	Chief Financial Officer (CFO), Secretary
Mark A. Collins	President, TumorGenesis
David Dauwalter	Product Management, Director
Kevin Hungerfod	Vice President, Sales and Marketing
Jean-Paul Rasschaert	International Vice President of Sales
Rodney Schmidt	Senior Design Engineer

Source: Precision Therapeutics Inc.

Dr. Carl Schwartz, Chief Executive Officer (CEO), Director

Dr. Schwartz was appointed to Precision Therapeutics' Board of Directors in March 2016, and became interim president and chief executive officer (CEO) in May 2016. He has owned and managed dental groups in Michigan, beginning with one practice in 1966, and oversaw its expansion into a 14-office practice when he left the active practice of dentistry in 1988. He currently owns two dental practices, in Burton, Michigan and Grand Blanc, Michigan. In 1988, Dr. Schwartz joined a family business, becoming CEO of Plastics Research Corporation, a Flint, Michigan manufacturer of structural foam molding, a low pressure injection molding process. During his tenure there, he led its growth from \$2 million in revenues and 20 employees, to it becoming the largest manufacturer of structural foam molding products under one roof in the U.S., with more than \$60 million in revenues and 300 employees when he retired in 2001. Dr. Schwartz previously served on the Board of Delta Dental Corporation of Michigan, was a member of the Michigan Advisory Board for Liberty Mutual Insurance, and was a member of the Board of Trustees of the Museum of Contemporary Art in Florida. He holds B.A. and D.D.S. degrees from the University of Detroit.

David Johnson, Chief Operating Officer (COO)

Mr. Johnson was appointed COO in 2012. He has over 35 years of experience in executive, operations, and management training positions in rapidly growing medical device organizations, directing growth domestically and internationally with products ranging from consumer-based disposable commodity items to class III implantable devices. Prior to Precision Therapeutics, Mr. Johnson also served as a medical device consultant, president, and CEO of Spring Forest Qigong, co-founder and vice president of operations at Epitek, Inc., and co-founder, president and COO of Timm Medical Technologies. He has held positions, including vice president-operations/technology at UroHealth/Imagyn, vice president-operations at Dacomed Corporation, and various technical, operations, and training positions at American Medical Systems and Pfizer Corporation.

Bob Myers, Chief Financial Officer (CFO), Secretary

Mr. Myers was appointed CFO and secretary in 2012. He has over 30 years of experience in multiple industries, focused on medical devices, services, and manufacturing. He has spent much of his career as a CFO and/or controller. As a public accountant with the international firm of Laventhol & Horwath, he was CFO at Disetronic Medical and corporate controller for Diametric Medical Devices. He also held executive positions with American Express, Capitol Distributors, and International Creative Management. Mr. Myers has an MBA in Finance from Adelphi University and a BBA in Public Accounting from Hofstra University.

Dr. Mark A. Collins, President, TumorGenesis

Dr. Collins embarked on a career in the pharmaceutical industry following his postdoctoral work. Pursuing a passion for both biology and computing, Dr. Collins has held multiple executive roles in a variety of discovery, informatics and bioinformatics functions within global pharma, and founded three startup software companies in the machine learning and drug discovery space. He relocated to the U.S. in 2001 to work for Cellomics (now part of Thermo Fisher Scientific), where he played a pivotal role in establishing the High-Content cell analysis market, building and commercializing several key informatics and bioinformatics products. Since leaving Thermo Fisher, Dr. Collins has focused on developing and commercializing informatics solutions for clinical and translational research, specifically in the specimen tracking, 'omics data management and NGS analysis space, through key roles at BioFortis, Global Specimens Solutions and Genedata.

David Dauwalter, Product Management, Director

Mr. Dauwalter joined the Company in 2008 and has served as the director of product management since 2009. He brings several years of entrepreneurial and sales experience to Precision Therapeutics. Prior to joining the Company, he was a founder and owner of a company focused on infection control with applications in the medical sector. His sales, operational, and marketing experience suits the diverse activities for which he is currently responsible.

Kevin Hungerford, Vice President, Sales and Marketing

Mr. Hungerford is a visionary sales and marketing professional with proven experience developing and leading high-caliber teams through execution of sales and marketing initiatives. Mr. Hungerford has held several leadership positions in the medical device industry over the last 20 years, most recently with Boston Scientific and Sirtex Medical. Recognized as an engaging communicator, he has been able to launch products, manage multinational projects, and drive implementation of strategies in multiple roles (marketing, sales, training, communications, physician development, and product development). Mr. Hungerford's strong track record of success and of personnel development of leaders in organizations make him a valued individual for any organization.

Jean-Paul Rasschaert, International Vice President of Sales

Mr. Rasschaert is a senior executive with extensive expertise in the U.S. and international medical device markets (marketing and sales, R&D, clinical, regulatory, operations, and finance). Mr. Rasschaert, has a consistent track record of significant accomplishments with both large companies (Medtronic) and seven start-up companies—from scratch to acquisition or IPO (Cormove, MitralFlex, Epitek, CardialCare, Timm Medical Technologies, and InStent). He has shown strong leadership, strategic planning, and business development skills. Mr. Rasschaert has built and managed worldwide multi-functional teams. He is also member of several boards of directors at Medtech cardiovascular start-ups.

Rodney Schmidt, Senior Design Engineer

Mr. Schmidt has over 25 years of experience in the design and development of medical devices. His expertise is in bringing products from concept to manufacturing, with a strong background in pneumatic and pressure design.

BOARD OF DIRECTORS

Along with the Company's management team, the Board of Directors is committed to governing the Company to secure STREAMWAY Systems as a leading surgical fluid disposal system in hospitals and surgery centers. Figure 4 provides an overview of the Company's Board of Directors, followed by biographies.

Figure 4
BOARD OF DIRECTORS

Thomas J. McGoldrick	Chairman of the Board
Richard L. Gabriel	Director
Carl Schwartz	Director
Andrew P. Reding	Director
Timothy A. Krochuk	Director
J. Melville Engle	Director

Source: Precision Therapeutics Inc.

Thomas J. McGoldrick, Chairman of the Board

In May 2016, Mr. McGoldrick was elected Chairman of the Board. He has served as a director of the Company since 2005. Prior to that, he served as CEO of Monteris Medical Inc. from November 2002 to November 2005. He has been in the medical device industry for over 30 years and was co-founder and CEO of Fastitch Surgical in 2000. Fastitch is a start-up medical device company with unique technology in surgical wound closure. Prior to Fastitch, Mr. McGoldrick was president and CEO of Minntech from 1997 to 2000. Minntech was a \$75 million per year publicly traded medical device company offering services for the dialysis, filtration, and separation markets. Prior to Minntech, from 1970 to 1997, he held senior marketing, business development, and international positions at Medtronic, Cardiac Pacemakers, Inc., and Johnson & Johnson. Mr. McGoldrick is on the board of directors of two other start-up medical device companies.

Richard L. Gabriel, Director

Mr. Gabriel was appointed to the Board of Directors on December 1, 2016. He has more than 40 years of relevant healthcare experience, including two decades of executive leadership and as a director and consultant to development-stage companies. In addition to serving as COO of GLG Pharma since 2009, from 2003 until 2009, Mr. Gabriel was CEO of DNAPrint Genomics and DNAPrint Pharmaceuticals. He is currently a director of Windgap Medical. Mr. Gabriel holds an MBA from Suffolk University in Boston, and a BS in Chemistry from Ohio Dominican College in Columbus.

Dr. Carl Schwartz, Director

Biography on page 12.

Andrew P. Reding, Director

Mr. Reding is an executive with extensive experience in sales and marketing of capital equipment for the acute care markets. He has served as a director of the Company since 2006 and is currently the president and CEO of TRUMPF Medical Systems, Inc., a position he has held since April 2007. Prior to that, he was director of sales at Smith & Nephew Endoscopy; he also served as vice president of sales and director of marketing with Berchtold Corporation from 1994 to 2006. His experience encompasses the marketing and sales of architecturally significant products for the OR, emergency department, and the intensive care unit. Mr. Reding has successfully developed high quality indirect and direct sales channels, implemented programs to interface with facility planners and architects, and developed GPO and IDN portfolios. Mr. Reding holds a bachelor's degree from Marquette University and an MBA from The University of South Carolina.

Timothy A. Krochuk, Director

Mr. Krochuk is a co-founder and managing director of GRT Capital Partners, LLC, an investment adviser based in Boston, and is a portfolio manager and managing partner for the GRT BioEdge Ventures Fund, a fund focused on equity investments in privately held, emerging healthcare and biopharmaceutical companies. Prior to starting GRT Capital Partners in 2001, Mr. Krochuk became the youngest diversified portfolio manager in the history of Fidelity and was responsible for the development, programming, and implementation of investment models used by mutual funds with more than \$20 billion in assets under management. He currently serves as CEO of CHP Clean Energy, a full-service provider of biogas powered combined heat and power systems for wastewater treatment facilities with anaerobic digesters, which he founded in 2009. He also serves on the Board of Directors of Windgap Medical and Flatirons Bank. Mr. Krochuk holds an AB in Economics from Harvard College, a Chartered Financial Analyst designation, an Executive Masters Professional Director Certification from the American College of Corporate Directors, and is an active member of the Board of the Massachusetts General Hospital President's Council.

J. Melville Engle, Director

Mr. Engle has worked in the healthcare industry for the past three decades. Since 2012, he has served as president and CEO of Engle Strategic Solutions, a consulting company focused on CEO development and coaching, senior management consulting, corporate problem-solving, and strategic and operational planning. He is Chairman of the Board of Windgap Medical, Inc., a start-up medical device firm focused on unique drug delivery applications, and has held executive positions at prominent companies, including chairman and CEO at ThermoGenesis Corp., regional head/director, North America at Merck Generics (Darmstadt, Germany), president and CEO of Dey, L.P. and senior vice president, U.S. Sales at Allergan. In addition to ThermoGenesis, he has served on the Board of Directors of several public companies, including Oxygen Biotherapeutics and Anika Therapeutics. Mr. Engle holds a BS in Accounting from the University of Colorado Boulder and a MBA in Finance from the University of Southern California. He has served as a Trustee of the Queen of the Valley Medical Center Foundation, and a Board Member of the Napa Valley Community Foundation and the Napa College Foundation all in Napa, California, and as Vice Chair of the Thunderbird Global Council at the Thunderbird School of Global Management in Glendale, Arizona.

Core Story

Precision Therapeutics Inc. is a healthcare products and services company providing personalized medicine solutions and medical devices for the pharmaceutical, diagnostic, and biotechnology industries. The Company engages in the development of medical technology in two main areas of operation, highlighted in Figure 5: (1) precision medicine, which involves the development of a healthcare contract research organization (CRO) that aims to apply artificial intelligence (AI) to personalized medicine and drug discovery; and (2) Skyline Medical, which markets the FDA-cleared STREAMWAY System for automated, direct-to-drain medical fluid disposal.

Figure 5
BUSINESS SEGMENTS

PRECISION MEDICINE	MEDICAL DEVICE
Focused on applying artificial intelligence to personalized medicine and drug discovery	Producers of the STREAMWAY® System
Provider of precision diagnostics, bioinformatics, and integrated clinical contract research organization (CRO) services	An automated, patented, FDA-cleared waste fluid disposal system that virtually eliminates staff exposure to blood and other infectious fluids found in the healthcare environment
Clients include pharmaceutical, diagnostic, and biotechnology companies	STREAMWAY® is the only direct-to-drain, closed system in the fluid waste management market

Source: Precision Therapeutics Inc.

The Company's precision medicine and CRO services, designed to use AI and a comprehensive diseases database to improve the effectiveness of cancer therapy, were launched with Precision Therapeutics' investment in Helomics Corporation, a precision diagnostic company and integrated clinical CRO. The Definitive Merger Agreement was signed on June 28, 2018. Precision Therapeutics' investment in Helomics marked a key point in the Company's strategy to diversify its portfolio of products beyond the offerings of its Skyline Medical business, and into the precision medicine space and related emerging areas of the healthcare industry.

Through its partnership with Helomics, Precision Therapeutics has access to Helomics' AI-based bioinformatics diagnostic platform (D-CHIP) as well as a database containing the drug response profiles from over 149,000 patient tumors and their molecular and genomic data. Once a patient's tumor or a biopsy of the tumor is excised, the Company can compare the sample with its database and determine the type and strain of a patient's cancer. Using that data, as well as drug response data derived from tests performed on live specimens of that strain, the Company can provide a specific therapeutic roadmap for the patient and its oncologist.

To enhance the foundation provided by Helomics, as well as drive both diagnostic and CRO revenues, the Company intends to add additional strategic partnerships and acquisitions within the precision medicine space. One example of this strategic effort is the formation of a wholly-owned subsidiary, TumorGenesis Inc., to develop the next generation of patient-derived tumor models for precision cancer therapy and drug development.

The Company is also involved in the development and commercialization of the STREAMWAY System for automated and direct-to-drain medical waste fluid disposal. Sold through its Skyline Medical business, the STREAMWAY System virtually eliminates staff exposure to blood, **irrigation fluid**, and other potentially infectious waste fluids that result from surgical procedures and post-operative care. Skyline Medical's STREAMWAY System is designed to replace the antiquated manual fluid handling methods that require hand carrying and emptying filled fluid canisters, which present an exposure risk and potential liability. The Company distributes its products to hospitals, surgical centers, and other medical facilities. Skyline Medical also manufactures and sells two disposable products required for the System's operation: a bifurcated single procedure filter and tissue trap, and a single use bottle of cleaning solution. Both items are used on a single procedure basis and provide the Company with a profitable Razor/Razorblade type business model.

Through its Skyline Medical operations, as well as its partnership with Helomics, Precision Therapeutics has an established revenue stream, while positioning itself for additional revenue sources through the expansion of its precision medicine initiatives and businesses. Precision Therapeutics' strategic growth plan focuses on generating additional income streams to grow the value of the Company, and intends to do so by the following initiatives: (1) boost sales of Skyline's STREAMWAY business, (2) continued efforts for its precision medicine initiatives through the operations of Helomics and TumorGenesis; and (3) execute additional strategic partnerships and acquisitions in the precision medicine space and related emerging areas of the healthcare industry.

The Company believes that its Skyline Medical and precision medicine efforts have synergy, as both are involved in providing better care. In addition, the Company's long-term strategy involves the combination of both technologies—with its system able to perform tests- and run-test assays on the waste fluid that the STREAMWAY Systems collects and disposes of during all surgical procedures. For example, if a patient goes in for a knee operation, while fluid runs through the STREAMWAY machine, the System could eventually test and detect different diseases or cancers that were previously undetected.

PRECISION MEDICINE

The Company's precision medicine services business is committed to improving the effectiveness of cancer therapy using the power of artificial intelligence (AI) applied to diseases databases. This division is conducted through the operations of two entities: Helomics Corporation and TumorGenesis Inc.

This business was launched with Precision Therapeutics' investment in Helomics in January 2018, a precision diagnostic company and integrated clinical CRO, with a mission of improving patient care by partnering with pharmaceutical, diagnostic, and academic organizations to bring innovative clinical products and technologies to market. In addition, in February 2018, Precision Therapeutics announced the formation of a wholly-owned subsidiary, TumorGenesis, to develop the next generation of patient derived (PDx) tumor models for precision cancer therapy and drug development. A summary of these areas of operation is provided in Figure 6.

Figure 6

PRECISION MEDICINE AREAS OF OPERATION

PRECISION THERAPEUTICS	
Helomics® Corporation	TumorGenesis Inc.
Building out D-CHIP™ Artificial Intelligence (AI) database of tumor profiles Integrated CRO Services Precision oncology insights Strategic collaborations with academic and commercial partners	Developing patient derived (PDx) tumor models for precision cancer therapy and drug development. Licensing breakthrough technology: CellBridge: Biomimetic support technology 48HR Discovery: Ligand discovery technology SyntArray: Targeted peptide cell capture technology

Source: Precision Therapeutics Inc.

Helomics Investment Overview

Precision Therapeutics secured a strategic collaboration with Helomics Corporation to use Helomics' D-CHIP bioinformatics platform to develop and market new approaches for personalized cancer diagnosis and care, with an initial focus on ovarian and breast cancers.

In January 2018, the Company announced a partnership investment in Helomics, purchasing preferred stock in Helomics convertible into a 20% stake. Subsequently, in March 2018, the Company converted a previous \$500,000 loan to Helomics into a 5% equity stake, bringing Precision Therapeutics' total ownership to 25%. In April 2018, the Company announced a letter of intent (LOI) to acquire the remaining equity in Helomics Corporation. Under the terms of the agreement, a newly formed, wholly-owned subsidiary of Precision Therapeutics will merge with and into Helomics Corporation, thereby increasing Precision's equity stake from 25% to 100%. A definitive merger agreement was signed on June 28, 2018. TumorGenesis' operations, currently a subsidiary of Precision Therapeutics, would become integrated with Helomics, allowing it to leverage Helomics' complementary offering in the precision oncology market and benefit from operational synergies.

With its investment in Helomics, Precision Therapeutics obtains an established revenue stream poised for commercial ramp as it participates in earnings generated from pharmaceutical companies that use the Helomics platform when developing new therapies, while it continues to develop and expand its precision medicine offerings. Helomics is headquartered in Pittsburgh, Pennsylvania, where the company maintains state-of-the-art, **CLIA-certified** clinical and research laboratories.

Precision Therapeutics' strategy within this sector is to participate in the growth of the precision medicine market by providing customized services to pharmaceutical, diagnostic, and academic organizations as they seek to bring novel drugs and targeted therapies to the marketplace. Through its equity stake in Helomics and the operations of its TumorGenesis subsidiary, the Company believes that it is well positioned to take advantage of different segments within the expanding precision medicine marketplace—actionable **big data analytics**, diagnostics, and bioinformatics—while at the same time generating revenues through the current activities of Helomics. Precision Therapeutics intends to add additional strategic partnerships and acquisitions within the precision medicine space, with the goal of growing diagnostic and CRO revenues beyond the strong foundation provided by its Helomics and TumorGenesis operations.

Precision Medicine Background

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, disease strains, environment, and lifestyle for each case in developing effective therapies. This approach aims to allow doctors and researchers the ability to predict more accurately which treatment, dose, and therapeutic regimen could provide the best outcome, tailoring the treatment to the individual. Precision medicine aims to eliminate the one-size-fits-all approach, in which disease treatment and prevention strategies are developed for the average person, with less consideration for the differences between individuals or specific disease strains.

Advances in precision medicine have already led to new discoveries and several new treatments that are tailored to specific characteristics, such as a person's genetic makeup, or the genetic profile of an individual's tumor. This is helping transform the way diseases, such as cancer, are treated. Patients with breast, lung, and colorectal cancers, as well as melanomas and leukemia, for instance, routinely undergo molecular testing as part of patient care, enabling physicians to select treatments that improve chances of survival and reduce exposure to adverse effects.

Precision Medicine Market Overview

The global precision medicine marketplace is estimated to reach \$141.7 billion by 2026, up from \$43.6 billion in 2016. The increase in popularity of precision medicine can be gauged by the increase in precision medicine research during the past few years. For instance, in 2015, there were 1,737 papers with the term "precision medicine" on Pubmed, versus just a single paper mentioning precision medicine in 2005 (Source: Transparency Market Research's *Precision Medicine Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2016 – 2024*). This trend is supported by the industry investment in precision medicine, with leading biopharmaceutical companies doubling their investments in the technology over the last five years, and expected to increase it by additional 33% over the next five years, as precision medicine continues to become an integral component of patient care (Source: BIS Research's *Global Precision Medicine Market to Reach \$141.70 Billion by 2026, Reports BIS Research, December 2017*).

