# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

**CURRENT REPORT** Pursuant to Section 13 or 15(d) of the **Securities Exchange Act of 1934** 

Date of Report (Date of earliest event reported): November 14, 2018

# **Precision Therapeutics Inc.**

(Exact name of Registrant as Specified in its Charter)

Delaware	001-36790	33-1007393
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)
2915 Commers I Eagan, M (Address of Principa	linnesota	<b>55121</b> (Zip Code)
Registrant's telephone number, including area code: <b>(6</b> 5	51) 389-4800	
Former Name or Former Address, if Changed Since La	st Report: Not Applicable	
Check the appropriate box below if the Form 8-K filing provisions (see General Instruction A.2. below):	g is intended to simultaneously satisfy the filing ob	ligation of the registrant under any of the following
-		
ndicate by check mark whether the registrant is an emo or Rule 12b-2 of the Securities Exchange Act of 1934 (		he Securities Act of 1933 (§230.405 of this chapter
Emerging growth company ⊠		
f an emerging growth company, indicate by check mar evised financial accounting standards provided pursua		ed transition period for complying with any new or

#### Item 2.02. Results of Operations and Financial Condition.

On November 14, 2018, Precision Therapeutics Inc. issued a press release attached hereto as Exhibit 99.1 announcing its financial results for the period ended September 30, 2018. In addition, Precision Therapeutics Inc. held a conference call for investors on November 14, 2018. The script of the conference call is attached hereto as Exhibit 99.2.

#### Item 8.01. Other Events.

The press release attached hereto as Exhibit 99.1 and the script attached hereto as Exhibit 99.2 are considered a filing under Rule 425 under the Securities Act of 1933 and deemed filed under Rule 14a-12 of the Securities Exchange Act of 1934.

#### Additional Information and Where to Find It

This communication does not constitute an offer to sell or the solicitation of an offer to buy any securities or a solicitation of any vote or approval. This communication may be deemed to be solicitation material in respect of the proposed merger transaction between Precision and Helomics Holding Corporation ("Helomics"). In connection with the proposed transaction, Precision has filed a registration statement on Form S-4, containing a proxy statement/prospectus (the "S-4") with the Securities and Exchange Commission ("SEC"). This communication is not a substitute for the registration statement, definitive proxy statement/prospectus or any other documents that Precision has filed or may file with the SEC or that Precision or Helomics has sent or may send to their respective security holders in connection with the proposed transaction.

SECURITY HOLDERS OF HELOMICS ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH THE SEC, INCLUDING THE PROXY STATEMENT/PROSPECTUS, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION.

Investors and security holders will be able to obtain copies of the S-4, including the proxy statement/prospectus, and other documents filed with the SEC (when available) free of charge at the SEC's website, http://www.sec.gov after they are filed. Copies of documents filed with the SEC by Precision will be made available free of charge on Precision's website at www.precisiontherapeutics.com.

#### Item 9.01. Financial Statements and Exhibits.

- (a) Not applicable.
- (b) Not applicable.
- (c) Not applicable.
- (d) Exhibits.

#### Exhibit No. Description

99.1 Press Release dated November 14, 2018

99.2 Script of Conference Call held on November 14, 2018

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# PRECISION THERAPEUTICS INC.

By: /s/ Bob Myers

Name: Bob Myers

Title: Chief Financial Officer

Date: November 14, 2018



Filing under Rule 425 under the Securities Act of 1933 and deemed filed under Rule 14a-12 of the Securities Exchange Act of 1934 Filing by: Precision Therapeutics Inc.: SEC File Nos. 001-36790; and 333-221966

# **Precision Therapeutics Reports Third Quarter 2018 Financial Results**

MINNEAPOLIS (November 14, 2018) - Precision Therapeutics Inc. (NASDAQ: AIPT) ("Precision" or "the Company"), a company focused on applying artificial intelligence to personalized medicine and drug discovery, announced today financial results for the three and nine months ended September 30, 2018 and provided a business update.

## Highlights of the third quarter of 2018 and recent weeks include:

- · Filed a Form S-4 registration statement with the Securities and Exchange Commission ("SEC") regarding its proposed merger transaction with Helomics Holding Corporation ("Helomics")
- TumorGenesis, Inc. ("TumorGenesis"), a wholly owned subsidiary of Precision, achieved its first milestone by developing a discovery kit for screening ovarian cancer cell types, which is now being offered to its clients. The kit was developed using technology that Precision's joint venture partner, GLG Pharma LLC ("GLG"), licensed from a research institution.
- Formed a new Scientific and Medical Advisory Board and announced the appointment of:
  - o Marc Malandro PhD, CLP, RTTP, Vice President of Operations for Science at the Chan Zuckerberg Initiative.
  - o Amelia Wall Warner, PharmD, RPh, Founder and CEO of Clinical Trial Concepts.
  - o Robert Murphy, Ph.D. Ray and Stephanie Lane Professor of Computational Biology and Head of the Computational Biology Department in the School of Computer Science at Carnegie Mellon University.
  - o Paul Kornblith, M.D., Founder and former Chairman and CEO of Helomics Corporation. Dr. Kornblith currently serves as the Medical Advisor to Helomics, the Pittsburgh Life Sciences Greenhouse, and the Innovation Institute; as an Adjunct Professor in the School of Health and Rehabilitation at the University of Pittsburgh; and as the Western Pennsylvania Director for Life Sciences.
  - o Hector Gomez, MD, PHD, President & CEO, Co-Founder of GLG Pharma, LLC.
  - o Paul Sweetnam, founder of CellBridge, LLC.
  - Tony Frudakis. Previously Co-Founder & Chief Scientific Officer at DNAPrint Genomics.
  - o Ratmir Derda, Associate Professor at the University of Alberta.