Growth in the marketplace is being fueled by advances in cancer biology, tests, and technologies; favorable government initiatives (such as the **Precision Medicine Initiative [PMI]**); the integration of big data analytical tools to improve decision making; and increased government and private investment in the technology (Source: Global Market Insights' *Precision Medicine Market Size By Technology, By Application, Industry Analysis Report, Regional Outlook, Application Potential, Price Trends, Competitive Market Share & Forecast, 2017 – 2024, October 2017*).

For instance, in 2015, the U.S. government launched the Precision Medicine Initiative (PMI), under which a grant of approximately \$215 million was sanctioned for the PMI collaboration with the U.S. National Institutes of Health, the U.S. Food and Drug Administration (FDA), and the Office of the National Coordinator for Health Information Technology. The short-term goals involve expanding precision medicine in the area of cancer research, with the National Cancer Institute (NCI) using \$70 million of that investment to advance the field of precision oncology. The long-term goals focus on bringing precision medicine to all areas of health and healthcare on a large scale, with emphasis on designing tools and regulations to facilitate the analysis of large medical data sets with the goals of better predicting disease risk, understanding how diseases occur, and finding improved diagnosis and treatment strategies (Source: U.S. National Institutes of Health).

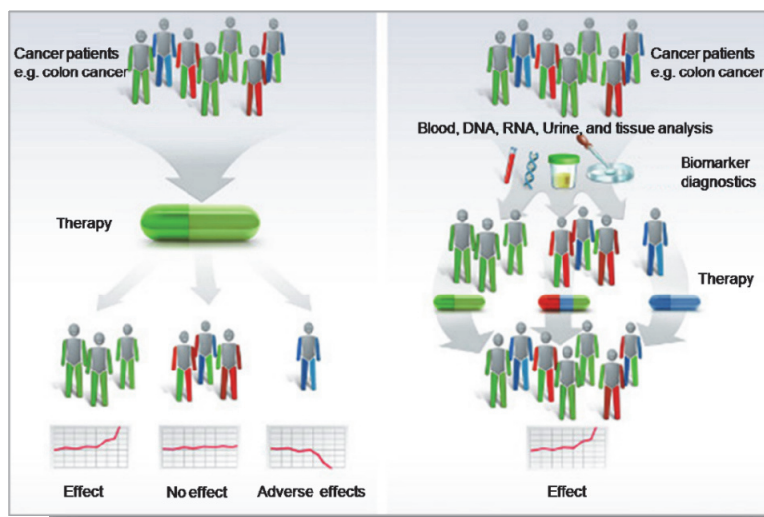
Precision Oncology

Precision oncology, or precision medicine of cancer, focuses on matching the most accurate and effective treatment to each individual cancer patient based on the genetic understanding of their disease and the tumor biology of each patient. Precision oncology applies genomic and other molecular analyses of tumor biopsies to improve the diagnosis and treatment of cancers, resulting in therapies that treat an individual’s cancer based on specific genetic abnormalities of that person’s tumor.

In standard cancer care, when diagnosed with cancer, patients would receive the same treatment as others who have the same type and stage of cancer despite the fact that different people responded differently to the same treatments. After decades of research, scientists now understand that patients’ tumors have genetic changes that cause different cancer strains of the same disease to react differently to the treatment options (Source: National Cancer Institute at the National Institutes of Health).

Over the past several decades, researchers have identified molecular patterns that are useful in defining the prognosis of a given cancer, determining the appropriate treatments to administer, and designing targeted treatments to address specific molecular alterations. The objective of precision oncology is to develop treatments tailored to the genetic changes in each person’s cancer, improving the effectiveness of the therapeutic regimen and minimizing the effects of the treatment on healthy cells, as illustrated in Figure 7 (Source: The American Journal of Managed Care’s *Recognizing the Value of Precision Medicine: Oncology and Beyond*, August 2017). In addition, precision oncology tracks the response of a tumor to a specific treatment option for future use and reference.

Figure 7
PRECISION ONCOLOGY



Source: IBM Big Data and Analytics.

Precision oncology is the dominating therapeutic application and prime research focus within the precision medicine market, a segment driven by a rising prevalence of cancer and the suitability of precision medicine for the treatment of the disease (Source: BIS Research’s *Global Precision Medicine Market to Reach \$141.70 Billion by 2026*, Reports BIS Research, December 2017).

Precision Medicine Technologies – The Role of Diagnostics, Actionable Big Data Analytics, and Artificial Intelligence (AI)

As the field of oncology continues to evolve, researchers are dedicating extensive resources developing not only innovative drug regimens, but also companion diagnostics that can provide essential information about the safety and effectiveness of a specific therapeutic product and its ability to treat patient groups or a specific disease strain. A companion diagnostic is a medical device or test, often performed *in vitro*, which provides information that is essential for the safe and effective use of a corresponding drug or biological product.

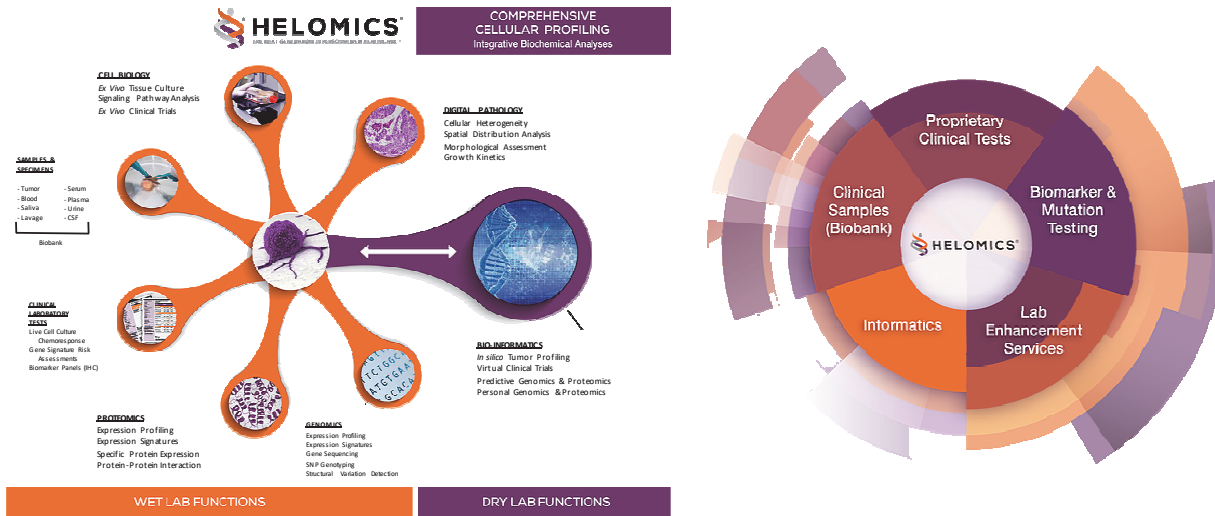
The effectiveness of precision oncology and companion diagnostics was proven with the approval Trastuzumab (Herceptin®) in 1998. During its clinical development, scientists recognized that only women whose breast tumors overexpressed the **HER2 receptor** were benefiting from the drug. This resulted in Trastuzumab being approved simultaneously with a companion diagnostic, HercepTest®, which accurately detects and quantifies HER2. Companion diagnostics helped launch oncology into a new era of discovery and treatment. However, these tests are normally co-developed to work with a specific therapeutic agent, and only test for a specific mutation or characteristics that the agent targets. The discovery and development of more extensive and comprehensive diagnostic options, such as **next-generation sequencing (NGS)**, has resulted in diagnostic tools that allow for the testing of as many mutations as possible. As the understanding of cancer continues to advance, and as cancers continue to be subdivided by their molecular characteristics, the need for a comprehensive test that can more finely dissect cancer's characteristics is key in the advancement of precision oncology (Source: *Oncology Times*, Vol 39 (9):24-26, 2017).

Precision medicine requires vast amounts of data, including information regarding socio-demographics, medical conditions, genetics, and treatments, as well as analytics to make decisions based on this data. In this environment, actionable big data and AI can be considered the foundation of precision medicine. Big data analysis plays an important role in storing and analyzing the medical data, leveraging the ability to analyze large pharmacogenetic databases to create a tailored prescription approach based on genomic profiles and drug-response data. Increased focus on actionable big data analysis and the development of innovative software tools to integrate and analyze health data is one of the major strategies adopted by companies in the precision medicine space (Source: Transparency Market Research's *Precision Medicine Market - Global Industry Analysis, Size, Share, Growth, Trends and Forecast 2016 – 2024*). Big data analytics is one area where AI is needed. AI algorithms could analyze big medical data sets, draw conclusions, find new correlations based on existing precedence, and support a physicians' job in the decision-making process (Source: *Expert Review of Precision Medicine and Drug Development*, Vol. 2 (5):239-241, 2017).

HELOMICS CORPORATION

Helomics offers advanced clinical laboratory tests as well as scientific and non-scientific product enhancement services to provide a customized solution to its clients' specific product development needs—offering a portfolio of products aimed at delivering tumor and cellular profiling services and precision oncology services for gynecologic, lung, colon, and solid tumor. Its key offering is its precision oncology service, driven by its proprietary bioinformatics platform D-CHIP. D-CHIP is a cloud-based bioinformatics platform used to power precision oncology diagnostics and services. In addition, Helomics offers boutique CRO services, clinical and research tests, and biorepository and banking, as shown in Figure 8 (page 22).

Figure 8
HELOMICS® SERVICES



Source: Helomics Corporation.

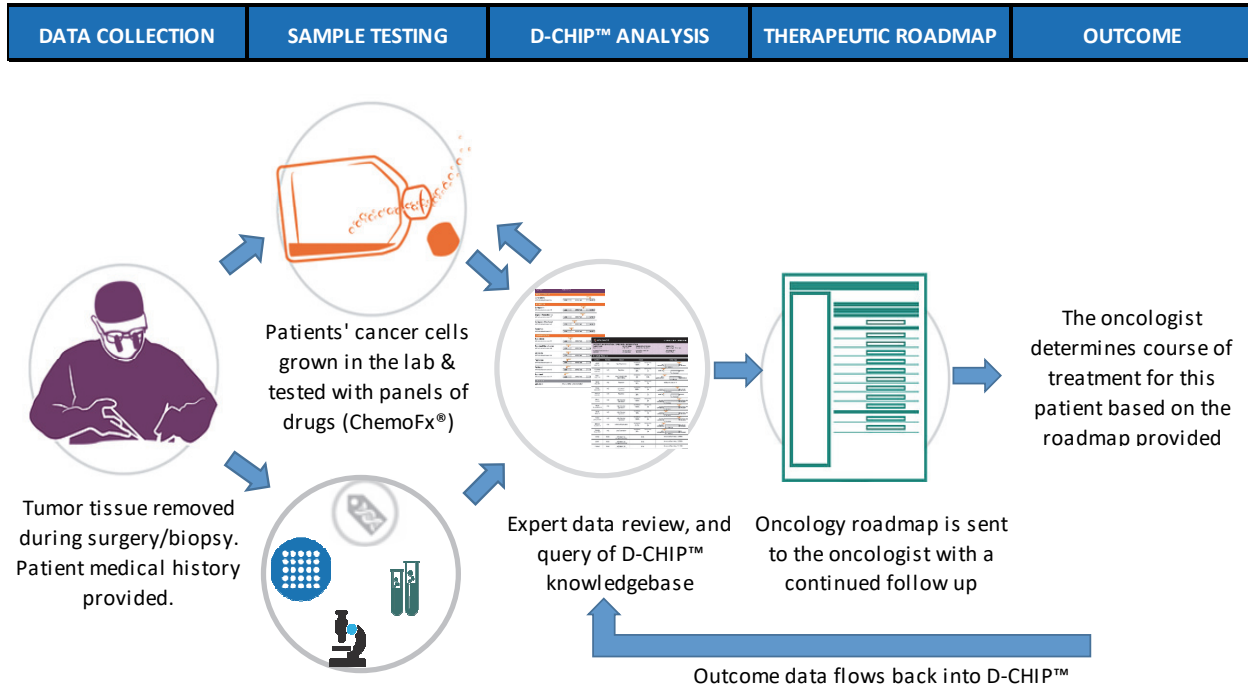
Helomics proprietary clinical tests include tools to give physicians a cellular profile of their cancer patients' tumors, helping to identify potential drug response and treatment choice that may be more likely to be effective. Its main product in this area is ChemoFx®, a unique, live cell **chemosensitivity** test and drug response marker platform that allows researchers to test multiple single or combination chemotherapies on a patient's own live cancer cells in the lab, helping to identify treatment choices that are more likely to be effective. ChemoFx is associated with a 50% improvement in progression-free survival and a 14-month improvement in overall survival when patients receive a sensitive therapy, while patients treated with a sensitive agent identified by ChemoFx lived 2.5 times longer than patients treated with a resistant agent.

In addition, Helomics offers a range of on-site specimen processing and analysis services in its CLIA-regulated facility, including a group of clinically validated biomarker tests and Next Generation Sequencing (NGS) and multiomics to evaluate a patient's tumor at a molecular level. Helomics further offers a full range of biorepository and specimen banking services for pharmaceutical and diagnostic companies to address the needs for specimen lifecycle management—from transport, to storage, and processing. Helomics' CRO services address a range of needs: from discovery through clinical and translational research, to clinical trials and diagnostics development and validation.

Helomics Precision Oncology Approach

Helomics' precision oncology approach combines comprehensive molecular profiling of the patient's tumor and the use of its D-CHIP AI-driven bioinformatics platform to determine which therapeutic option will work best for a particular tumor profile. Helomics' approach to precision oncology is based on the following steps, as seen in Figure 9 (page 23): (1) obtain a sample of the tumor, along with the patient's detailed medical history; (2) test to determine the genetic profile of the patient's tumor; (3) test to determine the drug response profile of the patient's tumor (unique to Helomics); (4) analyze the results utilizing D-CHIP to determine the best therapeutic options for that particular tumor profile; and, (5) provide an actionable roadmap for patient therapy to the oncologist to positively impact patient outcomes.

Figure 9
HELOMICS® PRECISION ONCOLOGY APPROACH



Source: Precision Therapeutics Inc.

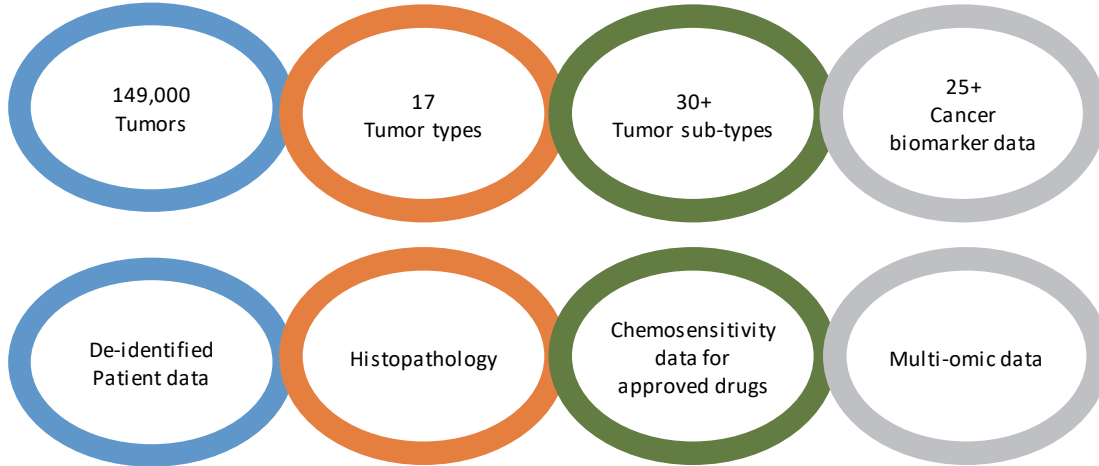
The competitive advantages of Helomics includes its extensive actionable big data repository, its ability and expertise to work on live tumor cells, and its proprietary D-CHIP bioinformatics platform.

Data Collection and Live Tumor Cell Analysis

Helomics' proprietary TruTumor™ patient-derived specimen processing and analysis model provides it with the ability to work with actual live tumor cells (not modified cell lines), and study the unique biology of a patient's tumor to understand how the cancer cells grow and respond to treatments in real time. Each patient's cancer is unique due to the specific activation of biochemical pathways that drive cell growth and proliferation. By conducting *ex vivo* tumor growth characterization, studying the biochemical pathways that are activated in a patient's tumor cells, and evaluating the proteins and nucleic acids secreted by live and growing tumor cells, the specific tumor can be profiled using Helomics' D-CHIP bioinformatics engine.

Helomics has over 15 years of experience in growing and collecting human tumor and supportive stromal cells in multiple cancers, including gynecologic (ovarian, endometrial, and cervical), breast, lung, colon, brain, and prostate cancer. Its actionable big data repository contains the drug response profiles of the more than 149,000 patient tumors and their molecular, genomic, biochemical, and **histopathology** data coupled to patient demographics. According to Helomics, its ability to continually grow and conduct genetic and molecular analysis of its bio-banked specimen's results in a data bank that provides understanding of each cancer by sub-type and their chemosensitivity to different drugs and drug combinations, as well as provides it with the ability to generate treatment protocols personalized by the specific tumor type on a patient-by-patient basis. Figure 10 (page 24) provides an overview of Helomics' data repository.

Figure 10
HELOMICS® DATA



Source: Precision Therapeutics Inc.

D-CHIP Bioinformatics Platform

D-CHIP (Dynamic Clinical Health Insight Platform) is a cloud-based analytic and bioinformatics platform used by pharmaceutical and diagnostic companies to power their precision medicine efforts. The D-CHIP searchable database, consisting of genetic and molecular analysis information on over 149,000 tumors, contains data compiled from more than a decade of clinical testing of tumors’ responses to drugs. The D-CHIP platform generates and analyzes rich molecular profiles and drug response data from the patient’s own tumor and compares it to its database.

D-CHIP uses deep learning to understand the association between the mutational profile of the patient’s tumor and the drug response profile of tumors grown in the lab. Coupled to a proprietary AI-powered bioinformatics engine, this approach generates actionable insights that deliver a link between specific tumor mutations and those drugs or therapies to which the tumor is sensitive, resulting on a specific oncology roadmap for the patient and his/her oncologist. Once a therapeutic option is implemented, outcome data from the patient’s progression flows back to the D-CHIP platform, which allows it to continually learn the association between the genetic alterations and the drug response of the patient’s tumor, expanding its knowledge base.

Combining analysis from a patient-derived tumor sample with D-CHIP genetic, molecular, and drug response database allows Helomics to provide the following services: (1) compare the response of individual tumors to specific drugs; (2) understand how specific tumors adapt to different therapies and the mechanisms of action of the therapeutic effect; and (3) create a database that relates drug sensitivity and tumor genetics to select potential therapeutic strategies even when limited data is available.

The D-CHIP technology can also be used by pharmaceutical, medical, and diagnostic companies in the research and development of targeted cancer treatments and diagnosis, for drug repurposing initiatives, and to perform better clinical trials by improving patient recruitment and selection. Pharmaceutical companies have access to large amounts of complex clinical data on patients but lack the bioinformatics and analytical platforms to fully leverage it. Through its CRO business, Helomics provides access to its knowledge database and analytics engine, giving physicians and medical companies the ability to process the information to aid in the development and selection of therapeutic options that improve patient outcome.

The D-CHIP platform generates revenues from subscriptions coming from pharmaceutical, biopharmaceutical, and diagnostic companies, as well as service revenues from additional solutions that rely on the capabilities of the bioanalytics platform.

As one of the only diagnostic companies to be part of the UK's **100,000 Genome Project GENE consortium**, Helomics has been working closely together with other pharmaceutical companies, researchers, and the UK NHS (National Health Service), providing a unique perspective on how best to use a patient's whole genome sequence data to look for new diagnostic biomarkers for cancer. These insights are aiding in the next phase of development for the D-CHIP platform, which aims to associate whole genome data with Helomics' tumor profile and drug sensitivity data to provide a unique resource for the discovery of new biomarkers for improved diagnostics that, in turn, are expected to power personalized cancer treatments.

Expansion of Helomics Services

The Company's acquisition of Helomics aims to leverage the D-CHIP platform and its actionable big data and bioinformatics solutions to expand its applications and enable healthcare and biopharma companies to develop novel cancer treatment options. A key element to these efforts is the addition of next-generation sequencing (NGS) services via a license with Illumina, Inc. for its MiSeqDx[®] NGS platform. The MiSeqDx NGS platform can conduct gene sequencing of tumor specimens from cancer patients, resulting in rich genomic data and targeted sequence data for a range of cancers to be added to the D-CHIP bioinformatics platform.

To the Company's knowledge, the MiSeqDx is the first FDA-regulated platform for **In Vitro Diagnostic (IVD)** use. Precision Therapeutics anticipates that licensing the NGS platform could attract new clinical testing business from a variety of local hospitals, academic centers, and small- and medium-sized companies. Adding NSG capabilities is expected to drive commercial traction for both the D-CHIP platform and the additional CRO services offered by Helomics. To further enhance the foundation provided by Helomics and drive both diagnostic and CRO revenues, Precision Therapeutics intends to add additional strategic partnerships and acquisitions within precision medicine, such as additional molecular tests for cancer and other diseases, companion diagnostics, and other technologies to complement NGS.

TUMORGENESIS, INC.

In February 2018, Precision Therapeutics announced the formation of a wholly-owned subsidiary, TumorGenesis, to develop the next generation of *ex vivo* patient derived (PDX) tumor models for precision cancer therapy and drug development. TumorGenesis is developing a new approach to growing tumor models in the laboratory that display *in vivo* like growth characteristics, invasion, and responses to therapeutics. The Company believes that the TumorGenesis approach is faster, less costly, and more closely mimics the characteristics of the patient's tumor inside the body than the traditional cancer animal models currently on the market. TumorGenesis' approach should provide a much more relevant model of the patient's tumor that may be used for testing of drugs for personalized therapy or for the development of new drugs. Upon completion of the Company's planned merger with Helomics, TumorGenesis operations (currently a subsidiary of Precision Therapeutics) are to become integrated with Helomics, allowing it to leverage Helomics' complementary offering in the precision oncology market and benefit from operational synergies.

The Company plans to initially develop the TumorGenesis PDX model for three orphan cancers that have a high unmet need for new and effective treatments and that are tailored to the patient's unique tumor profiles: multiple myeloma, triple-negative breast cancer (TNBC), and ovarian cancers.

TumorGenesis PDX Model

Through its TumorGenesis' operations, the Company is developing a new, rapid approach to growing tumors in the laboratory, which essentially "fools" the cancer cells into behaving as though they are still growing inside the patient. Analysis and testing of primary tumor cells derived from patient tissue and grown *in vitro* in the laboratory can produce results that can be applied to *in vivo* models and ultimately to clinical settings. However, to achieve positive results, this approach must allow the *ex vivo* tumor to grow in an environment that emulates the tumor's *in vivo*-like growth characteristics, invasion, and responses to therapeutics. By offering an external, structured environment that more closely mimics the environmental characteristics of the patient's tumor, TumorGenesis is expected to provide a much more relevant model of the patient's tumor. TumorGenesis' PDX model can allow drug developers to test potential cancer therapies in a model system that closely mimics the way a tumor grows in the body, which could optimize clinical trial outcomes and advance the development of personalized therapies.

Traditional Cancer Research Models

According to the Company, the TumorGenesis PDX model is faster, less costly, and expected to create more accurate results when testing drugs for personalized therapy as well as when developing new drugs, compared to testing with traditional animal or cell culture models that are currently used in the clinical development of cancer therapies.

Clinical trials are complex and expensive, and pre-clinical data and technology that helps increase the likelihood of success during clinical development are in high demand. Thus, pre-clinical biological models that capture both the molecular features of cancer and the diversity of therapeutic responses are a key need for the accurate and fast development of new cancer therapies and precision oncology technologies. Cell lines and xenografts are two approaches that are widely used to identify clinically meaningful gene-drug interactions and test potential new therapies.

Cell Lines

Human cancer cell lines have long been utilized to study the mechanisms underlying biologic processes. The use of human cell lines as a screen to detect the most promising candidate drugs or therapies before more time-consuming and labor-intensive studies are conducted is a routine experimental model widely employed for drug development.

Initially, only a limited number of lines for any given cancer were available, severely limiting the possibility for identifying responder subsets of a given type of cancer. However, the emergence of high-throughput data and genetic technologies has resulted in the creation of a large number of cell lines banks, representative of a wide range of genetic and epigenetic variation for different cancers being studied, and the corresponding response of a particular cancer subset to a therapeutic agent (Source: *Cancer Research*, Vol. 74 (9): 2377–84, 2014).

The comparisons of cell line and tumor genomics have offered insights into the relevance of *in vitro* models. However, limitations still exist. Research has shown that the cell lines most commonly used to study high-grade serous ovarian cancer (HGSOc) did not closely model the genomics of the disease. In addition, not all tumor subtypes are represented in current panels of cell lines, with some cancer types being poorly represented (e.g., prostate cancer) (Source: *Molecular Cancer Research*, Vol. 14(1): 3–13, 2016). Even for those cancer classes that are represented, there remains multiple drawbacks to the cell line technology:

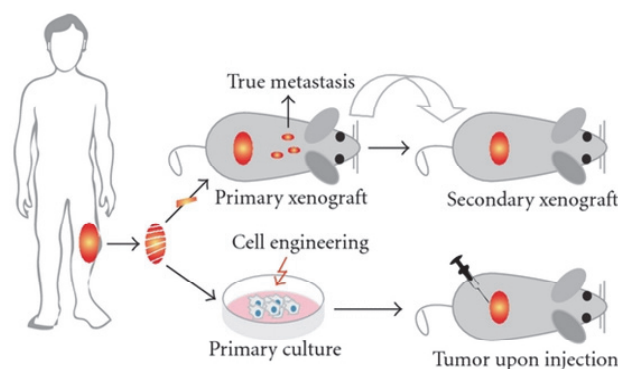
- Cell lines can change in culture (genetic changes have been reported);
- Cell lines no longer retain the tumor heterogeneity present in the primary cancer;
- Cell lines do not contain the relevant components of the tumor microenvironment and the tissue architecture from which they were derived; and
- For most cancer cell lines, there is little or no clinical or pathological data attached, limiting the possibility to correlate patient medical history and lifestyle into a therapeutic decision (Source: *Current Opinion in Genetics & Development* Vol. 24:114-11, 2014).

These limitations have led to the move away from cell lines and have provided more emphasis on the concept of tailored drug response profiling using patient-derived **xenografts**.

Xenografts

Traditional patient-derived xenograft mouse or rat models are used for personalized therapy decisions and by pharmaceutical companies to develop new drugs. Among the arguments made for these models is that they better represent tumor heterogeneity and better reflect the relevant human components of the tumor microenvironment than cell lines (Source: *Cancer Research* Vol. 74 (9):2377–84, 2014). The process to conduct patient-derived xenografts is shown in Figure 11. After excision, the tumor is dissected into pieces, one or more of which is then xenotransplanted into the mice. Subsequently, the process of xenotransplantation can be repeated as often as needed to keep the human tumor active, providing a source for research material. Alternatively, after tumor excision, cell cultures can be established, allowing for the engineered cancer cells to be injected into mice to assay the **tumorigenicity**, metastatic potential, and other features. (Source: *Sarcoma*, Vol. 2012(397), 2012)

Figure 11
XENOGRAFT



Source: *Sarcoma*.

Despite their popularity in cancer research, the overall usefulness of xenograft models may be hampered by several limitations. The xenograft model is burdened with high cost and low throughput, which has impacted its adoption both for recommending patient therapy as well as for screening new drugs. In addition, the mouse tumor models display relatively low engraftment rates and slow growth rates of the engrafted primary cancers in comparison with growing cells *in vitro*, as well as a limitation on the number of drug combinations that can be tested. Furthermore, not all cancer cell lines are tumorigenic, which limits the number of cell lines that are amenable for *in vivo* studies (Sources: *Cancer Research*, Vol. 74 (9):2377–84, 2014, and *Molecular Cancer Research*; vol. 14(1): 3–13, 2016). This realization has spurred the generation of new cell lines and 3-D culturing techniques that more closely reflects the features of the primary tumors from which they were derived.

Tumor Organoids and the TumorGenesis PDx Model

Despite the millions of dollars spent on target validation and drug optimization in preclinical models, the success rate of the drug approval process is still very low. Current model systems and the way the resulting data is interpreted does not result in a process with sufficient clinical predictive power. Researchers suggests that this is because the cell lines and xenografts that are commonly used are inadequate models and do not effectively mimic and predict human responses (Source: *Cancer Research*, Vol. 74 (9):2377–84, 2014).

Unlike the traditional cell line and mouse model, the TumorGenesis approach provides a faster, less costly approach that more closely mimics the characteristics of the patient’s tumor. TumorGenesis offers an external 3-D structured environment combining chemistry, biology, mechanics, and cell nutrients to allow the cancer cells to grow as closely as possible to the environment inside the human body. In addition, this approach is scalable for high throughput using standard consumables, equipment, and reagents.

Monolayer culturing methods, such as those applied for the creation of the large cell line databases, are limited in their capacity to accurately model the complexity of the *in vivo* tumor environment. Growth of cancer cells in 3-D matrices can result in the development of multidimensional structures—known as **organoids**—with properties that more closely resemble the tumors from which they were derived. Organoid technology differs from traditional cell culture by maintaining cancer cells in 3-D cultures, which allows the system to retain cell-cell and cell-matrix interactions that more closely resemble those of the original tumor (Source: *Cancer Discovery’ Personalized In Vitro and In Vivo Cancer Models to Guide Precision Medicine*, May 2017). There is evidence that 3-D cancer models respond to drug treatments differently compared to two-dimensional or monolayer traditional tissue culture. As such, the generation of 3-D organoids might be one of the key changes that can be implemented in *in vitro* drug screening to improve the ability to predict human drug responses (Source: *Cancer Research* Vol. 74 (9):2377–84, 2014).

TumorGenesis’ innovative approach is comprised of three key steps:

- (1) the tumor cells from the patient biopsy are tagged using **peptides** that target each cancer cell subtype within the specific tumor;
- (2) the peptide tags are used to “reassemble” the cells to a 3-D biomimetic support scaffold in a microplate, an environment that closely mimics the patient’s own body; and
- (3) the tumor cells are grown in the 3-D culture system until ready for testing.

TumorGenesis License Activity

In March 2018, the Company secured licenses with three medical technology companies to advance the development of these tumor models.

SyntArray LLC

The SyntArray technology provides a vital step in rapidly identifying the key **peptide ligands** that cause the cells to attach to the surface of a microplate and grow. The SyntArray technology ensures that TumorGenesis is able to capture and grow different types of cancer cells in the laboratory to closely mimic the tumor inside the patient's body for more relevant drug response testing.

48Hour Discovery

The license agreement with 48Hour Discovery (48HD) grants it access to 48HD's ligand discovery technology. The 48HD ligand discovery technology is vital to the first step on the TumorGenesis PDx model process as it screens the patient's tumor cells against large peptide libraries to identify the specific peptide ligands that bind to those cells. Once identified by 48HD's technology, SyntArray's targeted peptide cell capture technology screens these peptides to determine the best combination that will capture the cancer cells and allow them to attach and grow on the 3-D biomimetic support. The innovative 48HD technology allows TumorGenesis to capture all the heterogeneity of the tumor, including both the cancerous and non-cancerous cells. This is key to reassembling the tumor on an artificial scaffold, or 3-D biomimetic support, for it to grow in a way that closely mimics the patient's body.

CellBridge Incorporated

The license agreement with CellBridge grants TumorGenesis access to CellBridge's 3-D biomimetic support technology. After the patient's tumor cells have been screened and the tumor has been disaggregated into all its component parts, the cancer cells are attached to CellBridge's 3-D biomimetic support technology using the targeted peptides, so as to reassemble the tumor. The 3-D biomimetic support acts as a scaffold on which the tumor is regrown outside the patient's body.

TumorGenesis' Business Model and Revenue Operations

According to the Company, the TumorGenesis PDx model forms a key part of its strategy to expand the footprint on its AI-based healthcare business and the precision medicine market. Testing of patients' tumors using this new approach can result in a personalized therapy protocol for a patient while at the same time providing high-quality data for Helomics' D-CHIP platform. In addition, the TumorGenesis technology can be used to drive partnerships with pharmaceutical companies for the development of new therapies. This can be accomplished by offering clinical trial CRO services, in conjunction with Helomics, to pharmaceutical companies to test new drugs, or selling tumors to pharmaceutical companies for new drug research.

Testing of the TumorGenesis PDx tumors is expected to take place in collaboration with Helomics. This provides a synergy that would benefit both companies and enhance Helomics' capabilities in three key areas: (1) improve the precision of the tumor/drug response testing performed by providing a model that captures the full heterogeneity of the tumor and grows the tumor in a more physiologically relevant way; (2) provide higher quality, more biologically relevant data to improve the decision-making power of the Helomics D-CHIP AI platform; and (3) allow Helomics the ability to store these tumor cells, expanding its patient-derived tumor **biobank** that can be used for the testing of new drugs in partnership with pharmaceutical companies. The establishment of a living biobank consisting of tumor organoids can facilitate the integration and analysis of the tumor profile data and drug response within the D-CHIP platform. The combination of a personal tumor organoids library, a high-throughput drug test, and Helomics bioinformatics platform allows for the associations of the specific cancer subtype and the outcome of drug treatment in a searchable platform.

GLG PHARMA

In November 2017, Precision Therapeutics and Helomics announced a collaborative partnership with GLG Pharma focused on using their combined technologies to bring a personalized, precision medicine approach to ovarian and breast cancer patients. The Precision Therapeutic and Helomics proposed joint venture own 50%, with the remaining 50% owned by GLG Pharma.

GLG Pharma is developing an innovative capture, culture, and screening precision medicine platform as well as novel **STAT3 pathway** targeted therapies with an initial focus on breast cancer, ovarian cancer, and glioma. GLG proprietary precision medicine platform—Gx-C3TM—involves three key steps: (1) capture of patient’s cells from a biopsy, resection, or blood samples; (2) culture and expand the cells outside of the body in a 3-D environment in a manner that preserves ultrastructural and cellular identity of the tumor; and (3) screen the cells against libraries of drugs to identify the most appropriate therapeutic pathway for each patient’s disease.

In addition, GLG pharma is developing a family of therapeutic compounds that targets abnormal STAT3 pathway regulation, designed to be combined with standard-of-care chemotherapeutics, to form precision oncology treatments for breast cancer, ovarian cancer, and glioma. These cancer types are driven by and dependent on STAT3 misregulation, a condition that can be directly related to rapid, uncontrolled cell proliferation and metastasis in cancer cells.

Ascites Fluids in Ovarian and Breast Cancer

Ovarian cancer has the highest mortality rate of all gynecological cancers worldwide. As the disease is asymptomatic, early detection is difficult, with approximately 75% of ovarian cancers having already metastasized at the time of diagnosis. In these patients, treatment with surgery, together with combination chemotherapy, has resulted in a median progression-free survival of 16 to 22 months and a 5-year survival rate of only 27% (Source: *Nature Reviews Cancer*, Vol. 13(4): 273–282, 2013).

Ascites refers to abnormal accumulation of fluid in the abdominal (peritoneal) cavity. Ascitic fluid can have many sources, such as liver disease, congestive heart failure, or kidney failure. Ascites can also manifest as a result of cancers, called malignant ascites. For example, more than one-third of women with ovarian cancer develop ascites during the course of their disease. Malignant ascites can also develop secondary to extra-abdominal tumors, such as breast and lung cancer, as well as lymphoma. The term malignant ascites is commonly used when the fluid tests positive for malignant cells, suggesting that the ascites may contain tumor cells with high proliferative rates indicative of rapid progression of the disease.

In ovarian cancer, the presence of ascites correlates with the peritoneal spread of the disease and is associated with poor disease prognosis. Tumor cells within the ascites play dominant roles in metastatic spread, chemoresistance, and ultimately, the recurrence of the cancer. Malignant ascites act as a reservoir of a complex mixture of cellular components, which provide a pro-inflammatory and tumor-promoting microenvironment. Thus, detached ovarian tumor cells colonize distant sites under the influence of ascites flow. The malignant cells in the ascites fluids have demonstrated the features of self-renewal, multi-lineage differentiation, and tumor initiation characteristics *in vivo* (Source: *Frontiers in Oncology*, Vol. 3: 256, 2013).

The accessibility of ascites translates into a rich source of readily available tumor tissue during the course of a patient’s treatment, cells that can provide insights into effective therapeutic strategies, prognostic, and predictive biomarkers. Evaluation of the ascites-derived cells can help researchers and physicians develop a molecular and cellular profile of a patient’s ovarian cancer, helping to understand the various biological aspects of the underlying tumor, including pharmacodynamic information, drug resistance, and mechanisms of tumor progression. Thus, a thorough evaluation of ascites fluids can help identify and validate therapeutic targets and predictive biomarkers, helping to develop effective therapeutic intervention for metastatic ovarian cancer. Studies on malignant ascites suggest that the molecular profile is subject to considerable inter-patient variability and that the ability to provide accurate molecular characterization is crucial in designing the most appropriate intervention for patients in the era of precision oncology (Source: *Nature Reviews Cancer*, Vol. 13(4): 273–282, 2013).

Precision Therapeutics, Helomics, and GLG Pharma Partnership Initiative

The partnership plan is to add a collection and analysis system for ascites fluids to the STREAMWAY System—using GLG’s capture, culture, and screening platform—to bring personalized medicines and testing to ovarian and breast cancer patients. The STREAMWAY System would be used to drain the ascites fluids from the patient during the operation. Following the procedure, pathologists would then be able to process and send the fluid sample and analysis results to Helomics for further evaluation using Helomics’ precision oncology insights platform. Together with a combination of STAT3 inhibitors from GLG, the partnership is expected to create new revenue streams to be shared between Precision Therapeutics, Helomics, and GLG Pharma.

SKYLINE MEDICAL

Figure 12
THE STREAMWAY® SYSTEM



Source: Precision Therapeutics Inc.

Through the operations of its Skyline Medical division, Precision Therapeutics develops and manufactures the STREAMWAY System, an environmentally conscientious system for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. The STREAMWAY System, shown in Figure 12, is a wall-mounted fully automated system that disposes of an unlimited amount of potentially-infectious fluids collected during surgical and other patient procedures, providing uninterrupted performance while virtually eliminating healthcare workers' exposure to the fluids. The System is intended to replace the manual process of collecting fluids in canisters, then transporting and dumping in sinks outside of the operating room (OR), which is still being used by many hospitals and surgical centers around the world.

Skyline believes that the STREAMWAY System is unique to the industry in that it allows continuous suction and provides unlimited capacity, eliminating the need to interrupt a procedure to change canisters. In addition, the system minimizes the exposure potential to the healthcare workers who handle such fluids without significant changes to established operative procedures—overcoming a major roadblock that prevents physicians and medical establishments from adopting innovative technologies.

Precision Therapeutics distributes these products to hospitals, surgical centers, and other medical facilities where bodily and irrigation fluids produced during surgical procedures must be contained, documented, and disposed. The Company also manufactures and sells two disposable products required for the System's operation: a filter and tissue trap, and a bottle of cleaning solution, both used on a single procedure basis and discarded after use, providing the Company with a profitable Razor/Razorblade type business model.