# Highlights from Helomics, which is 25% owned by Precision Therapeutics:

- · Precision Oncology Insights business: continued to increase efforts on the outreach program to oncologists, driving growth in the numbers of specimens.
- · Contract Research Organization ("CRO") business: signed a major deal with a patient advocacy organization, the National Alopecia Areata Foundation, which is expected to generate both project fees and recurring revenue over many years.
- D-CHIP<sup>TM</sup> ("Digital Clinical Health Insights Platform"): continued to add to this large repository of genomic and drug response profiles by signing a
  partnership agreement with Genome England's 100,000 genomes project. This will allow Helomics to access data from the UK's 100,000 genomes
  project to build out D-CHIP, especially in the area of Ovarian Cancer.



#### Highlights from Skyline Medical, a division of Precision Therapeutics:

- · Sold ten STREAMWAY Systems in the third quarter of 2018, compared with two STREAMWAY Systems in Q3 2017, bringing the total number of STREAMWAY Systems sold to 142 as of September 30, 2018
  - o This included the first STREAMWAY sale in Europe, to a clinic based in Switzerland
- Attended MEDICA, the leading international trade fair for the medical sector, which attracts more than 5,000 exhibitors from 70 countries
- Partnered with Prenit World, an international distributor of medical infrastructure solutions for healthcare facilities, to market the STREAMWAY System in India. Signing this international distribution agreement represents the Company's entry into India's healthcare market.
- · Signed independent distribution agreement in Pakistan with MediUrge, which is contractually guaranteed to purchase eighteen units in 2019
- · Announced upgrades to the STREAMWAY System, with the anticipated launched of the Generation 3 STREAMWAY in Q1 2019, and the STREAMWAY Plus in the first half of 2019

Dr. Carl Schwartz, Chief Executive Officer of Precision, commented, "This is a critical period in the Company's evolution as we implement several major initiatives to advance our growth strategy in both the contract research organization ("CRO") services sector, through our TumorGenesis subsidiary and our investment in Helomics, and in the medical device market, through our Skyline Medical division.

"Our Skyline Medical division sold 10 STREAMWAY System units in the third quarter, which included our first sale outside North America - a turning point for us as it represents the opening up of a much larger market. The speed with which our first sale in Europe was secured, we believe, is indicative of how well-suited the STREAMWAY is to the European market and will pave the way for future sales in the region. As we look to expand our sales network globally, we also signed with Prenit World in India, and, in recent days, we partnered with an independent distributor in Pakistan, MediUrge, which has contractually guaranteed to purchase eighteen units next year, such is their confidence in their ability to sell our product in Pakistan. We continue to expand our global sales network and generate additional sales for the Company. To support our commercialization strategy in the U.S., we are hiring several additional seasoned sales people that have decades of experience in the OR and medical device field. These additional hires are expected to springboard our growth in 2019, coupled with our latest-generation STREAMWAY System technology which we will launch next year."



Dr. Schwartz continued, "At TumorGenesis, our aim is to produce a more accurate, predictive model of how treatments will perform, by growing human tumors outside the body that closely mimic the patient's internal environment and 'fool' the cancer cells into thinking they are inside a human patient's body. This is expected to generate a more accurate response when testing drugs for personalized therapy and in the development of new drugs. We are making solid progress executing against this strategy and have reached our first milestone, with TumorGenesis developing a discovery kit for screening of ovarian cancer cell types. The kit is now being made available to clients of TumorGenesis for whole cell screening in Clinical Research Projects. We are excited about this accomplishment as we believe this completely new and revolutionary method of screening will ultimately represent a major breakthrough for ovarian cancer patients, as these cells are unique and are difficult to culture."

Mr. Jerry Vardzel, CEO of Helomics, in which Precision Therapeutics has a 25% stake, commented, "Helomics has continued to execute on its business model in Q3 through its three complementary business pillars, all of which are revenue generating, with growth strategies in place. Our boutique contract research organization, or 'CRO', go-to-market strategy is via our HelomicsDiscover™ program which helps drive the discovery of the next generation of precision cancer therapies. In Q3 we signed a major deal with a patient advocacy organization, the National Alopecia Areata Foundation, which is expected to generate both project fees and recurring revenue over many years.

"The build out of our D-CHIP (AI-powered Bio Informatics Platform) continues as we continue to add to our large repository of genomic and drug response profiles from the initial 150,000 anonymized clinical tests, performed on the patient's own tumor. We recently signed a partnership agreement with Genome England's 100,000 genomes project. Through this partnership we have use of a very expensive whole genome sequencer and access to the data they have generated on patient's entire DNA which will allow us to build out D-CHIP especially in the area of ovarian cancer.

"We also continue to make progress at our Precision Oncology Insights business with our outreach program to oncologists, which is generating growth in our specimen numbers. Higher specimen numbers represent revenue from the clinical testing, plus additional revenue in the form of data for the D-CHIP and as appropriately consented material for our CRO services business," concluded Mr. Vardzel.

#### **Financial Results**

Revenue for the three months ended September 30, 2018 was \$329,930, compared with \$152,535 for the three months ended September 30, 2017. Revenue was derived from the sales of ten STREAMWAY Systems and the sale of STREAMWAY disposable products during the third quarter of 2018.

Gross profit for the three months ended September 30, 2018 was \$246,924 or 74.8% of revenue, compared with \$123,829 or 81.2% of revenue for the same period in 2017.

Total operating expenses for the three months ended September 30, 2018 were \$2.1 million, compared with \$1.1 million for the three months ended September 30, 2017. The increase was primarily the result of consulting fees due to the TumorGenesis build-up and higher sales and marketing fees related to the STREAMWAY System.



The Company also reported a \$645,786 loss related to the Company's 25% equity method investment in Helomics, for the three-month period.

Comprehensive loss for the three months ended September 30, 2018, which includes this loss on equity method investment, was \$2.5 million or a loss of \$0.19 per share. This compares with comprehensive loss for the three months ended September 30, 2017 of \$1.0 million or a loss of \$0.16 per share.

Revenue for the nine months ended September 30, 2018 was \$1,100,108, compared with \$434,523 for the nine months ended September 30, 2017. Revenue was derived from the sales of 35 STREAMWAY Systems and the sale of STREAMWAY disposable products during the first nine months of 2018.

Gross profit for the nine months ended September 30, 2018 was \$790,788 or 71.9% of revenue, compared with \$346,814 or 79.8% of revenue for the same period in 2017.

Total operating expenses for the nine months ended September 30, 2018 were \$5.8 million, compared with \$5.2 million for the nine months ended September 30, 2017. The increase was due to higher sales and marketing costs associated with the STREAMWAY System and higher operations expenses due to the TumorGenesis build-up and was partially offset by lower General and Administrative expenses.

The Company also reported a \$1,606,294 loss related to the Company's equity method investment in Helomics, for the nine-month period.

Comprehensive loss for the nine months ended September 30, 2018, which includes this loss on equity method investment, was \$6.6 million or a loss of \$0.55 per share. This compares with a comprehensive loss for the nine months ended September 30, 2017 of \$4.9 million or a loss of \$0.78 per share.

The Company had cash, cash equivalents and marketable securities of \$209,891 as of September 30, 2018, compared with \$766,189 as of December 31, 2017. In the first week of October 2018, the Company received \$1,815,000 net proceeds from the private placement of secured convertible promissory notes, which is represented on the Balance Sheet as a Loan Receivable; half of that amount was advanced to Helomics.

#### **Conference Call and Webcast**

Management will also hold a conference call to provide a general business update and discuss upcoming milestones. The conference call is scheduled to begin today at 4:30 p.m. Eastern Time. A webcast of the event will be available via the 'Investor Info' section of the Company's website at http://www.precisiontherapeutics.com/.

To access the conference call, U.S.-based listeners should dial +1 (800) 239-9838 and international listeners should dial +1 (323) 794-2551. All listeners should provide the following passcode: 7614019.



A dial-in replay of the call will also be available to those interested until November 28, 2018. To access the replay, dial +1 (844) 512-2921 (United States) or +1 (412) 317-6671 (International) and enter replay pin number: 7614019.

To be added to the Precision Therapeutics' database, please email Info@MoneyInfo-llc.com with your email address. This is solely for the use of Precision Therapeutics and will not be sold or distributed to third parties.

#### **About Precision Therapeutics Inc.**

Precision Therapeutics (NASDAQ:AIPT) operates in two business areas: first, applying artificial intelligence to personalized medicine and drug discovery to provide personalized medicine solutions for patients and clinicians as well as clients in the pharmaceutical, diagnostic, and biotech industries, and second, production of the FDA-approved STREAMWAY® System for automated, direct-to-drain medical fluid disposal. For additional information, please visit www.precisiontherapeutics.com.

Precision Therapeutics' medicine business is committed to improving the effectiveness of cancer therapy using the power of artificial intelligence (AI) applied to rich data diseases databases. This business has launched with Precision Therapeutics' investment in Helomics Corporation, a precision medicine company and integrated clinical contract research organization whose mission is to improve patient care by partnering with pharmaceutical, diagnostic, and academic organizations to bring innovative clinical products and technologies to the marketplace. In addition to its proprietary precision diagnostics for oncology, Helomics offers boutique CRO services that leverage their patient-derived tumor models, coupled to a wide range of multi-omics assays (genomics, proteomics and biochemical), and a proprietary bioinformatics platform (D-CHIP) to provide a tailored solution to our client's specific needs. Helomics is currently 25% owned by Precision Therapeutics. Helomics® is headquartered in Pittsburgh, Pennsylvania where the company maintains state-of-the-art, CLIA-certified, clinical and research laboratories. For more information, please visit www.Helomics.com.

Precision Therapeutics has also announced the formation of a subsidiary, TumorGenesis to pursue 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. Precision Therapeutics and Helomics have also announced a proposed joint venture with GLG Pharma 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 growth strategy in this business includes securing new partnerships and considering acquisitions in the precision medicine space.