In addition to simplifying the handling of medical waste fluids and improving the safety of healthcare workers, the Company believes its technologies provide cost savings to facilities over the traditional methods used for the collection, neutralization, and disposal of biohazard fluids. The STREAMWAY System is FDA-cleared in the U.S., has a medical device established license to sell in Canada, possesses a CE mark allowing sales in Europe, and is regulatory approved in Australia and New Zealand for sales. The Company has installed over 100 units in more than 50 facilities in the U.S., covering 19 states. Figure 13 (page 33) shows selected STREAMWAY clients, as the information has been made publicly available.

INFECTIOUS AND BIO-HAZARDOUS MEDICAL WASTE OVERVIEW

Medical waste is any kind of waste generated by healthcare facilities, including physician's offices, hospitals, dental practices, laboratories, medical research facilities, and veterinary clinics. The safe and effective management of healthcare biomedical waste is one of the biggest day-to-day challenges faced by healthcare providers and institutions, as waste derived from healthcare activities—particularly infectious and sharps material waste—can represent grave risks to the healthcare workers, the patients, and the environment if not properly handled and disposed. The hazards of exposure to medical waste can range from gastroenteric, respiratory, and skin infections to more deadly diseases such as HIV/AIDS and hepatitis. Additionally, medical waste contains potentially harmful micro-organisms which can infect hospital patients, healthcare workers, and the general public.

Figure 13
SELECTED STREAMWAY INSTALLATIONS



Source: Precision Therapeutics Inc.

The global medical waste management market was estimated at \$21 billion in 2016 and is expected to reach \$33.4 billion by 2025. This growth is driven by the overall development of the healthcare industry coupled with rising patient populations requiring prolonged medical and surgical aid, as well as the development of innovative medical devices (Source: Grand View Research’s *Medical Waste Management Market Analysis By Services, By Treatment, And Segment Forecasts, 2018 – 2025, 2017*).

Among the different categories of medical waste, infectious and liquid waste (such as blood and body fluids) possess one of the most serious threats to human health and the environment due to the proliferation of bloodborne diseases and their ability to enter watersheds and pollute ground water if improperly handled and disposed (Source: *Muller Journal of Medical Sciences and Research*, Vol. 4 (2):99-106, 2013). Medical fluid waste collected by hospitals, ambulatory surgery centers, and other medical treatment facilities—containing blood, body fluids, or other potentially infectious materials—are classified as a regulated infectious medical fluid waste in the U.S. by Federal, state, and local government agencies. Federal and state regulatory agencies have issued mandatory guidelines for the control of such materials. For example, The Occupational Safety and Health Administration’s (OSHA’s) Bloodborne Pathogens Standard 29 CFR 1910.1030 requires employers to adopt engineering and work practice controls that would eliminate or minimize employee exposure from hazards associated with bloodborne pathogens.

Skyline Target Market—Surgical and Procedural Medical Fluid Waste

The presence of infectious fluid materials is most prevalent in the surgical suite where often large amounts of bodily fluids, including blood and irrigation fluids, are continuously removed from the patient during the surgical procedure. Surgical teams and post-operative care personnel may be exposed to these potentially dangerous hazards during the procedure via direct contact of blood materials or more indirectly via splash and spray. Furthermore, the OR is one of the largest users of supplies within the hospital as well as one of the largest producers of waste. Case studies have estimated that approximately 20% to 30% of the total waste generated by the hospital comes from the OR (Source: Practice Greenhealth’s *Fluid Management Systems in the OR*).

In other areas of the hospital, outside of the OR, specialty procedures also generate a considerable amount of waste fluid. Take, for instance, the paracentesis and thoracentesis procedures performed regularly under the guidance of ultrasound. Due to the need for imaging for proper catheter placement, the procedures are most commonly performed in the radiology department. A large volume paracentesis can reach fluid removal volumes of over 10 liters of ascites.

Skyline places its STREAMWAY System in ORs and surgical centers for the collection and disposal of infectious fluids that result from surgical procedures and post-operative care. Skyline's target market includes the roughly 40,000 hospital ORs and surgical centers in the U.S. (AHA, Hospital Statistics, 2008). There were approximately 86 million surgical procedures conducted in hospital ORs (Source: American Hospital Association's [AHA] Hospital Statistics, 2013 edition) and 51.6 million inpatient procedures from surgical centers (Source: CDC's National Hospital Discharge Survey: 2010 table)—a number that is expected to increase due to population growth, the aging of the population, expansion of surgical procedures to new areas, and new medical technology.

MANAGEMENT OF SURGICAL WASTE FLUIDS

The management of surgical waste fluids produced during and after surgery is a complex mix of materials and labor that consists primarily of collecting fluid from the patient, transporting the waste fluid within the hospital to a disposal or processing site, and disposing of that waste. According to a 2007 study, removal and treatment of infectious fluid waste accounts for more than 75% of U.S. hospitals biohazard disposal costs (Source: Lewin Group, prepared for the Health Industry Group Purchasing Association, April 2007). As such, disposing of medical fluid waste from the operating suite is a task healthcare facilities must perform with an eye toward efficiency and cost effectiveness, while simultaneously protecting healthcare workers.

Suction Canisters

The most common medical fluid waste disposal methods used in hospitals and surgical centers involves these fluids being retained in suction canisters made of glass or high impact plastic (illustrated in Figure 14), where they can be monitored throughout the surgical procedure. Of note is that the glass evac bottle (illustrated on the right of Figure 14) is only used in radiology and is very expensive and difficult to get. Typically, during the course of the procedure, fluids are removed from the surgical site via suction and collected in large canisters, each typically with a capacity of 1.5 to 3.0 liters. Following the procedure, the fluids contained in the canisters are measured and a calculation of total blood loss is determined to ensure that no excessive blood loss occurred. Once the procedure is complete, these canisters and their contents are removed from the OR and disposed. Previously, many hospitals used incineration as the primary means of disposal, but environmental concerns have resulted in a decrease in this process as a viable option. There are several alternative methods used for disposal of surgical waste fluids, all of which present certain risks to the OR team, as well as the crews who clean the rooms and the other personnel involved in the process.

Figure 14
SUCTION CANISTERS



Source: Precision Therapeutics Inc.

Indirect Sewer Drain Disposal

Indirect sewer drain disposal is typically done by manually transporting the canisters from the OR to a waste station and directly pouring the material into a sink that drains to the sanitary sewer (Figure 15), where it is subsequently treated by the local waste management facility. This process exposes the healthcare worker to the most risk for direct contact, splash exposure, or aerosolization of bloodborne pathogens. In addition, once emptied, these canisters are often still considered regulated medical waste. The empty canisters are sent to central processing for re-sterilization (glass and certain plastics) or for disposal with the bio-hazardous/infectious waste. The latter requires them to be placed in large, red pigmented, trash bags (i.e. red-bagged, Figure 15) and disposed of as infectious waste, adding the weight of each empty container to the facility's disposal costs. An estimated 30% to 65% of hospitals have continued to use drain disposal, despite the exposure risks. Hospitals utilizing this practice also run the risk of OSHA citations, since even with personal protective equipment, this practice may be interpreted as violating OSHA's Bloodborne Pathogens Standard (Source: Practice Greenhealth's *Fluid Management Systems in the OR*).

Figure 15
MEDICAL LIQUID WASTE DISPOSAL



Source: Precision Therapeutics Inc.

An even more cumbersome and dangerous means of fluid removal centers around a product called an evacuated glass container, often referred to as an evac bottle. These bottles have long been the accepted practice for fluid removal in procedure rooms where paracentesis and thoracentesis procedures are performed. The bottles have a 1-liter capacity and 5 to 8 of them are used on average for a large volume paracentesis. Procedure costs for the glass bottles alone can climb to \$50 or \$60. Furthermore, the added weight of the glass and fluid makes glass bottles one of the most expensive collections options on the market.

Bloodborne Exposure

One of the main concerns of the indirect disposal of surgical waste fluids into the sewer drain, via the sink, is the possibility of direct contact by the healthcare worker with the fluid as a result of leakage, breakage, or splash exposure during the disposal process. Healthcare workers that come in contact with these fluids face potential infection from bloodborne pathogens, such as Hepatitis B and C, HIV/AIDS, HPV, and other infectious agents. Hospitals and healthcare facilities must treat every exposure incident as a potentially infectious incident, following a protocol that is both costly to the facility and stressful to the affected employee. It is hard to quantify the cost of treating employees who have had exposures related to disposal of fluid medical waste, but even using conservative numbers, hospital management costs associated with occupational blood exposure can be more than \$4,500 per exposure (Source: Infection Control Hospital Epidemiology, July 2007). In addition, the emotional effects can be longer lasting, even in a low risk exposure that does not result in infection. Employees may experience anger, depression, fear, anxiety, trouble sleeping, problems concentrating, and doubts regarding their career choice.

Despite the risks, healthcare worker exposures and potential exposures to these pathogens are widespread. An estimated 400,000 U.S. healthcare workers are exposed to blood-borne pathogens every year (Source: *The Journal of the American Medical Association [JAMA]*, Vol. 307(1):75-84, 2012) and approximately 1 out of 10 healthcare workers in the U.S. suffers a splash exposure or a needle stick injury every year. A survey found that 9.4% of healthcare workers reported exposure to potentially infectious blood or body fluids within the preceding year, 60% of which were a result of splash exposures. The risk of exposure is higher for OR personnel, where the exposure rate was reported to be 12.7% (Source: *American Journal of Infection Control*, Vol. 41(2), 185-186, 2013). However, the exact number of exposures is not known as exposure is normally under-reported; it has been estimated that approximately 50% to 67% of all needlesticks and exposures to bloodborne pathogens are not reported. Another study found that up to 50% of operating procedures resulted in at least one person becoming contaminated with blood (Source: *Annals of Surgery*, Vol. 214(5): 614–620, 1991).

Conversion to Gel for Red-Bag Disposal

In many hospital systems, the handling of medical fluid waste has become a liability issue due to worker exposure incidents. The medical industry has responded by developing chemical solidifier powders that, when added to the fluid in the canisters, produces a viscous, gel-like substance that can be handled more safely. Solidifiers can take up to 10 minutes to solidify completely, though many claim a two-minute solidification process, after which the canisters are placed on a service cart and removed to the red-bag disposal area with the other infectious waste. Material that has been red-bagged is disposed of separately (more expensively) from other non-infectious medical and non-medical waste. Some solidifiers contain disinfectant chemicals that may allow a solidified container to go to regular trash rather than be considered infectious waste. But these chemicals bring additional exposure risks to workers. Glutaraldehyde, for example, is known to cause throat and lung irritation, asthma, headaches, nausea, allergic dermatitis, nosebleed, burning eyes, nose irritation, sneezing, and wheezing.

One significant drawback of the solidifying gels is their operating cost. Gels increase the weight of the materials being sent to the landfill by a factor of five to seven times, resulting in a significant cost increase to the hospitals since handling and landfill costs are based upon weight rather than volume in most locations. From a waste perspective, in a hospital that performs 7,000 surgeries per year, use of solidifiers could be roughly equivalent to \$35,280 in disposal costs, with an additional supply cost estimate of \$105,000 for the solidifiers themselves (estimated to cost between \$5 to \$30 each). Furthermore, in terms of OR turnover time, at an estimated cost of \$17/minute, assuming just five minutes per case for suction canister solidification and disposal over eight cases a day can translate to \$680 per day in lost OR time (Source: Practice Greenhealth's *Fluid Management Systems in the OR*). In addition, the use of solidifying gels does not ensure complete protection for healthcare workers, as there remains the potential for splash when the top of the canister is opened.

Financial Impact of Canisters

Nursing personnel spend significant amount of time in the OR readying canisters for use, calculating blood loss, and removing or supervising the removal of the contaminated canisters after each procedure. The average nursing team spends 20 minutes pre-operatively and intra-operatively setting up, monitoring fluid levels and changing canisters as needed, and 20 minutes post-operatively readying blood loss estimates or disposing of canisters.

The widespread use of suction canisters has created other issues for medical facilities. The typical OR will generate about two tons of fluid waste each month. Suction canisters were found to comprise 25% of regulated medical waste at hospitals and up to 40% of surgical waste. In a single surgery, often three to four three-liter containers can be filled with fluids bound for disposal—weighing approximately six to eight pounds each. Disposal of a single three-liter canister can easily exceed \$2.25, with costs in locations, such as California, as high as \$8.00 per canister (Sources: Practice Greenhealth's *Fluid Management Systems in the OR* and Healthcare Purchasing News).

Fluid Waste Management Systems

Hospitals are finding that a third option, fluid waste management systems (FMS), which collects and disposes the fluid, is safer for the staff, better for the environment, and offers long-term cost-savings. Suction-based FMS can be integrated with the healthcare facility’s sewer system to both collect and dispose of fluid waste at the same time. They can be either stationary and hard-plumbed into the sanitary sewer, or portable and placed on a cart that employs a docking station for automated drainage to the sanitary sewer. Some utilize a canister that is disinfected and reused, while others use an integrated canister system that is completely closed, lowering ongoing supply costs for disposables as well. In addition, most require disposable elements, such as manifolds, lids, or filters.

Despite an initial capital cost for equipment, ranging from approximately \$20,000 to \$25,000 for each system, the use of a vacuum system that empties directly into the sanitary sewer has been found to help a facility cut its infectious waste volumes, and save money on labor, disposal, and canister purchase costs. In a typical hospital, an estimated \$75,000 could be saved annually in suction canister purchase, management, and disposal costs if a canister-free vacuum system was installed (Source: The University of Minnesota’s Technical Assistance Program).

SKYLINE’S STREAMWAY SYSTEM

The Company’s STREAMWAY System, depicted in Figure 16, is a wall-mounted, automated, FDA-cleared medical fluid waste disposal system that virtually eliminates staff exposure to blood, irrigation fluid, and other potentially infectious fluids found in the healthcare environment. To the Company’s knowledge, the STREAMWAY System is the only known fully automated direct-to-drain FMS system that is wall-mounted and designed to collect, measure, and dispose of surgical waste.

Figure 16
STREAMWAY® SYSTEM FEATURES



Source: Precision Therapeutics Inc.

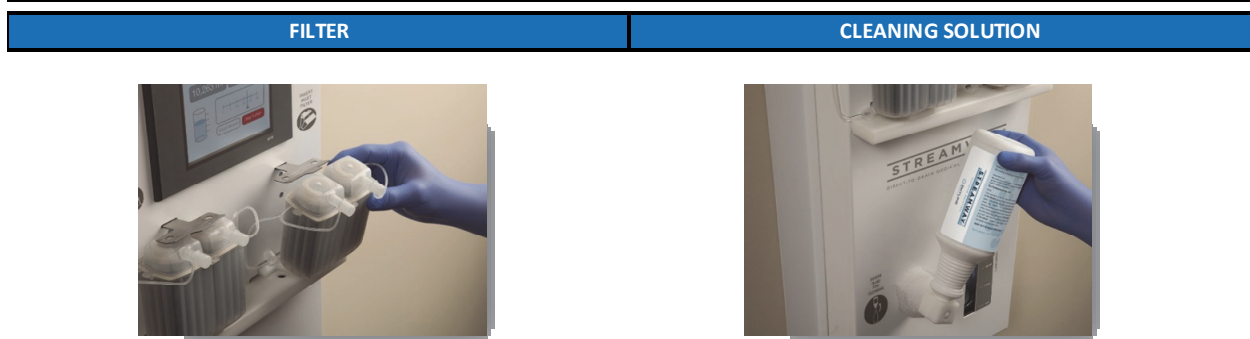
The STREAMWAY System suctions surgical waste fluid from the patient using standard surgical tubing. The waste fluid passes through the Company’s proprietary disposable filters and into the STREAMWAY device. The STREAMWAY System constantly updates and displays the fluid volume removed during the procedure, allowing the surgical team to assess the total amount of fluid removed from the patient at any point during the procedure. The waste fluid then gets disposed directly from the machine to the sanitary sewer through the plumbing of the hospital, significantly reducing the risk of healthcare worker exposure to these infectious fluids.

A simple, easy to use human interface display screen guides the user through the set-up process, ensuring that a safe vacuum level is identified and set by the user for each procedure, and additionally guides the user through the cleaning process post-procedure. The system is intended to replace the manual process of collecting fluids in canisters and transporting and dumping them in sinks outside the OR, which is still being used by many hospitals and surgical centers. The manual process, involving canisters, requires that the OR personnel open the canisters that contain waste fluid (often several liters) at the end of the surgical procedure and either add a solidifying agent or empty the canisters in the hospital drain system. Some facilities require that used canisters be cleaned by staff and reused. It is during these procedures that there is increased potential for contact with the waste fluid through splashing or spills. The STREAMWAY System eliminates the use of canisters and their cleaning and disposal steps by collecting the waste fluid in the internal collection chamber and automatically disposing of the fluid with no handling by personnel.

STREAMWAY Disposable Offerings

The Company also manufactures and sells two disposable products required for the STREAMWAY System’s operation: (1) a bifurcated dual port procedure filter with tissue trap (Figure 17, left), and (2) a bottle of cleaning solution (Figure 17, right)—both of which are used on a single procedure basis.

Figure 17
DISPOSABLE PRODUCTS



Source: Precision Therapeutics Inc.

Each procedure requires the use of a disposable filter that is designed specifically for use only on the STREAMWAY System. The filter is used only once per procedure followed by immediate disposal. In addition, at the end of each procedure, a proprietary pre-measured amount of cleaning solution in a plastic bottle is attached to the STREAMWAY System and an automatic cleaning cycle takes place, making the device ready for the next procedure. The cleaning solution bottle and its contents are used to clean the internal fluid pathway of the device, to which the medical personnel have no exposure. During the cleaning cycle, the solution is pulled from the bottle into the device, and then disposed of in the same manner as the waste fluid from the medical procedure. At the end of the cleaning cycle, the bottle is discarded and is 100% recyclable.

Skyline Medical’s disposables are a critical component of the Company’s business model, providing it with a profitable Razor/Razorblade type business model. The disposables provide an ongoing revenue stream for every unit installed, with the Company expecting revenues from the sale of the disposables to be significantly higher over time than the revenues from the sale of the unit. The Company estimates annual revenues from its disposables to be \$24,000 per unit (assuming 1,000 procedures per year), at gross profit margins of 80%.

Skyline has exclusive distribution rights to the disposable solution and filters, and ties the disposables usage to the product warranty.

STREAMWAY Features

Skyline Medical believes that the STREAMWAY System is unique to the industry in that it allows continuous suction to the procedural field and provides unlimited capacity, eliminating the need to interrupt a procedure to change canisters. In addition, the system can be put into operation without significant changes to established operative procedures, a benefit the Company believes helps in market adoption, as it eliminates a key obstacle that prevents physicians and medical establishments from adopting innovative technologies. The system is fully-automated, does not require transport to and from the procedure room, and eliminates the use of canisters that require emptying. The STREAMWAY System is positioned to penetrate its market segment due to its virtually hands-free operation, simple design, ease of use, continuous suction, continuous flow, unlimited capacity, and efficiency in removal of infectious waste with minimal exposure of healthcare personnel to potentially infectious material.