Sold through the Skyline Medical business of Precision Therapeutics, The STREAMWAY System virtually eliminates staff exposure to blood, irrigation fluid and other potentially infectious fluids found in the healthcare environment. Antiquated manual fluid handling methods that require hand carrying and emptying filled fluid canisters present an exposure risk and potential liability. Skyline Medical's STREAMWAY System fully automates the collection, measurement, and disposal of waste fluids and is designed to: 1) reduce overhead costs to hospitals and surgical centers; 2) improve compliance with OSHA and other regulatory agency safety guidelines; 3) improve efficiency in the operating room, and radiology and endoscopy departments, thereby leading to greater profitability; and 4) provide greater environmental stewardship by helping to eliminate the approximately 50 million potentially disease-infected canisters that go into landfills each year in the U.S. For additional information, please visit www.skylinemedical.com.



#### Forward-looking Statements

Certain of the matters discussed in this announcement contain forward-looking statements that involve material risks to and uncertainties in the Company's business that may cause actual results to differ materially from those anticipated by the statements made herein. Such risks and uncertainties include (1) risks related to the proposed merger with Helomics, including the fact that we may not complete the merger; we do not have complete information about Helomics; the combined company will not be able to continue operating without additional financing; possible failure to realize anticipated benefits of the merger; costs associated with the merger may be higher than expected; the merger may result in disruption of the Company's and Helomics' existing businesses, distraction of management and diversion of resources; delay in completion of the merger may significantly reduce the expected benefits; and the market price of the Company's common stock may decline as a result of the merger; (2) risks related to our partnerships with other companies, including the need to negotiate the definitive agreements; possible failure to realize anticipated benefits of these partnerships; and costs of providing funding to our partner companies, which may never be repaid or provide anticipated returns; and (3) other risks and uncertainties relating to the Company that include, among other things, current negative operating cash flows and a need for additional funding to finance our operating plan; the terms of any further financing, which may be highly dilutive and may include onerous terms; unexpected costs and operating deficits, and lower than expected sales and revenues; sales cycles that can be longer than expected, resulting in delays in projected sales or failure to make such sales; uncertain willingness and ability of customers to adopt new technologies and other factors that may affect further market acceptance, if our product is not accepted by our potential customers, it is unlikely that we will ever become profitable; adverse economic conditions; adverse results of any legal proceedings; the volatility of our operating results and financial condition; inability to attract or retain qualified senior management personnel, including sales and marketing personnel; our ability to establish and maintain the proprietary nature of our technology through the patent process, as well as our ability to possibly license from others patents and patent applications necessary to develop products; the Company's ability to implement its long range business plan for various applications of its technology; the Company's ability to enter into agreements with any necessary marketing and/or distribution partners and with any strategic or joint venture partners; the impact of competition, the obtaining and maintenance of any necessary regulatory clearances applicable to applications of the Company's technology; and management of growth and other risks and uncertainties that may be detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, which are available for review at www.sec.gov. This is not a solicitation to buy or sell securities and does not purport to be an analysis of the Company's financial position. See the Company's most recent Annual Report on Form 10-K, and subsequent reports and other filings at www.sec.gov.





## **Contacts:**

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# PRECISION THERAPEUTICS INC. CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

	September 30, 2018		<b>December 31, 2017</b>	
ASSETS				
Current Assets:				
Cash and Cash Equivalents	\$	209,891	\$	766,189
Certificates of Deposit		-		244,971
Accounts Receivable		238,598		137,499
Loan Receivable – Bridge Loan		1,815,000		-
Notes Receivable		163,468		667,512
Inventories		278,155		265,045
Prepaid Expense and other assets		404,428		289,966
Total Current Assets		3,109,540		2,371,182
Notes Receivable		1 124 774		1 070 000
		1,134,774		1,070,000
Fixed Assets, net		198,258		87,716
Intangibles, net	d.	973,127	d	95,356
Total Assets	\$	5,415,699	\$	3,624,254
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts Payable	\$	409,099	\$	140,462
Note Payable – Bridge Loan Net of Discount of \$1,293,047	•	1,004,680	•	-
Accrued Expenses		315,039		785,215
Derivative Liability		645,008		-
Deferred Revenue		15,306		6,663
Total Liabilities		2,389,132		932,340
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, 13,398,339 and 6,943,283 outstanding		133,983		69,432
Additional paid-in capital		64,297,137		57,380,256
Accumulated Deficit		(61,405,345)		(54,765,045)
Total Stockholders' Equity		3,026,567		2,691,914
Total Liabilities and Stockholders' Equity	\$	5,415,699	\$	3,624,254
Total Elabilities and Stockholders Equity	4	5, 115,555	Ψ	5,52 1,254



# PRECISION THERAPEUTICS INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS (Unaudited)

	Th	Three Months Ended September 30,		Nine Months Ended September 30,	
		2018	2017	2018	2017
Revenue	\$	329,930 \$	152,535 \$	1,100,108 \$	434,523
Cost of goods sold		83,006	28,706	309,320	87,709
Gross margin		246,924	123,829	790,788	346,814
General and administrative expense		762,603	621,716	2,708,274	3,968,493
Operations expense		723,939	192,536	1,390,434	575,467
Sales and marketing expense		621,465	301,672	1,726,087	680,396
Total Expense		2,108,007	1,115,924	5,824,795	5,224,356
Loss on equity method investment		(645,786)	-	(1,606,294)	-
Net loss attributable to common shareholders		(2,506,869)	(992,095)	(6,640,301)	(4,877,542)
Comprehensive loss	\$	(2,506,869) \$	(992,095) \$	(6,640,301) \$	(4,877,542)
Loss per common share - basic and diluted	\$	(0.19) \$	(0.16) \$	(0.55) \$	(0.78)
Weighted average shares used in computation - basic and diluted		13,252,605	6,232,761	12,178,285	6,283,567

See Notes to Condensed Consolidated Financial Statements



Filing under Rule 425 under the Securities Act of 1933 and deemed filed under Rule 14a-12 of the Securities Exchange Act of 1934 Filing by: Precision Therapeutics Inc.: SEC File Nos. 001-36790; and 333-221966

# Precision Therapeutics - Fiscal Third Quarter 2018 Earnings Script

## **Operator:**

Good day everyone, and welcome to the Precision Therapeutics Q3 2018 Business Update. Today's conference is being recorded, and at this time I would like to turn the call over to Elizabeth Barker, Investor Relations at KCSA Strategic Communications. Please go ahead.

#### Elizabeth Barker:

Thank you all for participating in today's call to discuss Precision Therapeutics' financial results for the third fiscal quarter of 2018. Joining me today are Dr. Carl Schwartz, Chief Executive Officer of Precision Therapeutics; Bob Myers, Chief Financial Officer of Precision Therapeutics; and Jerry Vardzel, President and Chief Executive Officer of Helomics Corporation.

Before we begin, I would like to caution that comments made during this conference call by Management will contain forward-looking statements regarding the operations and future results of Precision Therapeutics and Helomics Holding Corporation. I encourage you to review the Company's filings with the Securities and Exchange Commission, including but without limitation its Form 10-K, which identifies specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements.

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I would also like to refer to the Form S-4 Registration Statement filed by Precision Therapeutics with the SEC in connection with the proposed merger transaction with Helomics. Security holders of Precision and Helomics are urged to read all relevant documents filed with the SEC, including the proxy statement/prospectus, because they will contain important information about the proposed transaction as well as the identity of people who, under SEC rules, may be considered "participants in the solicitation" in connection with the proposed merger, and a description of their interests.

With that said, I would like to turn the call over to Dr. Carl Schwartz. Carl?

#### **Carl Schwartz:**

Thank you, Elizabeth, and welcome to everyone who has joined us today for today's Third Quarter 2018 Earnings Call. It's great to see so many people dial in to hear our updates as we progress through this critical period in the Company's evolution.

Eighteen months ago, we announced our intention to pivot into the specialty Contract Research Organization, or "CRO" services sector and, since then, we've been working on several initiatives to advance this strategy, including the formation of our TumorGenesis subsidiary and our 25% investment in Helomics, which we have also signed a definitive agreement to acquire. On today's call I'm going to talk a little about our progress in these areas. Later in the call I will also provide some exciting new information about our Skyline Medical division before Bob Myers, our CFO, goes into our financial results from the quarter.



CROs provide specialized services that are integral to the development of drugs, biologics and medical devices. With the age of personalized medicine redefining cancer therapies, *specialty* CROs, that rely on advanced technologies, are needed to optimize the drug development process. We believe this specialty CRO market, especially as it relates to drug discovery, is at least a \$2 billion-dollar market.

To position ourselves to leverage this exciting market opportunity, we formed our wholly-owned subsidiary, TumorGenesis, in the first quarter of this year to pioneer a powerful new approach to growing cancer tumors in laboratory, with an initial focus on ovarian cancer.

Currently, most existing CROs use traditional patient-derived tumors in PDX mouse models to understand cancer biology, aid drug discovery, and translate findings for optimal treatment of a human disease. However, PDX mouse models are not able to represent the whole plethora of the many cancer types and sub types. Questions have been raised about how well these models represent human cancers with the primary fear being that cancers can undergo different genomic changes when transplanted into mice than they do when transplanted into human hosts. These changes could affect the ability to predict individual patients' responses to drugs using PDX mouse models. This can lead to costlier, less accurate and longer lasting clinical trials. This PDX Mouse Model market is low hanging fruit for us.



At TumorGenesis, our aim is to produce a more accurate, predictive model of how treatments will perform, before they enter expensive clinical trials, by growing human tumors outside the body. These patient-derived tumor models will closely mimic the patient's internal environment and be designed to 'fool' the cancer cells into thinking they are inside a human patient's body. This is expected to generate a more accurate response when testing drugs for personalized therapy and in the development of new drugs.

As mentioned, our initial focus will be on ovarian cancer. Fewer than 40% of women with ovarian cancer survive from today's standard treatment. Our approach, which targets cancer by the patient's specific mutation, is designed to change this paradigm and significantly improve patient outcomes.

Currently, there are 24 mutations of ovarian cancer and TumorGenesis is focused on completing tumor generation for each of these mutations, with the aim of completing this process in the first half of 2019.

In recent weeks, we have made material progress toward this goal, including securing solid tumor samples for several ovarian cancer mutations and starting work towards validating our model of growing tumors outside the body.

Already, TumorGenesis has developed a discovery kit, using this technology, for screening of these ovarian cancer cell types. The development of the kit was the first major milestone in our quest to grow human tumors outside the body and the kit is now being made available to clients of TumorGenesis for whole cell screening in Clinical Research Projects.



The next three major milestones include:

- 1. Identifying the peptides and structure needed to grow a tumor,
- 2. Selecting the one that works the best, and
- 3. Growing a tumor exogenously. We expect that these tumors will be used in drug discovery projects with pharma at Helomics' CLIA laboratory, as part of our CRO service offering.