A summary of the key features of the STREAMWAY System include:

- *Minimal human interaction.* The wall-mounted system provides an internal reservoir that keeps surgical waste isolated from medical personnel and disposes the medical waste directly into the hospital sanitary sewer with minimal medical personnel interaction. This is facilitated by the automated cleaning procedures and the electronic controls, allowing for single touch operation of the device.
- *Ease of use.* The system easily connects to the existing suction tubing from the operative field (causing no change to the current operative procedures). Pressing the start button on the STREAMWAY System touch screen enacts step-by-step instructions with safety questions ensuring that the clinician is aware of the amount of suction that will be generated, minimizing the learning curve for operation.
- *Fluid measurement.* The STREAMWAY System volume measurement allows for in-process, accurate measurement of blood/saline suctioned during the operative procedure and eliminates much of the estimation of fluid loss currently practiced in the procedure room. This is particularly important in minimally invasive surgical procedures, where accounting for all fluids, including saline added for the procedure, is vital to the operation. The physician and nursing team can also view in real time the color of the extracted or evacuated fluid through the viewing window on the system.
- *Automated cleaning procedure.* The system performs an automated cleaning cycle at the conclusion of each procedure and prepares the STREAMWAY System for the next use, reducing procedure room turnover time. The cleaning solution bottle easily attaches to the STREAMWAY System by inserting the bottle into the mount located on the front of the unit, and facilitates the cleaning of the internal tubing, pathways, and chambers within the system. The automated cleaning process takes less than five minutes and requires minimal staff intervention.
- *Procedure filters.* One or two filters, depending on the type of procedure, are used for every surgical procedure. The filter is a two port, bifurcated, disposable filter that contains check valves and a tissue trap that allows staff to capture a tissue sample and send to pathology if needed. The filters are disposed of after each procedure.
- *Competitive pricing.* The list sales price to a hospital or surgery center is \$24,900 per system (one per procedure room) and \$16.00 per bifurcated filter and \$8.00 per bottle of cleaning solution for the proprietary disposables sold to the U.S. hospital market.

STREAMWAY Benefits

Skyline Medical's STREAMWAY System, the only closed direct-to-drain fluid waste management system with continuous suction, fully automates the collection, measurement, and disposal of waste fluids. The Company believes that its System provides substantial benefits in three key areas: (1) increased safety; (2) reduced cost; and (3) improved efficiency.

Safety

The STREAMWAY System is designed to replace the antiquated manual fluid handling methods that require hand carrying and emptying of fluid-filled canisters, significantly reducing the risk of healthcare worker exposure to these infectious fluids. The use of canisters requires procedure room personnel to open the canisters at the end of the surgical procedure and either add a solidifying agent or empty the canisters in the hospital drain system, creating a safety risk. The STREAMWAY System's internal surgical waste reservoir is isolated from medical personnel and disposes the medical waste directly into the hospital sanitary sewer, with no direct handling of the waste by healthcare workers. Furthermore, its automated cleaning feature creates another layer of safety, as the cleaning and preparation of the machine for the next procedure requires minimal medical personnel interaction.

In addition, the STREAMWAY System provides operational benefits over the competition. Other fluid waste management systems use portable configurations composed of canisters positioned on the floor or on rolling containers (shown in Figure 18). These systems take up floor space in the OR and require that the waste fluids be transported out of the OR and disposed of, increasing the risk of exposure. The Company's wall-mounted system does not take up any OR floor space and it does not require the use of any external canisters or handling by the medical personnel.

Figure 18
OPERATION ROOM FLOOR SPACE



Source: Precision Therapeutics Inc.

Operating Cost

Skyline Medical believes its products carry substantial cost savings, in terms of overhead and labor, as well as practically eliminating the costs associated with spills and healthcare workers' exposure that may occur due to manual handling of the medical waste. The System significantly reduces the labor costs associated with the disposal of fluids or the handling of contaminated canisters, as the fluid waste is automatically emptied into the sanitary sewer after measurements are obtained. In addition, in cases where healthcare organizations re-use canisters, the STREAMWAY system eliminates the need for cleaning the canisters for re-use. On an on-going basis, the System utilizes the same suction tubing currently being used in the procedure room, so no additional cost is incurred. The costs associated with each procedure also decreases, as the costs of the cleaning solution and filters needed for each procedure is less than the current procedural costs, which may include the cost of canisters, labor to transport the canisters, solidifying powder, gloves, gowns, mops, goggles, shipping, and transportation. Figure 19 (page 41) provides a cost comparison estimate between the STREAMWAY System and the use of canisters.

Figure 19
STREAMWAY® COST COMPARISON

Cost Per OR/Per Year	Canister Solidifier	Canister Pouring	STREAMWAY Year 1	STREAMWAY Year 2-7
Canisters and Lids	\$8,000	\$8,000	\$0	\$0
Solidifier	\$12,000	\$0	\$0	\$0
Streamway System	\$0	\$0	\$24,900	\$0
Biohazard disposal costs	\$12,800	\$1,600	\$0	\$0
Processing Labor	\$17,500	\$12,500	\$2,500	\$2,500
Processing Consumables	\$5,000	\$5,000	\$0	\$0
Spill Costs	\$10,000	\$30,000	\$0	\$0
Filter / Cleaning Solution	\$0	\$0	\$30,000	\$30,000
Total Year 1	\$65,300	\$57,100	\$57,400	\$32,500
Total Years 2-7	\$391,800	\$342,600	\$195,000	\$195,000

Source: Precision Therapeutics Inc.

Efficiency

In addition to eliminating the manual process of medical fluid waste and canister disposal, the STREAMWAY System saves medical personnel time before, during, and after the surgical procedure. The use of the System eliminates the need for a suction canister set-up, and the initiation of the process involves attaching the suction tube to the ports of the disposable filter on the STREAMWAY System and following step-by-step instruction. The System also eliminates the need for healthcare workers to swap out full canisters during the procedure. Finally, post-operative clean-up requires approximately five minutes, the time required to dispose of the suction tubing and disposable filter, calculate the patient's blood loss (eliminating the need for interpretation of an analog read out for calculating fluid loss), and perform the cleaning cycle. Figure 20 lists the key efficiency benefits of the STREAMWAY System as it relates to both physicians and staff in the OR.

Figure 20
OPERATION ROOM EFFICIENCY

PHYSICIANS	OR STAFF
No interruption in surgery – continuous suction and fluid disposal <ul style="list-style-type: none"> • Shorter procedure time • Better for the patient • Maximizes surgeon efficiency Filter includes built-in tissue trap Frees valuable floor space	No management of fluid canisters Nurses focus more on the patient Reduces exposure to potentially infectious fluids Rapid room turnover

Source: Precision Therapeutics Inc.

STRATEGY FOR THE STREAMWAY BUSINESS

The STREAMWAY System is FDA cleared in the U.S., has a medical device established license to sell in Canada, possesses a CE mark allowing sales in Europe, and is regulatory approved in Australia and New Zealand for sales. The Company believes that the STREAMWAY System is positioned to expand its market participation due to its virtually hands-free operation, simple design, ease of use, continuous suction and flow, unlimited capacity, and efficiency in removing infectious waste with minimal exposure by procedure room personnel to potentially infectious material. Skyline Medical's strategy is focused on expanding within its core product and market segments, while utilizing a progressive approach to manufacture and market to ensure maximum flexibility and profitability.

From a product standpoint, the Company intends to develop a complete line of wall-mounted fluid evacuation systems for use in hospital procedure rooms, radiological rooms, and free-standing surgery centers, as well as clinics and physicians' offices. The marketing plan is to emphasize infection control and prevention, in particular for radiology suites, where procedures are typically more expensive due to the cost and low supply of glass evac bottles, and for safety as procedures require handling numerous cannisters or evac bottles with significant amounts of waste fluid. Additionally, the Company expects to maximize profits through their innovative warranty program that is contingent on the exclusive use of the Company's disposables to enhance the success of the after-market disposable products, and with its service contracts establishing an additional revenue stream.

Marketing and Sales

The focus of Skyline Medical's marketing efforts is to introduce the STREAMWAY System as a standalone device capable of achieving three key benefits: (1) effectively removing infectious waste and disposing of it automatically; (2) providing accurate measurement of the fluids removed; and (3) limiting exposure of the surgical team and healthcare support staff to bloodborne pathogens.

The STREAMWAY System is sold to end-users through a combination of direct sales personnel, independent distributors, and distribution companies. In addition, the Company plans to continue to utilize OR consultants, builders, and architects as referrals to hospitals and day surgery centers, as well as partnering with leading Group Purchasing Organizations (GPOs) to gain access to the hospital systems.

Direct Sales Force

The Company has one vice president of sales, one vice president of international sales, one in-house sales person, and five regional sales managers on staff as of March 2018. In 2017, the Company implemented a refocused sales and marketing campaign, which included the hiring of key sales personnel, increased participation at major industry conferences, and an awareness campaign to encourage its customers to use its disposable products, which are an important source of recurring revenues to the Company. These efforts resulted in an acceleration of STREAMWAY System sales in the fourth quarter 2017, with that increase continuing into 2018. As a result, in the first three months of 2018, the Company sold 16 STREAMWAY Systems (10 systems in March 2018 alone), compared with the 10 units sold throughout all of 2017. Four of the 16 unit sales were incremental sales to a prominent Minnesota-based hospital system. Generating additional unit sales to existing customers is not only a faster method of securing sales, it also validates the Company's market positioning as a credible and industry-leading provider of medical waste management solutions. The Company has stated that it expects to sell a projected 100 STREAMWAY Systems in 2018.

Distribution

The Company has three independent distributors in the U.S., Canada, and Europe. In the U.S., the Company has hired three independent contractors in addition to partnering with two Group Purchasing Organizations (GPO), Vizient and Intalere, providing customer exposure to more than 10,000 hospitals. The Company has also contracted with Alliant Enterprises, LLC, a Service Disabled Veterans Owned Small Business (SDVOSB) supplier to the Federal government, to distribute to the Veterans Administration, Department of Defense (DoD), and other government contractors.

International Distribution

Skyline is expanding its international presence through independent distribution agreements and the recent hiring of key personnel to support the growth of its business. In the first quarter of 2018, the Company hired a new international vice president of sales and marketing, who is incorporating Skyline Medical Europe with an office in Belgium. In addition, the Company has hired a sales representative to directly handle Germany. Skyline Medical Europe is a wholly-owned subsidiary of Skyline Medical.

In addition to its direct sales efforts, Skyline has executed contracts with three international distributors. (1) Quadromed, a Canadian distributor; (2) MediBridge Sarl, a Swiss distributor representing the Company in Switzerland; and (3) Device Technologies Australia PTY LTD, is an Australian distributor whose territories include Australia, New Zealand, Fiji, and the Pacific Islands.

The Company supports its sales organization by attending major scientific meetings where large numbers of potential users are in attendance, including meetings and conferences from the Ambulatory Surgery Center Association, the Association for Professionals in Infection Control and Epidemiology, and the Association of Hospital Radiology Administrators. The communication theme for trade show focusses on the awareness of the hazards of exposure to infectious waste fluids, educating medical staff regarding the risks of contamination using current waste collection procedures, and the Company's innovative solution to the problem.

Pricing

The Company believe prices for the STREAMWAY System and its disposables reflect a substantial cost savings to hospitals compared to their long-term procedure costs. Skyline Medical's pricing strategy is designed to ensure that the customer realizes actual cost savings when using the System versus replacing traditional canisters, considering the actual costs of the canisters and associated costs, such as biohazard processing labor and added costs of biohazard waste disposal.

The STREAMWAY System lists for \$24,900 per system (one per procedure room) and \$24.00 per unit retail for the proprietary disposables: one filter and one bottle of cleaning solution. By comparison, the disposal system of Stryker Instruments, a market leader in fluid waste management system sector, retails for approximately \$25,000 plus an \$11,000 docking station, and requires a disposable component with an approximate cost of \$25.00 to \$50.00 per procedure. In addition, the Company has in place a leasing program and/or "pay per use" program as alternatives to purchasing.

Engineering and Manufacturing

The Company plans to capitalize on the manufacturing experience of its management team to develop multiple manufacturing and supply sources that can provide high quality at reduced costs. The Company currently conducts its manufacturing operations in-house within a facility that provides the capability to manufacture, test, house, and ship directly from its warehouse. In addition, as the Company prepares for additional demand of its products from its sales activities, it has contracted a manufacturing company, Wair Products (Bloomington, Minnesota), that can produce six times the current in-house production capabilities. The disposables, including a bottle of proprietary cleaning solution and a 2-port disposable filter, is sourced through Diversified Manufacturing Corporation (cleaning solution) in Prescott, Wisconsin and MPP Corporation (filters), in Osceola, Wisconsin. Installation is conducted by distributors, independent contractors, manufacturer's representatives, hospital supply companies, or in-house engineering installation.

Investment Highlights

- Precision Therapeutics Inc. is a healthcare company that provides personalized medicine solutions and medical devices in two main areas: (1) precision medicine, which aims to apply artificial intelligence (AI) to personalized medicine and drug discovery; and (2) Skyline Medical, which markets the FDA-cleared STREAMWAY System for automated disposal of medical fluid waste.
- The Company's precision medicine services, designed to use AI and a comprehensive disease database to improve the effectiveness of cancer therapy, were launched with Precision Therapeutics' investment in Helomics Corporation (the Definitive Merger Agreement was signed on June 28, 2018)—a key element in the Company's strategy to diversify its product portfolio beyond the offerings of its Skyline Medical business.
 - The Company's precision oncology services center around Helomics' diagnostic technology—Dynamic Clinical Health Insight Platform or D-CHIP—that combines a database containing the molecular, genomic, and drug response profiles of over 149,000 tumors with an AI-based searchable bioinformatics platform.
 - Helomics' precision oncology services include the following steps: (1) obtain a sample of the patient's tumor and medical history; (2) test and determine the genetic profile of the tumor, establishing the type and strain of cancer; (3) compare the results with its database utilizing the Company's D-CHIP to determine the best therapeutic options for that particular tumor profile; and (4) provide an actionable therapeutic roadmap.
 - The Company intends to add additional strategic partnerships and acquisitions to expand its precision medicine footprint. One example of this is the formation of a wholly-owned subsidiary, TumorGenesis Inc., to develop the next generation patient-derived tumor models for precision cancer therapy.
- Helomics generates revenues through a range of CRO services, which include tumor profiling, biorepository, and clinical and diagnostics tests, and through subscriptions from medical companies that require access to its D-CHIP database and analytics engine to support their internal product development efforts.
- Precision Therapeutics also markets the STREAMWAY System for automated and direct-to-drain medical fluid waste disposal. Sold through its Skyline Medical business, the STREAMWAY System is FDA-cleared in the U.S., has a medical device established license to sell in Canada, possesses a CE mark allowing sales in Europe, and is regulatory approved in Australia and New Zealand for sales. The Company has installed over 100 units in more than 50 facilities in the U.S. To the Company's knowledge, the STREAMWAY System is the only known wall-mounted direct-to-drain system designed to collect, measure, and dispose of surgical fluid waste.
- The STREAMWAY System is a fully automated system that disposes of an unlimited amount of potentially-infectious fluids collected during surgical procedures, virtually eliminating the exposure risk to bloodborne pathogens. The System is intended to replace the manual process of collecting fluids in canisters (which is still being used by many hospitals and surgical centers), resulting in safety, cost, and efficiency benefits.
 - In 2017, the Company implemented a refocused sales and marketing campaign, which included the hiring of key sales personnel and the expansion of its international presence. These efforts resulted in an acceleration of STREAMWAY System sales, with 16 units sold in the first quarter of 2018 compared to 10 units sold throughout all of 2017. The Company has stated that it expects to sell 100 systems in 2018.
- Through the operation of its Skyline Medical and Helomics businesses, Precision Therapeutics has an established revenue stream, while positioning itself for additional revenue sources through the expansion of its precision medicine initiatives.
- At March 31, 2018, the Company had cash, cash equivalents, and marketable securities of \$2.2 million.

Competition

Precision Therapeutics engages in the development of medical technology in two main areas of operation: (1) precision medicine, which involves the development of a healthcare contract research organization (CRO) that aims to apply artificial intelligence (AI) to personalized medicine and drug discovery; and (2) Skyline Medical, which markets the FDA-cleared STREAMWAY System for automated, direct-to-drain medical fluid disposal. As the Company continues to advance the commercialization of its products and services, it may face competition from a wide range of companies in both the precision oncology market and the medical waste market. The following list is not intended to be an exhaustive collection of potential competitors to the Company, but rather, is believed to be representative of the type of competition Precision Therapeutics may encounter as it seeks to further develop and commercialize its product and services.

PRECISION MEDICINE

Helomics' competitive advantage lies in its extensive data repository, its expertise in working with live tumor cells, and its proprietary D-CHIP bioinformatics platform. According to Helomics, its ability to continually grow and conduct genetic and molecular analysis of tumors result in a data bank that provides understanding of each cancer by sub-type and its chemosensitivity to different drugs. The Company achieves this by relying mainly on two proprietary tumor processing and analysis technologies that it believes provide a competitive advantage over other CRO and precision oncology companies: (1) TruTumor, a patient-derived specimen processing and analysis model, which provides the Company with the ability to work with actual live tumor cells (not modified cell lines) and study the unique biology of a patient's tumor; and (2) ChemoFx, a unique, live cell chemosensitivity test and drug response marker platform that allows researchers to test multiple single or combination chemotherapies on a patient's own live cancer cells in the lab, helping to identify treatment choices that are more likely to be effective.

Helomics' experience in growing and analyzing human tumor cells in multiple cancers, including more than a decade of clinical testing tumors' responses to drugs, have resulted in a database consisting of genetic and molecular genomic, and drug response profiles for over 149,000 patient tumors. The D-CHIP platform combines the searchable database with a proprietary AI-powered bioinformatics engine aiming to understand the association between the mutational profile of the patient's tumor and its drug response profile, resulting in the generation of treatment protocols personalized by the specific tumor type on a patient-by-patient basis.

As the Company continues to expand its portfolio of precision medicine services, it might encounter competition from established companies in the medical diagnostic market, such as Laboratory Corporation of America Holdings (LabCorp) and Quest Diagnostics; large cap pharmaceutical companies who are developing precision oncology services through in-house research or partnerships, such as Pfizer Inc., Novartis International AG, and Roche Holdings AG; as well as from other companies developing and offering novel services in the precision medicine and precision oncology market.

Ferrer inCode SL

Ferrer inCode provides biotechnological services to help doctors make clinical decisions for patients in the areas of oncology, cardiovascular nutrition, and pharmacology. It engages in promoting and granting access to personalized medicine through the combination of genetics and molecular diagnosis, prognosis, and prediction-based primarily in genomics, proteomics, metabolomics, and bioinformatics technology. Ferrer inCode's precision oncology services, which aims to detect tumor mutations and implement the appropriate therapeutic strategies, includes CancerType ID®, a genetic test that helps to identify the primary tumor origin following metastasis, as well as various tests and services for patients with breast cancer, including Symphony Blueprint™, which classifies breast cancer into different molecular subtypes, and Symphony TheraPrint™, which identifies potential indicators of prognosis and response to breast cancer treatment. Ferrer inCode operates as a subsidiary of Grupo Ferrer Internacional S.A., an international privately-held pharmaceutical company, with headquarters in Barcelona, Spain, and a presence in more than 90 countries.

Genoptix, Inc.

Genoptix provides hematology and solid tumor molecular profiling and diagnostics services to oncologists and pathologists. Genoptix is one of the largest hematopathology centers in the U.S. and is a leading clinical oncology laboratory specializing in hematology and solid tumors. Genoptix provides personalized and comprehensive diagnostic services to hematologists, oncologists, and pathologists, with a specialization in diagnosing cancers and disorders in bone marrow, blood, and lymph nodes, as well as in molecular testing of solid tumors. The company offer its COMPASS® or CHART® process, a comprehensive, integrated, centrally-managed diagnostic approach that delivers individualized, actionable results for each patient to help the referring physician make the best treatment decisions, as well as individual profiling and molecular diagnostic testing solutions and next-generation sequencing services. Genoptix was acquired by Novartis in 2011, and sold to Genesis Holdings, LLC in 2017. The company is headquartered in Carlsbad, California.