Upon completion of these next milestones, researchers will be able to fool ovarian cancer cells into growing as if they were still in the patient. This will help our pharmaceutical clients research and develop new drugs or identify a combination therapy with previously approved drugs to improve patient outcomes.

The progress we have made at TumorGenesis in just a few months is encouraging and has firmly positioned us as a unique CRO. First, we are breaking new ground in our effort to grow tumors outside the body. Another very significant differentiator is our application of artificial intelligence within our CRO platform.

I am now going to turn the call over to Jerry Vardzel, President and CEO of Helomics, to discuss this further and to provide further updates at Helomics, in which we have a 25% ownership stake.

## **Jerry Vardzel - President and CEO of Helomics:**

Thanks, Carl.

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Helomics has continued to execute on its business model in Q3 through its three complementary business pillars, all of which are revenue generating, with growth strategies in place.

As a reminder, our pillars are

- 1. CRO services
- 2. The D-Chip (Our Artificial Intelligence Platform for drug discovery)
- 3. Clinical testing tests for oncology centers (Precision Oncology Insights).

Let me begin by talking about our boutique CRO offering, which dovetails with what is happening at TumorGenesis and supports Precision Therapeutics' position as a Contract Research Organization. Our "CRO" go-to-market strategy is driven by our artificial intelligence platform applied to our database, which has 150,000 tumors in it currently and growing Our goal is to leverage this platform into the drug discovery market with our pharmaceutical clients to usher in the next generation of precision cancer therapies.

We are positioning ourselves as a key partner for driving the discovery of new precision therapies from target/biomarker discovery through drug screening and patient stratification and screening for clinical studies to companion diagnostics.

In Q3 we signed a major deal with a patient advocacy organization, the National Alopecia Areata Foundation. One of our key differentiators was our ability to offer a full service of specimen storage and processing. This means we will store, process and perform tests to identify specific mutations on demand for researchers that access this registry. This contract will generate both project fees and recurring revenue over many years.



We have also made progress with our biorepository services as part of our CRO services to address the needs for specimen lifecycle management from transport, through storage to processing and destruction. With over 20 years of experience in shipping live tumor tissue, Helomics helps clients with all aspects of specimen logistics from study site collection to transport to the Helomics facilities and to other laboratories. The recent signing of the National Alopecia Areata Foundation contract includes our biorepository services with additional proposals in the pipeline as well.

Finally, the build out of our D-CHIP (AI powered Bio Informatics Platform) continues as we continue to add to our large repository of genomic and drug response profiles from the initial 150,000 anonymized clinical tests, performed on the patient's own tumor. The Helomics D-CHIP knowledgebase is unlike other databases that just contain genomic information as it is unique in linking together genomic data and phenotype data, i.e., how the tumor responds to drugs.

We also have signed deals for D-CHIP which will not only generate revenues from our informatics platform but will also generate revenues from additional NGS sequencing we will perform as part of these contracts to generate additional data.

One of the key objectives for our D-CHIP business was to partner with other key genomic data sources and I am pleased to announce that we recently signed a partnership agreement with Genome England's 100,000 genomes project. Through this partnership we have use of a very expensive whole genome sequencer *and* access to the data they have generated on patient's entire DNA which will allow us to build out D-CHIP especially in the area of Ovarian Cancer. Our artificial intelligence programs can now map whole DNA of the patients against individual tumor mutations to create therapy maps!



Finally, let me turn to our Precision Oncology Insights business. Our primary focus in this business is on ramping up specimen numbers and completing the necessary work to offer key tests that identify specific mutations.

The Precision Oncology Insights business captures upfront revenues from the patient testing. It involves comprehensive tumor profiling of the patient's own tumor, together with the power of Artificial Intelligence and the D-CHIP (Digital Clinical Health Insights Platform), to generate a personalized oncology roadmap that provides additional context to help the patient's oncologist personalize treatment.

We continue to make progress with our outreach program to existing oncologists, and we have over 1400 in our network, which is generating growth in our specimen numbers. Our initial efforts of the outreach program has resulted in dialogue with over 150 previous senders and 10 current senders. We look for this to continue to grow in Q4 through 2019. We started this outreach program in Q3, with the addition of 3 new Registered Nurse (RN) Consultants, in order to move away from the basic "sales representative" approach and more towards the "relationship building" approach. The utilization of registered nurses has enabled us to provide a CONSULTATIVE approach that has been well received.

These specimens represent revenue from the clinical testing business (through reimbursement), plus additional revenue for our other two verticals: 1) in the form of data for the D-CHIP and 2) as appropriately consented material for our drug discovery services)



We are also pleased to report that our Next Generation Sequencing ("NGS") panel is up and running, which impacts both our Precision Oncology Insights business as well as our Contract Research Business and D-CHIP.

For clinical testing at the Precision Oncology Insights business, we are offering 37 mutations over 4 key genes for cancers. However, we measure many more genes – together, these genes provide data to power our AI-based D-CHIP platform.

It is an exciting time at Helomics. We continue to ramp our CRO business with additional strategic collaborations and newly signed and executed contracts, including a strong pipeline for the fourth quarter and beyond.

I'll now turn the call back over to Carl.

#### **Carl Schwartz**

As you can see, there is a great deal to be excited about when considering the market opportunity ahead of us and we are executing on all fronts to position Precision Therapeutics as a unique player in the CRO market. Through the development of TumorGenesis and our investment in Helomics, we are positioning our company to take advantage of a multi-billion market opportunity By creating a Contract Research Organization poised to displace the existing PDX Mouse models that are obviously flawed, yet so prevalent today, we are positioning ourselves to be pioneers. Through the application of Artificial Intelligence, we believe that our work will bring about better patient outcomes, first... in Ovarian Cancer and later in many other indications.

To provide additional support and guidance to the Company as we advance our growth strategy in the precision medicine market, we have launched a Scientific and Medical Advisory Board, to be comprised of world-renowned scientific and medical experts, who will work closely with Precision Therapeutics' senior management team throughout this crucial stage in our development.



We have been able to attract eight world-class experts to the board already, which I believe is a testament to the promise that our business model holds.

- 1. Dr. Marc Malandro, Vice President of Operations for Science at the Chan Zuckerberg Initiative. Prior to his position Dr. Malandro was the founding director of the Innovation Institute and Vice Chancellor for Technology Management and Commercialization at the University of Pittsburgh.
- 2. Dr. Amelia Wall Warner, Founder and CEO of Clinical Trial Concepts. She was previously the CEO and founder of the successful Global Specimen Solutions, Inc. which created a novel analytics solution for global specimen data tracking.
- 3. Dr. Robert Murphy, Ray and Stephanie Lane Professor of Computational Biology and Head of the Computational Biology Department in the School of Computer Science at Carnegie Mellon University. Dr. Murphy is also a Professor of Biological Sciences, Biomedical Engineering, and Machine Learning, and was a founding director (with Ivet Bahar) of the Joint Carnegie Mellon University-University of Pittsburgh Ph.D. Program in Computational Biology
- 4. Paul Sweetnam, founder of CellBridge, LLC.
- 5. Tony Frudakis, previously Co-Founder & Chief Scientific Officer at DNAPrint Genomics.
- 6. Ratmir Derda, Associate Professor at the University of Alberta



- 7. On the Medical Advisory Board, we have appointed Dr. Paul Kornblith, Founder and former Chairman and CEO of Helomics Corporation. Paul currently serves as the Medical Advisor to Helomics, the Pittsburgh Life Sciences Greenhouse, and the Innovation Institute; as an Adjunct Professor in the School of Health and Rehabilitation at the University of Pittsburgh; and as the Western Pennsylvania Director for Life Sciences.
- 8. Also on the Medical Advisory Board, we have Dr. Hector Gomez, President & CEO, Co-Founder of GLG Pharma, LLC.

Their combined skills and experience cover molecular biology, bioinformatics, forensic DNA and clinical drug development, as well as establishing and growing new, highly successful businesses. We consider these advisors important to the future of Precision Therapeutics and I would encourage you to read more about each of them through the press releases that we have issued over the past few weeks, which include detailed biographies for each of them.

With that, I'd now like to move onto our Skyline Medical division where we have several positive developments to discuss related to our sales strategy for the STREAMWAY system.

During the third quarter we sold 10 units, of which 1 sale took place outside North America. This was the first time we have reported sales outside of North America, which is a turning point for us as it represents the opening up of a *much* larger market.

While we are pleased to be gaining plenty of traction internationally, this coincided with a change in direction in our U.S. operations that impacted sales. We have been approached by a number of large hospitals and medical centers that expressed interest in purchasing the STREAMWAY, but provided feedback requesting certain modifications to address the needs of all facilities - especially those with poor vacuum. We have therefore made the decision to temper our U.S. sales efforts, implement certain modifications, and then focus on ramping up domestic sales in 2019.



To that end, we are releasing our Generation 3 STREAMWAY that uses the hospitals vacuum supply in Q1 2019, followed by an enhanced version of the STREAMWAY, called STREAMWAY Plus, which has an on-board vacuum. As a result of this decision, our STREAMWAY sales fell short of our predictions for the year, however we believe this is the best approach to maximize our total U.S. sales potential and we strongly believe we will recapture those foregone sales and then some with this improved strategy.

Compared to the STREAMWAY, the STREAMWAY Plus is 50% smaller than the previous model which frees up space in operating rooms and procedure rooms. It is also quieter, and, most importantly, has a powerful, efficient on-board vacuum pump to satisfy any fluid evacuation requirements. This vacuum pump was something that medical centers have requested, and we believe will enable us to generate significant sales next year. The new STREAMWAY Plus is nearly complete and we expect to receive 510(k) approval from the FDA in time for us to commence sales of it in the first half of 2019.

To support our revamped growth strategy, we are hiring several additional seasoned sales people that have decades of experience in the OR and medical device field. At the start of the year we only had five sales reps, which, of course, limited our capacity to form new relationships in the medical field. These additional hires, coupled with our latest-generation STREAMWAY technology, are expected to springboard our growth in 2019 and we could not be more excited about this opportunity.



In the meantime, as I alluded to earlier, our international sales efforts have already gained significant traction. Earlier this year we established our European arm, and over the past several months have developed a strong European sales presence consisting of both direct sales reps and a network of reputable independent distributors covering Portugal, Switzerland, Austria, and part of France. These partners are constantly in discussions with potential new customers and we are pleased with the rapid progress they have made penetrating the European market. The speed with which our first sale in Europe was secured, we believe, is indicative of how well-suited the STREAMWAY is to the European market and will pave the way for future sales in the region.