Intomics A/S

Intomics provides contract research services to public and private organizations, specializing in deriving core biological insights from analysis and integration of biomedical big data. The company integrates and analyzes different medical datasets to enable pharmaceutical companies to increase the success rate of drug discovery and development process by using integrative bioinformatics. Intomics offers bioinformatics services, which include genome assembly, gene finding, sequence alignment, and prediction of protein function. Intomics has developed a proprietary protein-protein interaction network, inBio Map™, a database of high-confidence, experimentally derived protein-protein interactions for the understanding of different biological pathways. The company also offers data and text mining tools, such as whole genome sequences and genetic variation information among individuals, including its own text mining tool, inBio Know™, which finds significant pairwise associations among genes/proteins, anatomies (cells and tissues), and diseases in published scientific literature abstracts. Intomics A/S was founded in 2008 and is based in Kongens Lyngby, Denmark.

Menarini-Silicon Biosystems Inc.

Menarini-Silicon Biosystems manufactures and sells the DEPArray™ system, which enables researchers to identify, quantify, and recover individual rare cells with single-cell precision. The DEPArray system is an automated platform that can identify and recover target tumor cells with the resolution and purity required for sensitive downstream genomic and expression analyses. DEPArray technology allows purification of multiple different types of cells to be collected from a single sample. The use of the DEPArray system for oncology is the driving force behind a collaboration with Swift Biosciences Inc. to offer customized NGS products for oncology research and diagnostics. The two new products, DEPArray OncoSeek Panel and DEPArray LibPrep Kit, allow for analysis of tumor and stromal cells isolated with the DEPArray system from minute and low-cellularity specimens, which were previously inaccessible for genetic analysis. The company is based in San Diego, California, and operates as a subsidiary of A. Menarini Industrie Farmaceutiche Riunite Srl.

SKYLINE MEDICAL

As the Company continues to market its STREAMWAY system, it may encounter competition from companies offering the standard canister systems for medical waste disposal, as well as companies offering alternative automated Fluid Waste Management Systems. The STREAMWAY System is a wall-mounted, automated, FDA-cleared waste fluid disposal system designed to completely replace the use of canisters—rendering them unnecessary. The STREAMWAY System eliminates the use of canisters and their cleaning and disposal steps by collecting the waste fluid in the internal collection chamber and automatically disposing of the fluid with no handling by personnel.

A key competitive advantage of the STREAMWAY System is its increased safety. The wall-mounted system provides an internal reservoir that keeps surgical waste isolated from medical personnel and disposes the medical waste directly into the hospital sanitary sewer with minimal medical personnel interaction, virtually eliminating staff exposure to blood, irrigation fluid, and other potentially infectious fluids found in the healthcare environment. Another key advantage is its continuous suction and limitless capacity, which eliminates the need to interrupt procedures for canister changeover. To the Company’s knowledge, the STREAMWAY System is the only known direct-to-drain FMS system that is wall-mounted and designed to collect, measure, and dispose of surgical waste.





In addition to simplifying the handling of medical waste fluids and improving the safety of health workers, the Company believes its technologies provide cost savings to facilities over the traditional methods in terms of overhead and labor costs, as well as practically eliminating the expenses associated with spills and healthcare worker’s exposure that may occur due to manual handling of the medical waste. The System minimizes the exposure potential to healthcare workers who handle such fluids without significant changes to established operative procedures—a major roadblock that prevents physicians and medical establishments from adopting innovative technologies.

The following companies are considered the leading competitors within this market:

- Stryker Instruments has the Neptune™ system, offering a combination of bio-aerosol and fluid management in a portable two-piece system;
- DeRoyal (previously Waterstone Medical) has the Aqua Box™ stationary system for fluid disposal;
- Zimmer Biomet (which acquired Dornoch Medical Systems in 2012) has the IntelliCart System for fluid collection and disposal; and
- MD Technologies, Inc. markets the DM6000, which allows direct disposal of suctioned fluids without operator exposure.

Figure 21 (page 48) highlights the key features of devices currently available as they compare to Precision Therapeutics’ STREAMWAY System. Other fluid waste management systems use portable configuration composed of canisters positioned on the floor or on rolling containers. While the mobility associated with the majority of competing products adds time and labor to the process and increases the chance of worker exposure to waste fluids, it does permit for the hospital to purchase only as many mobile units as needed for simultaneous procedures in multiple ORs. With the Company’s STREAMWAY System, the unit must be purchased and installed in each room where it is intended to be used.

Figure 21
STREAMWAY® SYSTEM COMPETITIVE COMPARISON

Product	Canister free	Continuous suction	Free operating floor space	Disposes directly into sewer	Measures & displays totals	Minimizes exposure of harmful fluids to healthcare personnel	Turnover time
 STREAMWAY® System	✓	✓	✓	✓	✓	✓	Less than 5 minutes
 Stryker	✗	✗	✗	✗	✓	✗	10 min. +
 Zimmer (acquired Dornoch Medical Systems)	✗	✗	✗	✗	✓	✗	10 min. +
 Canister methods	✗	✗	✗	✗	✗	✗	10 min. +

Source: Precision Therapeutics Inc.

Precision Therapeutics' existing competitors have an advantage with regard to brand recognition and market exposure. In addition, the aforementioned companies have extensive marketing and development budgets that are potentially much larger than that of Precision Therapeutics given that the Company is in the development stage. Precision Therapeutics believes that Stryker Instruments has the dominant market share position within this category.

MD Technologies, Inc., Cardinal Health, Inc., Zimmer (previously Dornoch Medical Systems, Inc.), and Stryker Instruments have all developed systems that provide disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using expensive gel powders. Most of these newer products are currently sold with 510(k) concurrence from the FDA. Most of these competing products incorporate an internal collection canister with finite capacity, and while not directly eliminating the need to transport a device to and from the surgical room, most have been successful at eliminating the need for expensive gel and its associated handling and disposal costs. Existing competitors that already have products on the market have a competitive advantage in terms of brand recognition and market exposure. In addition, the aforementioned companies have extensive marketing and development budgets that could overpower an early stage company like Precision Therapeutics.

Precision Therapeutics is unique from its competitors as its technology is completely direct-to-drain with the most automatic, hands-free process of any of the systems available on the market today. The Company's competitors (with the exception of MD Technologies, Inc.) have a fair amount of manual handling involved in the process, where some competing products require transport of the mobile unit to a docking port, which is followed by the emptying of the fluid. Others technologies (except MD Technologies, Inc.) require that the canister be transported by hand to a more efficient dumping station. Zimmer and Stryker Instruments have all developed systems that provide for disposal into the sanitary sewer without pouring the infectious fluids directly through a hopper disposal or using gel powders and most are sold with 510(k) concurrence from the FDA. These competing products continue to utilize some variant of the existing canister technology, and while not directly addressing the canister, most

have been successful at eliminating the need for expensive gel and its associated handling and disposal costs. Nevertheless, most of the Company's competitors involve a substantial amount of human interaction with the fluid.

Descriptions of Precision Therapeutics' primary competitors are provided below.

Stryker Corporation: Neptune 3 Waste Management System

Stryker Corporation, with global headquarters in Kalamazoo, Michigan, is a global medical technology company with products and services in orthopedics, medical and surgical, and neurotechnology and spine. Within the category of waste collection, Stryker's Neptune 3 Waste Management System was developed to help protect against potential OR hazards—specifically from the floor to the air—with its E-SEP Smoke Evacuation Pencil and Floor Fluid Disposables. The product was designed with safeguards, including locking away surgical fluid and smoke. The Neptune 3 has dual canisters to allow for the collection and containment of fluids in either one procedure or multiple procedures, and the 4L canister, which empties into 20L three times before requiring docking, with privacy doors opening and closing to reveal/conceal contents. Two independently controlled canisters deliver up to 8 lines of suction when using a 4-port manifold in each canister. The Neptune 3 has internal rotating power washers to provide added cleaning power; has seamless integration; is backwards compatible with Neptune 2 manifolds, filters and docking stations; and provides electromagnetic couplers to automatically engage to limit physical touch points. As well, it has an 8.4" interactive touch screen navigation with displays and controls to access multiple options and functions.

Issues with Earlier Product Models

Noteworthy with regard to an earlier version of the Neptune product is that in 2012, Stryker's suction system for collecting surgical waste killed one patient and seriously injured another, prompting the company to recall it and several related devices, according to the FDA. The recall covered Stryker Instruments' Neptune 1 Silver and two models of its Neptune 2 Ultra Waste Management Systems. These high-powered, mobile vacuum devices were developed to dispose of surgical fluid waste in ORs and other surgical facilities, as well as to clean the room air of smoke generated from electrocautery and laser surgery. According to Stryker, the patient death and injury reports indicated that the high-flow, high-suction vacuum had been incorrectly applied, and that the instructions for use on the device did not specifically warn against this action. Stryker had issued revised labeling for these and four other models in the Neptune 1 and Neptune 2 lines; however, the FDA determined that the Neptune 1 Silver and Neptune 2 Ultra models also contained modifications that should have been submitted for premarket 510(k) notification, which Stryker did not do.

Despite the violation, the FDA did not require Stryker to remove the Neptune 2 Ultra Waste Management System and the Neptune 1 Silver Waste Management System from the U.S. market because it believed that the removal could create market shortages. In its place, the FDA instructed customers not to use their devices unless they have no other alternative system to collect and dispose of surgical fluid wastes. For these customers, the FDA and Stryker issued a series of detailed instructions and warnings.

Zimmer Biomet (Dornoch Medical Systems acquired by Zimmer Biomet Holdings): IntelliCart™ System

Zimmer Biomet is a global leader in musculoskeletal healthcare with headquarters in Warsaw, Indiana. The Company designs, manufactures, and markets orthopedic reconstructive products; sports medicine, biologics, extremities and trauma products; office based technologies; spine, craniomaxillofacial and thoracic products; dental implants; and related surgical products. Within the area of infectious waste technology, Zimmer Biomet has IntelliCart System, which was developed to make managing surgical fluid and smoke waste hazards simple and convenient. The IntelliCart System has 34-liter fluid capacity, extra quiet vacuum pump, clog-free suction manifolds, and portable smoke evacuation. It further has a redesigned vacuum pump with greater usable vacuum flow at a sound level of 47.5dB (3.87 sones); dual 17-liter lighted reservoirs with ConSeal™ Tint Technology to selectively hide surgical fluids; and a clog-free manifold with integrated high-flow filter to protect against vacuum system moisture ingress. The product has an interactive, high-definition touch screen display; flexible docking system; and PlumeVac™ Smoke Evacuator available on or off the cart. Furthermore, the product's reservoir doors

close when manifolds are removed; it has reusable reservoirs and recyclable manifolds, which reduce OR red bag waste by up to 70%; has advanced cleaning technology that uses hot water, enzymatic, and an EPA approved disinfectant; and is backward compatible with the Ultraflex Fluid Cart Manifolds and Ultra Evac Station.

MD Technologies, Inc.: Environ-mate® Suction-Drain™ Systems

MD Technologies, Inc. of Galena, Illinois markets the wall-mounted Environ-mate® Suction-Drain™ Systems, which provides silent disposal of suctioned fluids directly from suction field to a sanitary sewer, protecting healthcare workers from exposure to fluids. With the elimination of disposable supplies, the Company’s DM6000 systems has saved millions of dollars, with further savings coming from eliminating actual disposal costs. In early 2010, MD Technologies acquired Promethean® Medical and the Island® line. The Island® uses suction to capture fluids before they reach the floor, supporting Orthopedics, Cysto/Urology, Ob-Gyn, and General Surgery. The 4400 anti-fatigue mat is the most popular of five models. MD Technologies further markets the PT20® Trap, a polyp trap for Endoscopy that is a removable, fine-mesh screen to permit capture of even the smallest (sessile) polyps. The PT20®C with connector retrieves shavings in arthroscopy.

A summary of the key features of each of these technologies is provided in Figure 22

Figure 22
KEY FEATURE COMPARISON

Feature	Skyline Medical	Stryker Instruments	DeRoyal	Dornoch Medical Systems (Zimmer)	MD Technologies
Portable to Bedside vs. Fixed Installation	Fixed	Portable	Fixed	Portable	Fixed
Uses Canisters	No	Yes	Yes	Yes	No
Secondary Installed Device Required for Fluid Disposal	No	Yes	Yes	Yes	No
Numeric Fluid Volume Measurement	Yes	Yes	No	Yes	Optional
Unlimited Fluid Capacity	Yes	No	No	No	Yes
Continuous, Uninterrupted Vacuum	Yes	No	No	No	No
Installation Requirements					
Water	No	Yes	Yes	Yes	No
Sewer	Yes	Yes	Yes	Yes	Yes
Vacuum	Yes	No	No	No	Yes

Source: Precision Therapeutics Inc.

Recent Events

06/28/2018—Announced that it has signed a definitive merger agreement with Helomics Holding Corporation. Upon completion of the merger, Precision will increase its equity stake in Helomics from 25% to 100%. This merger will provide Precision Therapeutics with full access to Helomics' suite of Artificial Intelligence (AI), precision diagnostic, and integrated CRO capabilities, which improve patient care and advances the development of innovative clinical products and technologies for the treatment of cancers.

05/31/2018—Announced that it has launched a new website: www.precisiontherapeutics.com. This new site offers quick and easy access to essential information and features while offering a more comprehensive understanding of the Company's value proposition and strategic direction in the precision medicine industry.

05/15/2018—Announced financial results for the three months ended March 31, 2018 and provided a business update.

05/10/2018—Announced that it expects to secure its first European sales of the STREAMWAY Systems in the second half of 2018. Based on the interest generated to date, and the stage of negotiations with several potential customers, the Company expects these sales to generate meaningful revenues.

04/23/2018—Announced that it has signed an LOI to acquire the remainder of the equity in Helomics not currently owned by Precision Therapeutics. Under the terms of the agreement, a newly formed, wholly owned subsidiary of Precision Therapeutics will merge with and into Helomics, thereby increasing the Company's equity stake in Helomics from 25% to 100%. A definitive merger agreement is expected to be signed by June 15, 2018, subject to confirmatory due diligence and with closing subject to certain closing conditions, including, among others, approval of the transaction by the boards of directors and stockholders of Precision Therapeutics and Helomics.

04/09/2018—Announced that it has engaged Richard Gabriel as a consultant to lead the external business development strategy for TumorGenesis, Inc., its wholly-owned subsidiary. In this role, Richard will work closely with TumorGenesis' newly appointed President, Dr. Mark Collins. Richard Gabriel, BS, MBA, is an experienced consultant to early stage healthcare companies and has been a board member of Precision Therapeutics since 2016. Mr. Gabriel will continue to serve as a board member for Precision Therapeutics in addition to providing consulting services to TumorGenesis. Mr. Gabriel has spearheaded TumorGenesis' licensing of new technologies from 48 Hour Discovery, SyntArray, and CellBridge for 3-D cell culturing. Together, these ground-breaking technologies are expected to advance the development of the next generation of patient-derived tumor models for precision cancer therapy and drug development, with an initial focus on ovarian cancer.

04/04/2018—Released highlights from its business update call for the three and twelve months ended December 31, 2017. During the earnings call, members of Precision Therapeutics' management team discussed the Company's recent progress executing against its new growth strategy in the precision medicine market. The call also featured commentary from Kevin Hungerford, the Company's new Global VP of Sales and Marketing, who discussed the factors behind the significant sales growth projected by the Company's Skyline Medical division.

04/02/2018—Announced financial results for the three and twelve months ended December 31, 2017 and provided a business update on its plans to transition its strategic focus to precision medicine and the Contract Research Organization (CRO) services sector.

03/29/2018—Provided a sales update from its Skyline Medical division, producer of the FDA-cleared STREAMWAY System for automated, direct-to-drain medical fluid disposal. Skyline Medical sold 16 STREAMWAY Systems in the first quarter of 2018, to a combination of both new customers as well as its existing customer base. This represented significant growth compared with the five STREAMWAY Systems sold in the fourth quarter of 2017 and the three STREAMWAY Systems sold in the first quarter of 2017. This ramp in sales is due to the Company's refocused sales and marketing campaign, which included the hiring of key sales personnel, increased participation at major industry conferences and an awareness campaign related to its disposable products.

03/26/2018—Announced that management will report its financial results for the fiscal year 2017 on April 2, 2018 after U.S. markets close.

03/21/2018—Announced that its wholly-owned subsidiary, TumorGenesis Inc., has secured a license agreement with CellBridge Incorporated, which grants it access to CellBridge’s 3D biomimetic support technology. This follows the Company’s recently announced license agreements with SyntArray, LLC and 48Hour Discovery and is the latest milestone in the Company’s strategy to bring together ground-breaking technologies to develop the next generation of patient derived (PDX) tumor models for precision cancer therapy and drug development.

03/15/2018—Announced that its wholly owned subsidiary, TumorGenesis Inc., has secured a license agreement with 48Hour Discovery (48HD), which grants it access to 48HD’s ligand discovery technology. This follows a license agreement with SyntArray, LLC, announced on March 13th and is the latest milestone in the Company’s strategy to bring together ground-breaking technologies to develop the next generation of patient derived (PDX) tumor models for precision cancer therapy and drug development.

03/14/2018—Announced that it has converted a previous \$500,000 loan to Helomics into a 5% equity stake. This follows the purchase of preferred stock convertible into 20% of the outstanding common stock of Helomics® Corporation in January 2018, bringing the Company’s total ownership of Helomics to 25%.

03/13/2018—Announced that its wholly owned subsidiary, TumorGenesis Inc., has secured a license agreement with SyntArray LLC. This license agreement will advance the Company’s strategic plan to develop the next generation of patient derived (PDX) tumor models for precision cancer therapy and drug development by granting it access to SyntArray’s targeted peptide cell capture technology.

03/12/2018—Announced that it has appointed Kevin Hungerford as Global Vice President of Sales and Marketing. Based in the U.S., Mr. Hungerford will be responsible for overseeing all sales and marketing activities for the Company’s FDA-cleared STREAMWAY System for automated, direct-to-drain medical fluid disposal to hospitals and medical centers. He will report to Dr. Carl Schwartz, Chief Executive Officer, and replaces Mr. Peter Alex, who is stepping down to pursue other opportunities.

02/27/2018—Announced that it has formed a wholly owned subsidiary, TumorGenesis Inc., to develop the next generation of patient derived (PDX) tumor models for precision cancer therapy and drug development. The Company formed TumorGenesis Inc. to develop a new, rapid approach to growing tumors in the laboratory, which essentially “fools” the cancer cells into thinking they are still growing inside the patient. This approach is expected to provide a much more relevant model of the patient tumor that may be used for testing drugs for personalized therapy or for the development of new drugs. Testing of the TumorGenesis PDX tumors will take place in collaboration with Helomics, in which Precision has a 20% equity stake. The Company is currently in negotiations with several medical technology companies to license their technology to advance TumorGenesis’s strategic plan and expects to announce these potential agreements in the near future.

02/02/2018—Announced that its NASDAQ Capital Market ticker symbol will change from ‘SKLN’ to ‘AIPT’ effective February 2, 2018. The new symbol has been chosen to align the Company’s symbol with its new name, Precision Therapeutics, which better reflects the Company’s new strategic focus on applying artificial intelligence to precision medicine and drug discovery.

01/31/2018—Announced that it currently projects sales of approximately 100 STREAMWAY Systems in 2018. This projection is based on ongoing negotiations with U.S.-based hospital chains and medical clinics, as well as recent sales patterns. Sales projections for 2018 are based on a combination of both projected sales to its existing customer base as well as sales to new clients. These 2018 sales projections, which do not include potential sales in Europe and Asia Pacific, if realized, would represent a tenfold increase over the Company’s 2017 sales figures.

01/26/2018—Announced that it has opened new European headquarters in Belgium and appointed Jean-Paul Rasschaert as Vice President of International Sales to drive international sales for the STREAMWAY System. Based in Brussels, Mr. Rasschaert will be responsible for overseeing sales of the Company’s FDA-cleared STREAMWAY System for automated, direct-to-drain medical fluid disposal to hospitals and medical centers across Europe.