Looking even further afield, we also partnered with Prenit World, an international distributor of medical infrastructure solutions for healthcare facilities, to market the STREAMWAY System in India. Prenit World was carefully selected by us for their 10-year track record providing technologically advanced and superior quality medical infrastructure solutions to operating theaters and other healthcare facilities in India.

India has an enormous population of approximately 1.4 billion and growing, which is fueling a bourgeoning healthcare industry, supported by the expansion of the emerging middle-income class. According to research from IBEF, the hospital industry in India stood at US\$62 billion in 2017 and is expected to reach US\$133 billion by 2023. Even capturing a small portion of market share in India could drive meaningful revenue growth to the Company.



In recent days, we also signed with MediUrge, an independent distributor in Pakistan. We already know that this partnership will drive revenue growth at Precision Therapeutics because MediUrge has contractually guaranteed to purchase eighteen units next year, such is their confidence in their ability to sell our product in Pakistan.

Furthermore, Skyline Medical is currently in negotiations with several other international distributors in the United Arab Emirates, Kuwait and Libya, and is also in direct negotiations with a number of hospital suppliers in the Middle East that are instrumental in the building of hospitals and operating rooms.

We expect this global sales network to continue to grow, and with its expansion generate additional sales for the Company. We'll continue to issue regular updates on each of these initiatives as they materialize.

I'll now turn the call over to Bob Myers, CFO, to talk about our financial results for the third quarter.

Bob, please go ahead.

# **Bob Myers:**

The financial results for the fiscal quarter ended September 30, 2018, were filed with the SEC yesterday afternoon.



Revenue for the quarter ended September 30, 2018, was \$323,000 compared with \$153,000 for the quarter ended September 30, 2017.

We sold ten STREAMWAY Systems during the third fiscal quarter, compared with two STREAMWAY systems in the third quarter of 2017. Our sales and marketing campaign has continued to generate solid results, having now sold 35 Streamway systems so far this year. We expect this campaign for the Streamway system will continue to accelerate in 2019 with the commercial launch of the Generation 3 STREAMWAY followed by the STREAMWAY Plus.

Further, our awareness campaign to improve the use of disposable filters and cleaning products has continued to produce recurring revenues from higher usage by existing customers, with sales from disposable products growing 55% in quarter three from quarter two 2018.

Gross profit for the quarter ended September 30, 2018, increased to \$245,000 compared with gross profit of \$124,000 in 2017. Gross profit margin was 74.8% of revenue, a decrease of nearly six basis points, due to a higher cost compared with a gross profit margin of 81.2% of revenue for the same period in 2017. As sales continue to increase, we expect that over time this will enable us to achieve volume purchasing discounts on both equipment components and our cleaning solution, which should both bolster our margins.

Total operating expenses for the quarter ending September 30, 2018, were \$2.1 million, an increase of approximately \$992,000 compared with \$1.1 million in the prior year period.



General and administrative expenses decreased by \$0.1 million year over year, primarily from investors' stock compensation that we recorded in 2017, due to our registered direct offering in November of 2016 with warrants that vested in 2017. This was offset by higher operations expense, which increased by \$531,000 due to \$327,000 in consulting fees due to the TumorGenesis build-up; \$68,000 in stock-based compensation for employee options; \$93,000 in research & development; \$7,000 toward testing for new STREAMWAY parts development; and higher payroll, taxes and benefits costs.

The net loss available to common shareholders for the quarter ended September 30, 2018, was \$2.5 million compared with a net loss available to common shareholders for the quarter ended September 30, 2017, of \$1.0 million. The Company also reported a \$646,000 loss related to the Company's equity vested investment in Helomics, of which we own 25%. Our comprehensive net loss for the quarter, which includes this loss and equity method investment was \$2.5 million or \$0.19 per share on 13.3 million weighted average shares outstanding, compared with \$1.0 million or \$0.16 per share on 6.2 million weighted average shares outstanding for the third quarter of 2017.

The Company had cash and cash equivalents of \$0.2 million as of September 30, 2018, compared with \$0.8 million as of December 31, 2017.

In the first week of October 2018 we received \$1,815,000 net proceeds from the private placement of secured convertible promissory notes; half of that amount was advanced to Helomics.



This concludes the financial portion of today's earnings call.

#### **Carl Schwartz**

Thank you, Bob. Operator, can you please open the call for Q&A.

### Carl - Closing remarks for after Q&A

Thank you for joining us on today's call. As you can see, it is a very busy time here at Precision Therapeutics, with many major initiatives in progress to drive growth in both our industry verticals: precision medicine and the medical device market.

Skyline Medical has never been in a stronger position to secure sales. We have established a strong and growing network of sales hubs that encompass North America, Europe, Australia and, now, South East Asia. Already, we are generating revenues from this network which we believe will continue to ramp up as our sales teams advance their negotiations and we sign with additional independent distributors.

At TumorGenesis, we are undoubtedly entering an exciting market, where we are now successfully working toward what can only be called a groundbreaking solution that could create a paradigm shift in the way that pharmaceutical companies discover new drugs.

Our investee, Helomics, is making strides across all three of its pillars, securing new client agreements and building its revenue base.



We are excited about our progress this quarter and we thank each of you for your support.

With that, I'll turn the call back to the operator to close the call.