01/25/2018—Announced it will change its name to Precision Therapeutics Inc., effective February 1, 2018. The new name has been chosen to better reflect the Company’s new strategic focus on applying artificial intelligence to precision medicine and drug discovery and marks a new chapter of the Company’s growth. In addition to the new corporate name, the Company will change its ticker symbol on NASDAQ to ‘AIPT’.

01/16/2018—Announced it has completed the purchase of preferred stock convertible into 20% of the outstanding common stock of Helomics in exchange for total consideration of 1.1 million shares of newly issued Skyline Medical common stock. In addition, Skyline has the right to convert a previous \$500,000 loan to Helomics into a further 5% equity stake, which would bring its total ownership to 25%.

01/11/2018—Announced that it received a letter from the Listing Qualifications Department of the NASDAQ Capital Market notifying the Company that it has regained compliance with the Nasdaq Listing Rule requiring companies to maintain a minimum of \$2,500,000 in stockholders’ equity for continued listing as of January 10, 2018. As previously disclosed, on November 21, 2017, the Company received a notice from NASDAQ stating that the Company was not in compliance with Nasdaq Listing Rule 5550(b)(1) because the Company did not have a minimum stockholders’ equity, as of September 30, 2017, of \$2.5 million and the Company did not alternatively meet the market capitalization or income from continuing operations tests.

01/10/2018—Helomics announced the addition of Marc Malandro PhD, CLP, RTTP, currently Vice President of Operations for Science at the Chan Zuckerberg Initiative, to its Advisory Board. The addition of Dr. Malandro provides significant scientific and business expertise to Helomics as well as Helomics’ recently announced joint venture with Precision Therapeutics to build-out and commercialize the Helomics D-CHIP platform.

01/05/2018—Announced the pricing of a firm commitment underwritten public offering of 2,900,000 Units at an offering price of \$0.95 per Unit, with each Unit consisting of one share of the Company’s Common Stock and 0.3 of a Series E Warrant, with each whole Series E Warrant purchasing one share of the Company’s common stock at an exercise price of \$1.00 per whole share. To the extent that the purchase of Units would cause the beneficial ownership of a purchaser in the offering, together with its affiliates and certain related parties, to exceed 4.99% of the Company’s outstanding Common Stock, a number of shares of the Company’s Series D Preferred Stock (Preferred Stock), which is initially convertible on a 1-for-1 basis into Common Stock, will be issued in lieu of shares of Common Stock. The shares of Common Stock, Preferred Stock, and Series E Warrants are immediately separable and will be issued separately. Dawson James Securities, Inc. is acting as the sole underwriter for the offering.

01/03/2018—Announced an update on commercial activities for its FDA-cleared STREAMWAY System for automated, direct-to-drain medical fluid disposal. The Company sold ten STREAMWAY Systems in 2017, five of which were sold in the fourth fiscal quarter of 2017. A further six STREAMWAY units have been booked for sale in January 2018, and will be shipped to customers during the month.

12/20/2017—Helomics Corporation and Ariel Precision Medicine, Inc. (Ariel), an integrated genomics and digital health company enabling early treatment and targeted management of complex chronic diseases, announced that they have signed a service agreement to support the further commercial application of Ariel’s proprietary, clinically integrated genomic assay, PancreasDx®. This agreement solidifies the shared vision of making the Pittsburgh region a leader in Precision Medicine, as Helomics and ARIEL explore opportunities to work together in research and clinical applications, to establish a Next-Generation Sequencing (NGS) “hub” and provide products and services to life-sciences organizations within the region and beyond.

12/20/2017—Announced that it is expanding into Next Generation Sequencing (NGS) through the licensing of an NGS platform MiSeqDx, from Illumina. The MiSeqDx NGS platform will allow gene sequencing of tumor specimens from cancer patients which will provide rich genomic data for the D-CHIP AI-based bioinformatics platform being built out as part of the Skyline-Helomics joint venture. The D-CHIP platform then identifies the correlations between the patient demographic data, the tumor gene sequence (obtained by NGS), and the drug responses of the individual patient’s tumor. Pharma partners who subscribe to the D-CHIP service can mine the knowledgebase of tumor mutations and drug response to design the next generation of cancer treatments.

12/19/2017—Announced it has agreed to purchase an equity stake in Helomics, a precision diagnostic company and integrated clinical contract research organization. Under the terms of the agreement, Skyline Medical is purchasing preferred stock convertible into 20% of the outstanding common stock of Helomics, representing 20% of the company, in exchange for total consideration of 1.1 million shares of newly issued Skyline common stock. In addition, Skyline has the right to convert a previous \$500,000 loan to Helomics into a further 5% equity stake, bringing its total ownership to 25%. The completion of the purchase is subject to listing of the shares on NASDAQ.

12/07/2017—Issued a press release with a letter to shareholders.

11/30/2017—Dawson James Securities, Inc., in conjunction with Skyline Medical Inc., closed a private placement of a newly created series of preferred stock designated as “Series C Convertible Preferred Stock” with a New York-based Family Office. The closing of the private placement occurred on November 28, 2017. Pursuant to the Securities Purchase Agreement, the Investor purchased 1,213,819 shares of Series C Stock at a purchase price of \$1.071 per Series C Share, together with a warrant to purchase up to 606,910 shares of common stock. The Warrant has an exercise price of \$1.26 per share, subject to adjustment, has a five and one-half year term and is exercisable commencing six months following the date of issuance.

11/28/2017—GLG Pharma, a Jupiter, Florida company developing precision medicines that target the Signal Transducer and Activator of Transcription factor 3 (p-STAT3 and STAT3) pathway, Precision Therapeutics, and Helomics Corporation jointly announced a strategic partnership among these three companies, focused on using their combined technologies to bring personalized medicines and testing to ovarian and breast cancer patients, especially those who present with ascites fluid (over one-third of patients). The partnership brings GLG’s new Cell Capture, Culture, and Screening system to help isolate samples of ascites fluids from patients that may contain cancer stem cells, cancer cells, and other cells together with the previously announced Skyline-Helomics venture being developed to utilize the STREAMWAY System for automated, direct-to-drain medical fluid disposal, in combination with the Helomics ChemoFx diagnostic platform to target patient drug treatment, quickly and cost effectively.

11/15/2017—Skyline Medical Inc. announced that it has signed a term sheet with Helomics Corporation to leverage its Helomics D-CHIP platform to develop and market new approaches for personalized cancer diagnosis and care. The joint venture follows a strategic collaboration between Helomics and Skyline announced on November 1, 2017 and represents a deeper partnership between the two companies that is expected to provide Skyline with opportunities to generate revenues from additional markets. Skyline Medical will own 51% of the joint venture, with Helomics owning the remaining 49%. The day to day operations of the Joint Venture will be managed by Helomics subject to the direction and oversight of the Joint Venture’s Board of Directors.

11/14/2017—Skyline Medical Inc. reported financial results for the three and nine months ended September 30, 2017 and provided a business update on its plans to diversify its revenue streams to include precision medicine and the Contract Research Organization (CRO) services sector.

11/13/2017—Uptick Newswire’s “Stock Day” announced that it has interviewed Gerald Vardzel, CEO of Helomics Corp., the planned joint venture partner of Skyline Medical. Starting off the interview, Mr. Vardzel discussed the company’s new key reconstruction and the three strategic pillars making Helomics profitable in discovery and development. Continuing the interview, he touched on the overall value and variation of Helomics’ CRO Services for clinical research organizations. Furthermore, Mr. Vardzel elaborated on the impact and differentiation that Helomics has for the future of testing live tumors from patients and briefly discussed the potential joint venture with Skyline Medical Inc.

11/10/2017—Skyline Medical Inc. announced that management will hold a conference call on November 15, 2017 to provide a business update and host a discussion on recent and upcoming milestones.

11/09/2017—Announced it has partnered with Device Technologies, an established distributor of quality and technologically-advanced medical equipment, to market the STREAMWAY System in Australia, New Zealand, Fiji and the Pacific Islands. Founded in 1992, Device Technologies employs more than 600 healthcare specialists and support staff in Australia and New Zealand. All the products it distributes are professionally supported by qualified Product Managers and specialists who are trained to work in surgical and operating room environments. It has on staff Clinical Educators to provide accredited training, in-servicing and ongoing clinical support, as well as Technical Service personnel to service and maintain its extensive range of capital equipment.

11/08/2017—Announced two proposed joint ventures with Helomics Corporation and CytoBioscience, which are expected to diversify the Company’s business into the CRO services sector and to provide opportunities for the Company to generate additional revenues.

11/07/2017—Announced it has partnered with two independent distributors to support sales of Skyline’s FDA cleared STREAMWAY System to medical centers in Canada and Switzerland. Securing the extensive sales and marketing capabilities of these distributors is expected to allow Skyline to penetrate the Switzerland market for the first time and expand its presence in Canada.

11/01/2017—Announced a strategic collaboration to use the Helomics D-CHIP platform to develop new approaches for personalized cancer diagnosis and care.

10/12/2017—Announced that management presented at the Dawson James Securities 3rd Annual Small Cap Growth Conference on Thursday, October 19, 2017 at 3:30 p.m.

09/29/2017—Provided an update on progress toward completing its merger with CytoBioscience. The Company has submitted all necessary paperwork to NASDAQ for review, subject to additional financial and due diligence documentation being provided by third parties, which is expected to be submitted in the coming weeks.

09/05/2017—Announced that the Company has entered into an innovative technology partnership with Intalere for the STREAMWAY System. Intalere is a professional supply chain company offering a comprehensive suite of services to empower healthcare providers to better manage their entire spend and ultimately deliver superior care. This contract includes STREAMWAY in Intalere’s Innovation and New Technology category, indicating STREAMWAY demonstrates unique capabilities compared to existing products on contract or available in the market. Preferred pricing for more than 90,000 Intalere members extends to 3,733 acute care hospitals, 3,715 ambulatory surgery centers, and 175 hospital-based physicians.

Historical Financial Results

Figures 23, 24, and 25 provide a summary of Precision Therapeutics' most recently released financial statements.

Figure 23
Precision Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS and OTHER COMPREHENSIVE INCOME
(Unaudited)

	Three Months Ended March 31,	
	2018	2017
Revenue	\$ 411,593	\$ 175,166
Cost of goods sold	117,343	36,992
Gross margin	294,250	138,174
General and administrative expense	1,216,144	1,132,073
Operations expense	287,590	200,494
Sales and marketing expense	550,538	147,454
Total Expense	2,054,272	1,480,021
Net loss attributable to common shareholders	(1,760,022)	(1,341,847)
Comprehensive loss	\$ (1,760,022)	\$ (1,341,847)
Loss per common share - basic and diluted	\$ (0.15)	\$ (0.21)
Weighted average shares used in computation - basic and diluted	11,383,217	6,450,967

Source: Precision Therapeutics Inc.

Figure 24
Precision Therapeutics Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
Current Assets:		
Cash and Cash Equivalents	\$ 2,232,803	\$ 766,189
Certificates of Deposit	—	244,971
Accounts Receivable	241,764	137,499
Notes Receivable	167,512	667,512
Inventories	272,556	265,045
Prepaid Expense and other assets	208,305	289,966
Total Current Assets	<u>3,122,940</u>	<u>2,371,182</u>
Notes Receivable	1,112,524	1,070,000
Investment in Subsidiary	1,542,250	—
Fixed Assets, net	106,009	87,716
Intangibles, net	115,714	95,356
Total Assets	<u>\$ 5,999,437</u>	<u>\$ 3,624,254</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 186,309	\$ 140,462
Accrued Expenses	558,439	785,215
Deferred Revenue	38,856	6,663
Total Liabilities	<u>783,604</u>	<u>932,340</u>
Commitments and Contingencies	—	—
Stockholders' Equity:		
Series B Convertible Preferred Stock, \$.01 par value, 20,000,000 authorized, 79,246 and 79,246 outstanding	792	792
Series C Convertible Preferred Stock, \$.01 par value, 20,000,000 authorized, 0 and 647,819 outstanding	—	6,479
Common Stock, \$.01 par value, 50,000,000 authorized, 11,804,073 and 6,943,283 outstanding	118,040	69,432
Additional paid-in capital	61,622,067	57,380,256
Accumulated Deficit	(56,525,066)	(54,765,045)
Total Stockholders' Equity	<u>5,215,833</u>	<u>2,691,914</u>
Total Liabilities and Stockholders' Equity	<u>\$ 5,999,437</u>	<u>\$ 3,624,254</u>

Source: Precision Therapeutics Inc.

Figure 25
Precision Therapeutics Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2018	2017
Cash flow from operating activities:		
Net loss	\$ (1,760,022)	\$ (1,341,847)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18,167	18,574
Vested stock options and warrants	226,387	587,444
Loss from sale of marketable securities	—	(1,837)
Changes in assets and liabilities:		
Accounts receivable	(104,265)	(29,587)
Inventories	(7,511)	23,022
Prepaid expense and other assets	81,661	(11,645)
Accounts payable	45,847	(140,848)
Accrued expenses	(226,775)	(265,893)
Deferred Revenue	32,193	6,409
Net cash used in operating activities:	<u>(1,694,318)</u>	<u>(1,156,208)</u>
Cash flow from investing activities:		
Proceeds from sale of marketable securities	—	284,665
Purchase of certificates of deposit	—	(2,593,985)
Redemption of certificates of deposit	244,971	—
Advance on notes receivable	(42,524)	—
Purchase of fixed assets	(32,789)	(26,898)
Purchase of intangibles	(24,029)	(194)
Net cash provided by (used in) investing activities:	<u>145,629</u>	<u>(2,336,412)</u>
Cash flow from financing activities:		
Proceeds from exercise of warrants into common stock	55,794	—
Issuance of common stock	2,959,509	3,814,938
Net cash provided by (used in) financing activities	<u>3,015,303</u>	<u>3,814,938</u>
Net increase in cash and cash equivalents	1,466,614	322,318
Cash at beginning of period	766,189	1,764,090
Cash at end of period	\$ 2,232,803	\$ 2,086,408
Non-cash transactions:		
Conversion of Preferred Stock to Common Stock	6,479	—
Investment in Subsidiary	<u>1,542,250</u>	<u>—</u>

Source: Precision Therapeutics Inc.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Precision Therapeutics Inc. (“Precision Therapeutics” or “the Company”) with the assistance of Crystal Research Associates, LLC (“CRA”) based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Precision Therapeutics statements on Forms 10-K, 10-Q, and 8-K as well as other forms filed from time to time. The content of this report with respect to Precision Therapeutics has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings. Precision Therapeutics is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Precision Therapeutics or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA has been compensated by the Company in cash of forty thousand dollars for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about Precision Therapeutics’ business, as described below. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in Precision Therapeutics’ SEC filings are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Precision Therapeutics or that it currently believes to be immaterial may also adversely affect the Company’s business. If any of such risks and uncertainties develops into an actual event, Precision Therapeutics’ business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company’s shares could decline. This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved in an investment in the Company as well as for copies of this report, please contact Precision Therapeutics by calling (651) 389-4800.

Investors should carefully consider the risks described below before making an investment decision. The Company’s business could be harmed by any of these risks. The trading price of Precision Therapeutics’ common stock could decline due to any of these risks, and an investor may lose all or part of the investment. In assessing these risks, one should also refer to the other information contained in the Company’s Form 10-K, including Precision Therapeutics’ financial statements and related notes.

The Company will require additional financing to fund operating expenses and fulfill its business plan. Such financing will be dilutive. Precision Therapeutics’ independent public accounting firm has indicated in their audit opinion, contained in the Company’s financial statements, that they have serious doubts about Precision Therapeutics’ ability to remain a going concern.

The Company has not achieved profitability and anticipates that it will continue to incur net losses at least through the first two quarters of 2018. Precision Therapeutics had revenues of \$655,000 in 2017, but had negative operating cash flows of \$4.5 million. In January 2017, the Company received proceeds of \$3.9 million because of its public offering. In November 2017, Precision Therapeutics received proceeds of \$1.3 million because of its private placement. The Company’s cash and cash equivalents balance was \$0.8 million as of December 31, 2017, and its accounts payable and accrued expenses were an aggregate \$0.9 million. Precision Therapeutics is currently incurring negative operating cash flows of approximately \$380,000 per month. Although they are attempting to curtail expenses, there is no guarantee that Precision Therapeutics’ will be able to reduce these expenses significantly, and expenses for some periods may be higher as the Company prepares its product for broader sales, increases its sales efforts, and maintains adequate inventories.

As of December 31, 2017, Precision Therapeutics had no debt. On January 9, 2018, the Company received proceeds of \$2.8 million because of an S-3 public offering. Subsequently, in connection, the underwriter exercised for an aggregate of 215,247 shares of common stock, the over-allotment option; the Company received additional net proceeds of \$188,000 on February 20, 2018. Precision Therapeutics' cash and cash equivalents balance on January 31, 2018 was approximately \$2.8 million.

Precision Therapeutics may require additional funding to finance operating expenses and to invest in its sales organization and new product development and to enter the international marketplace. The Company will attempt to raise these funds through equity or debt financing, alternative offerings, or other means. If successful in securing adequate funding, Precision Therapeutics plans to make significant capital or equipment investments, and will continue to make human resource additions over the next 12 months. Such additional financing will be dilutive to existing stockholders, and there is no assurance that such financing will be available upon acceptable terms. If such financing or adequate funds from operations are not available, Precision Therapeutics will be forced to limit its business activities, which will have a material adverse effect on the Company's results of operations and financial condition.

Because of the above factors, the Company's independent registered public accounting firm has indicated in their audit opinion, contained in Precision Therapeutics' financial statements on Form 10-K, that they have serious doubts about the Company's ability to continue as a going concern. The financial statements have been prepared assuming the Company will continue as a going concern.

Precision Therapeutics' limited operating history makes evaluation of its business difficult.

The Company was formed on April 23, 2002 and, to date, has generated only moderate revenue year by year. Precision Therapeutics' ability to implement a successful business plan remains unproven and no assurance can be given that it will ever generate sufficient revenues to sustain its business. The Company has a limited operating history which makes it difficult to evaluate its performance. An investor should consider the Company's prospects in light of these risks and the expenses, technical obstacles, difficulties, market penetration rate, and delays frequently encountered in connection with the development of new businesses. These factors include uncertainty as to whether Precision Therapeutics' will be able to:

- Be successful in uncertain markets;
- Respond effectively to competitive pressures;
- Successfully address intellectual property issues of others;
- Protect and expand its intellectual property rights; and
- Continue to develop and upgrade its products.

Precision Therapeutics' business is dependent upon proprietary intellectual property rights, which, if the Company were unable to protect, could have a material adverse effect on its business.

The Company relies on a combination of patent, trade secret, and other intellectual property rights and measures to protect its intellectual property. Precision Therapeutics currently owns and may in the future own or license additional patent rights or trade secrets in the U.S., with non-provisional patents elsewhere in the world that cover certain of its products. The Company relies on patent laws and other intellectual property laws, nondisclosure and other contractual provisions and technical measures to protect its products and intangible assets. These intellectual property rights are important to ongoing operations and no assurance can be given that any measure the Company implements will be sufficient to protect its intellectual property rights.

Additionally, as it relates to trade secrets and proprietary know-how, Precision Therapeutics cannot be certain that the confidentiality agreements it has entered into with employees will not be breached, or that it will have adequate remedies for any breach. The Company may lose the protection afforded by these rights through patent expirations, legal challenges, or governmental action. If Precision Therapeutics cannot protect its rights, the Company may lose its competitive advantage if these patents were found to be invalid in the jurisdictions in which Precision Therapeutics sells or plans to sell its products. The loss of the Company's intellectual property rights could have a material adverse effect on its business.

If Precision Therapeutics becomes subject to intellectual property actions, this could hinder its ability to deliver its products and services and its business could be negatively impacted.

Precision Therapeutics may be subject to legal or regulatory actions alleging intellectual property infringement or similar claims against it. Companies may apply for or be awarded patents or have other intellectual property rights covering aspects of its technologies or businesses. Moreover, if it is determined that the Company's products infringe on the intellectual property rights of third parties, Precision Therapeutics may be prevented from marketing its products. While the Company is currently not subject to any material intellectual property litigation, any future litigation alleging intellectual property infringement could be costly, particularly in light of the Company's limited resources. Similarly, if it is determined that third parties are infringing on the Company's patents or other intellectual property rights, its limited resources may prevent Precision Therapeutics from litigating or otherwise taking actions to enforce its rights. Any such litigation or inability to enforce its rights could require Precision Therapeutics to change its business practices, hinder or prevent its ability to deliver products and services, and result in a negative impact to the Company's business. Expansion of Precision Therapeutics' business via product line enhancements or new product lines to drive increased growth in current or new markets may be inhibited by the intellectual property rights of its competitors and/or suppliers. The Company's inability to successfully mitigate those factors may significantly reduce its market opportunity and subsequent growth.

Precision Therapeutics faces significant competition, including competition from companies with considerably greater resources, and if the Company is unable to compete effectively with these companies, its market share may decline and its business could be harmed.

The Company's industry is highly competitive with numerous competitors ranging from well-established manufacturers to start-ups. A number of Precision Therapeutics' competitors have significantly greater financial, technological, engineering, manufacturing, marketing, and distribution resources than it does. Their greater capabilities in these areas may enable them to compete more effectively on the basis of price and production and more quickly develop new products and technologies.

Precision Therapeutics estimates that the total market for surgical suction canisters is approximately \$94 million and that the total cost of using surgical canisters could be greater than \$94 million since this amount does not include the labor to handle the canisters, disposal costs, and solidifying compounds commonly used to minimize exposure to healthcare workers. The Company's competitors include Cardinal Health, Inc., a medical manufacturer and distributor, and Stryker Instruments, a wholly owned subsidiary of Stryker Corporation, which has a leading position in Precision Therapeutics' market. Both of these competitors are substantially larger than Precision Therapeutics and are better capitalized than it is. Companies with significantly greater resources than Precision Therapeutics may be able to reverse engineer its products and/or circumvent its intellectual property position. Such action, if successful, would greatly reduce the Company's competitive advantage in the marketplace.

Precision Therapeutics believes that its ability to compete successfully depends on a number of factors, including its technical innovations of unlimited suction and unlimited capacity capabilities, its innovative and advanced research and development capabilities, strength of its intellectual property rights, sales and distribution channels, and advanced manufacturing capabilities. The Company plans to employ these and other elements as it develops its products and technologies, but there are many other factors beyond its control. Precision Therapeutics may not be able to compete successfully in the future, and increased competition may result in price reductions, reduced profit margins, loss of market share, and an inability to generate cash flows that are sufficient to maintain or expand the Company's development and marketing of new products, which could adversely impact the trading price of the shares of Precision Therapeutics' Common Stock.

The Company's business is subject to intense governmental regulation and scrutiny, both in the U.S. and abroad.

The production, marketing, and research and development of Precision Therapeutics' product is subject to extensive regulation and review by the FDA and other governmental authorities both in the U.S. and abroad. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record keeping. If the Company does not comply with applicable regulatory requirements, violations could result in warning letters, non-approvals, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Periodically, legislative or regulatory proposals are introduced that could alter the review and approval process relating to medical products. It is possible that the FDA will issue additional regulations further restricting the sale of the Company's present or proposed products. Any change in legislation or regulations that govern the review and approval process relating to Precision Therapeutics' current and future products could make it more difficult and costly to obtain approval for new products, or to produce, market, and distribute existing products.

If Precision Therapeutics' product is not accepted by its potential customers, it is unlikely that the Company will ever become profitable.

The medical industry has historically used a variety of technologies for fluid waste management. Compared to these conventional technologies, Precision Therapeutics' technology is relatively new, and the number of companies using the Company's technology is limited. The commercial success of its product will depend upon the widespread adoption of its technology as a preferred method by hospitals and surgical centers. In order to be successful, Precision Therapeutics' product must meet the technical and cost requirements for these facilities. Market acceptance will depend on many factors, including:

- the willingness and ability of customers to adopt new technologies;
- the Company's ability to convince prospective strategic partners and customers that its technology is an attractive alternative to conventional methods used by the medical industry;
- its ability to select and execute agreements with effective distributors to market and sell the Company's product; and
- the Company's ability to assure customer use of the Skyline proprietary cleaning fluid and in-line filter.

Because of these and other factors, Precision Therapeutics' product may not gain market acceptance or become the industry standard for the healthcare industry. The failure of such companies to purchase the Company's products would have a material adverse effect on its business, results of operations, and financial condition.

If demand for the Company's product is unexpectedly high, there is no assurance that there will not be supply interruptions or delays.

Precision Therapeutics is currently manufacturing the STREAMWAY System, following GMP compliance regulations of the FDA, at its own facility and anticipates the capability of producing the STREAMWAY System in sufficient quantities for future near term sales. The Company has contracted with a manufacturing company that can manufacture products at higher volumes. However, if demand for its product is unexpectedly high, there is no assurance that the Company or its manufacturing partners will be able to produce the product in sufficiently high quantity to satisfy demand. Any supply interruptions or inadequate supply would have a material adverse effect on the Company's results of operations.

Precision Therapeutics is dependent on a few key executive officers for its success. The Company's inability to retain those officers would impede its business plan and growth strategies, which would have a negative impact on its business and the value of an investment.

The Company's success depends on the skills, experience, and performance of key members of Precision Therapeutics' management team. Precision Therapeutics heavily depends on its management team: Carl Schwartz, the Company's chief executive officer, David O. Johnson, its chief operating officer, and Bob Myers, its chief financial officer. Precision Therapeutics has entered into employment agreements with the CEO, the COO, and the CFO of the senior management team and may expand the relatively small number of executives in its company. If the Company were to lose one or more of these key individuals, it would be forced to expend significant time and money in the pursuit of a replacement, which could result in both a delay in the implementation of its business plan and the diversion of its limited working capital. The Company can give investors no assurance that it can find satisfactory replacements for these key individuals at all, or on terms that are not excessively expensive or burdensome to the Company.

The Company's success is dependent on its ability to attract and retain technical personnel, sales and marketing personnel, and other skilled management.

Precision Therapeutics' success depends to a significant degree on its ability to attract, retain, and motivate highly skilled and qualified personnel. Failure to attract and retain necessary technical, sales, and marketing personnel and skilled management could adversely affect its business. If the Company fails to attract, train, and retain sufficient numbers of these highly-qualified people, its prospects, business, financial condition, and results of operations will be materially and adversely affected.

Costs incurred because of being a public company may affect the Company's profitability.

As a public company, Precision Therapeutics may incur significant legal, accounting, and other expenses, and are subject to the SEC's rules and regulations relating to public disclosure that generally involves a substantial expenditure of financial resources. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC, requires changes in corporate governance practices of public companies. Precision Therapeutics expects that full compliance with such rules and regulations will significantly increase its legal and financial compliance costs and make some activities more time-consuming and costly, which may negatively impact the Company's financial results. To the extent Precision Therapeutics' earnings suffer as a result of the financial impact of its SEC reporting or compliance costs, its ability to develop an active trading market for the Company's securities could be harmed.

Limitations on director and officer liability and indemnification of the Company's officers and directors by Precision Therapeutics' may discourage stockholders from bringing suit against a director.

The Company's certificate of incorporation and bylaws provide, with certain exceptions as permitted by governing state law, that a director or officer shall not be personally liable to the Company or to its stockholders for breach of fiduciary duty as a director, except for acts or omissions which involve intentional misconduct, fraud, or knowing violation of law, or unlawful payments of dividends. These provisions may discourage stockholders from bringing suit against a director for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by stockholders on the Company's behalf against a director. In addition, Precision Therapeutics' certificate of incorporation and bylaws may provide for mandatory indemnification of directors and officers to the fullest extent permitted by governing state law.

The Company does not expect to pay dividends for the foreseeable future, and may never pay dividends; investors must rely on stock appreciation for any return on investment in the Company's common stock.

Precision Therapeutics currently intends to retain any future earnings to support the development and expansion of its business and does not anticipate paying cash dividends in the foreseeable future. The Company's payment of any future dividends will be at the discretion of its Board of Directors after taking into account various factors, including but not limited to, Precision Therapeutics' financial condition, operating results, cash needs, growth

plans, and the terms of any credit agreements that the Company may be a party to at the time. In addition, Precision Therapeutics' ability to pay dividends on its common stock may be limited by state law. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize certain returns on an investor's investment. As a result, investors must rely on stock appreciation and a liquid trading market for any return on investment in the Company's common stock.

Shares eligible for future sale may adversely affect the market.

From time to time, certain stockholders may be eligible to sell some or all of their shares of common stock pursuant to Rule 144, promulgated under the Securities Act subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied the applicable holding period and is not deemed to have been one of the Company's affiliates at the time of sale, or at any time during the three months preceding a sale, may sell their shares of common stock. Any substantial sale, or cumulative sales, of Precision Therapeutics' common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of the Company's securities.

Precision Therapeutics expects volatility in the price of its common stock, which may subject the Company to securities litigation.

If established, the market for Precision Therapeutics' common stock may be characterized by significant price volatility when compared to seasoned issuers, and the Company expects that its share price will be more volatile than a seasoned issuer for the indefinite future. In addition, there is no assurance that the price of its common stock will not be volatile. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. Precision Therapeutics may in the future be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

Precision Therapeutics' Board of Directors' ability to issue undesignated preferred stock and the existence of anti-takeover provisions may depress the value of its common stock.

The Company's authorized capital includes 20 million shares of preferred stock. Of this amount, 18,950 shares have been designated as Series B Convertible Preferred Stock and the remaining authorized shares are designated as Series C Preferred Stock. Precision Therapeutics' Board of Directors has the power to issue any or all of the shares of undesignated preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights and limitations of such class or series, without seeking stockholder approval. Further, as a Delaware corporation, the Company is subject to provisions of the Delaware General Corporation Law regarding "business combinations." Precision Therapeutics may, in the future, consider adopting additional anti-takeover measures. The authority of its Board of Directors to issue undesignated stock and the anti-takeover provisions of Delaware law, as well as any future anti-takeover measures adopted by it, may, in certain circumstances, delay, deter, or prevent takeover attempts and other changes in control of the Company not approved by its Board of Directors. As a result, the Company's stockholders may lose opportunities to dispose of their shares at favorable prices generally available in takeover attempts or that may be available under a merger proposal and the market price, voting, and other rights of the holders of Common Stock may also be affected.

Future sales and issuances of the Company's Common Stock or rights to purchase Common Stock could result in additional dilution of the percentage ownership of Precision Therapeutics' stockholders and could cause its share price to fall.

Precision Therapeutics also expects that significant additional capital will be needed in the future to continue its planned operations. To the extent that the Company raises additional capital by issuing equity securities, its stockholders may experience substantial dilution. Precision Therapeutics may sell Common Stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner, determined by the Company from time to time. If it sells Common Stock, convertible securities, or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to existing stockholders and new investors could gain rights superior to existing stockholders. In addition,

in the past, Precision Therapeutics' has issued warrants to acquire shares of common stock. To the extent these warrants are ultimately exercised, investors will sustain further dilution.

The Company's Board of Directors' ability to issue "blank check" preferred stock and any anti-takeover provisions adopted may depress the value of Precision Therapeutics' common stock.

The Company's certificate of incorporation authorizes 20,000,000 shares of "blank-check" preferred stock, of which 19,272,935 remain available for issuance. The Board of Directors has the power to issue any or all of the shares of such preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights, and limitations of such class or series, without seeking the approval of its common stockholders, subject to certain limitations on this power under the listing requirements of The NASDAQ Capital Market and the laws of the state of Delaware. The authority of Precision Therapeutics' Board of Directors to issue "blank-check" preferred stock, along with any future anti-takeover measures which may be adopted, may, in certain circumstances, delay, deter, or prevent takeover attempts and other changes in control of the Company not approved by its Board of Directors. Thus, Company stockholders may lose opportunities to dispose of their shares of Common Stock at favorable prices generally available in takeover attempts or that may be available under a merger proposal and the market price of the Common Stock and the voting and other rights of its stockholders may also be affected.

From inception, through December 2013, Precision Therapeutics' shares and other securities were issued in violation of the preemptive rights of existing stockholders, which could result in claims against the Company.

In 2013, it was brought to the attention of the Company's management and Board of Directors that the Company was subject to preemptive rights under Minnesota corporate law, because the articles of incorporation did not "opt out" and deny them. Prior to the Company's reincorporation in Delaware in December 2013, the Company issued shares of Common Stock and other equity securities on numerous occasions to raise capital and for other purposes and, to its knowledge, never complied with the Minnesota preemptive rights statute in connection with such issuances. Starting in December 2013, stockholders no longer had preemptive rights. In connection with issuances of securities prior to that time, the Company may be still subject to the claims of previous and current stockholders based on violations of their preemptive rights; the risk and magnitude of these claims are uncertain. If there are any future claims, the Company has stated that it intends to vigorously defend against such claims; however, there can be no assurance that the Company would not be liable for damages or other remedies that might have a material adverse effect on its financial condition or results of operations.

Glossary

100,000 Genome Project GENE consortium—A UK Government project that is sequencing 100,000 whole genomes from U.K.'s National Health Service patients. The project is focusing on rare diseases, some common types of cancer, and infectious diseases. Genomics England, a company wholly-owned and funded by the U.K. Department of Health & Social Care, was set up to deliver this flagship project.

Ascites fluids—Ascites refers to abnormal accumulation fluid in the abdominal (peritoneal) cavity.

Artificial Intelligence (AI)—The theory and development of computer systems able to perform tasks and solve cognitive problems commonly associated with human intelligence, such as decision-making, problem solving, and pattern recognition.

Assay—A procedure in laboratory medicine and pharmacology for assessing or measuring the presence, amount, or functional activity of a target entity.

Big Data Analytics—Big data is data sets that are so voluminous and complex that traditional data-processing application software are inadequate to deal with them. Big data analytics are advanced data analytics methods that examines large amounts of data to extract value from the data and uncover hidden patterns, correlations, and other insights.

Biobank—A large collection of biological or medical data and tissue samples, amassed for research purposes.

Bioinformatics—The science of collecting and analyzing complex biological data, such as genetic codes.

Biorepository—A biological materials repository that collects, processes, stores, and distributes biospecimens to support future scientific investigation.

Bloodborne—A disease or pathogen carried or transmitted by the blood.

Cell Lines—Cell cultures grown under controlled conditions, generally outside their natural environment, derived from a usually homogeneous tissue source (such as an organ or tumor) and therefore consisting of cells with a uniform genetic makeup.

Chemosenitivity—Susceptibility (as of a disease-causing bacterium or a cancer cell) to the action of a chemical agent or therapeutic agent.

CLIA-certified—The Clinical Laboratory Improvement Amendments (CLIA) regulate laboratory testing and require clinical laboratories to be certificated by their state as well as the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing.

Contract Research Organization (CRO)—An organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

Genomic—Relating to the complete set of genes in a cell or organism. Genomics is the branch of molecular biology concerned with the structure, function, evolution, and mapping of genomes (an organism's complete set of DNA).

HER2 Receptor—HER 2 is a protein called human epidermal growth factor receptor 2 (HER2), which promotes the growth of cancer cells. Amplification or over-expression of this oncogene has been shown to play an important role in the development and progression of certain aggressive types of breast cancer. In recent years the protein has become an important biomarker and target of therapy, as about 1 of every 5 breast cancers, the cancer cells have a gene mutation that makes an excess of the HER2 protein.

Histopathology—The study of changes in tissues caused by disease.

In Vitro Diagnostic (IVD)—Medical devices and technology used to perform tests on samples, (e.g., blood, urine and tissue that has been taken from the human body) in order to diagnose a medical condition or monitor a person’s overall health to help cure, treat, or prevent diseases.

Irrigation Fluid—Any fluid used to rinse or wash an organ, wound, body cavity, or surgical site.

Medical Fluid Waste—Any kind of fluid waste generated by healthcare facilities that may contain infectious material (or material that’s potentially infectious).

Multiple Myeloma—A cancer that forms in a type of white blood cell called a plasma cell. Plasma cells help fight infection by making antibodies that recognize and attack germs. Multiple myeloma causes cancer cells to accumulate in the bone marrow, where they crowd out healthy blood cells.

Next-Generation Sequencing (NGS)—A high-throughput DNA sequencing technology that can process millions or billions of DNA strands in parallel, yielding substantially more throughput and minimizing the need for the fragment-cloning methods that are often used in alternative methods used for the sequencing of genomes.

Organoids—An artificially grown mass of cells or tissue that resembles an organ or a biological entity, such as a tumor.

Patient Derived (PDX) Tumor—Tumor tissue grown *in vitro* that used a sample of a patient’s tumor as the original material.

Peptides—Any of a group of compounds or molecules consisting of two or more amino acids linked by peptide (amide) bonds. Peptides are smaller than proteins, which are also chains of amino acids.

Peptide Ligands—Small molecules that transmit signals in between or within cells. Ligands exert their effects by binding to specific cellular protein or peptide (receptors).

Personalized Medicine—A type of medical care in which treatment is customized for an individual patient.

Precision Oncology— Precision oncology, or precision medicine of cancer, is defined as molecular profiling of tumors to identify targetable alterations. It is an approach to personalized medicine, using technologic advances in genomics and molecular profiling of tumors and individuals for the creation of individual therapeutic processes aimed at enhancing clinical outcomes.

Precision Medicine—A medical model that proposes the customization of healthcare, with medical decisions, treatments, practices, or products being tailored to the individual patient. In this model, diagnostic testing is often employed for selecting appropriate and optimal therapies based on the context of a patient’s genetic content or other molecular or cellular analysis.

Precision Medicine Initiative [PMI]—A U.S. Government-backed research project, involving the National Institutes of Health (NIH) and multiple other research centers, which aims to understand how a person’s genetics, environment, and lifestyle can help determine the best approach to prevent or treat disease. The project was created in 2015 and provides \$215 million in funding aimed to make advances in tailoring medical care to the individual. In October 2016, the project was renamed “All of Us” research program.

STAT3 pathway—Signal transducer and activator of transcription 3 (STAT3) is a member of the STAT protein family and a transcription factor which, in humans, is encoded by the STAT3 gene. STAT3 can promote oncogenesis by being active through various pathways, and constitutive STAT3 activation is associated with various human cancers and commonly suggests poor prognosis. Multiple lines of evidence place STAT3 at a central node in the development, progression, and maintenance of many human tumors, and STAT3 has been validated as an anti-cancer target in several contexts.

Triple-negative breast cancer (TNBC)—A diagnosis of triple negative breast cancer means that the three most common types of receptors known to fuel most breast cancer growth—estrogen, progesterone, and the HER-2/neu gene—are not present in the cancer tumor. This means that the breast cancer cells have tested negative for hormone epidermal growth factor receptor 2 (HER-2), estrogen receptors (ER), and progesterone receptors (PR). Since the tumor cells lack the necessary receptors, common treatments like hormone therapy and drugs that target estrogen, progesterone, and HER-2 are ineffective. Using chemotherapy to treat triple negative breast cancer is still an effective option, where breast cancer may respond even better to chemotherapy in the earlier stages than many other forms of cancer.

Tumorigenicity—Capable of causing or producing tumors.

Xenografts—A tissue graft or organ transplant from a donor of a different species from the recipient.

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FACTS WITHOUT FICTION

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