

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): October 30, 2018

Precision Therapeutics Inc.  
(Exact name of Registrant as Specified in its Charter)

Delaware  
(State or Other Jurisdiction of Incorporation)

001-36790  
(Commission File Number)

33-1007393  
(IRS Employer Identification No.)

2915 Commers Drive, Suite 900  
Eagan, Minnesota  
(Address of Principal Executive Offices)

55121  
(Zip Code)

Registrant's telephone number, including area code: (651) 389-4800

Former Name or Former Address, if Changed Since Last Report: Not Applicable

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 8.01 Other Events.**

On October 30, 2018, Precision Therapeutics Inc. (“Precision”) presented at the Dawson James Small Cap Growth Conference the materials attached hereto as Exhibit 99.1.

**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](http://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](#) [Company Presentation dated October 30, 2018](#)

[99.2](#) [Form S-4 \(Registration No.333-228031\), \(filed October 29, 2018 and incorporated herein by reference\)](#)

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**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: October 30, 2018



**PRECISION**  
THERAPEUTICS

Corporate Mission:  
To Apply Artificial Intelligence ('AI')  
To Personalized Medicine and Drug Discovery

Nasdaq: AIPT  
October 2018

## Forward-Looking Statements

This presentation includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include but are not limited to our plans, objectives, expectations and intentions and other statements that contain words such as “expects,” “contemplates,” “anticipates,” “plans,” “intends,” “believes” and variations of such words or similar expressions that predict or indicate future events or trends, or that do not relate to historical matters. These statements are based on our current beliefs or expectations and are inherently subject to significant uncertainties and changes in circumstances, many of which are beyond our control. There can be no assurance that our beliefs or expectations will be achieved. Actual results may differ materially from our beliefs or expectations due to economic, business, competitive, market, regulatory, and other factors. A full discussion of our operations and financial conditions, including risk factors that may affect our business and future prospects, is contained in our most recent regulatory filings with the U.S. Securities and Exchange Commission (“SEC”), including our Form 10-K filed April 2, 2018.

# Corporate Overview

## *Precision Therapeutics operates two business segments:*

### Precision Medicine

- Focused on applying artificial intelligence to personalized medicine and drug discovery
- 25% investment in Helomics, a provider of precision oncology insights, integrated clinical contract research organization (CRO) services, D-CHIP bioinformatics
- Helomics' clients include pharmaceutical, diagnostic, and biotech companies, as well as physicians and patients

### Medical Device

- Producers of the STREAMWAY® System
- The only direct-to-drain, closed system on the fluid waste management market
- A fully automated, patented, FDA-cleared waste fluid disposal system that virtually eliminates staff exposure to blood, irrigation fluid and other potentially infectious fluids

# Precision Medicine

# Emerging Market Opportunity

- Precision Therapeutics is targeting two markets:
  1. Drug discovery / CRO Services
    - Development of effective therapies to treat disease
  2. Precision Oncology
    - An innovative approach to cancer treatment that ensures your treatment is specifically designed and targeted to your unique form of cancer and its DNA mutation
  
- Industry growth catalysts:
  - Advances in cancer biology
  - Favourable government initiatives (ex: Precision Medicine Initiative)
  - Overall increased investment in the space



# The TumorGenesis Solution

## Approach:

- Pioneering a powerful new approach to growing cancer tumors in laboratory
  - Initial focus on ovarian cancer. There are 24 genetic mutations of “Ovarian cancer”, each needs the best combination of drugs targeting the tumor by mutation
- Tumors to be grown in an external, structured environment that more closely mimics the patient’s internal environment
  - These patient-derived tumor models will be designed to ‘fool’ the cancer cells into thinking they are inside the patient’s body

## Outcome:

- This tumor model is expected to generate a cheaper, faster, more accurate response when testing drugs for personalized therapy and in the development of new drugs, compared with the animal models that are currently used in the clinical development of cancer therapies

# The TumorGenesis Opportunity

## Market Opportunity:

- The National Cancer Institute (NCI) is searching for more robust and lower cost alternatives to the traditional, patient-derived tumor mouse model (the “PDX mouse model”) to screen new drugs, as are many other pharmaceutical companies and developers
- The global PDX models market is estimated to grow at a CAGR of 16.7% from 2017 to 2022, to reach USD 167.6 million ([MarketsandMarkets](#))
- The key factors driving the growth of the overall PDX models market include:
  - ✓ The growing demand for personalized medicine,
  - ✓ Continuous support for cancer research from the public as well as private sectors, and
  - ✓ Growth in the number of R&D activities in the pharmaceutical industry.
- According to BCC Research, the non-human cell cultured market is expected to top \$300 million for the Clinical Research Organization services, and \$250 million for assay kits, by 2019.

## Commercial strategy:

1. Challenge the tumors with different treatment protocols *recommended by D-Chip* to provide the oncologist with treatment road maps
2. *Sell tumors* to Pharma for new drug research
3. Provide *contract research* for Pharma to test new drugs

# TumorGenesis Overview

## Unmet Medical Need

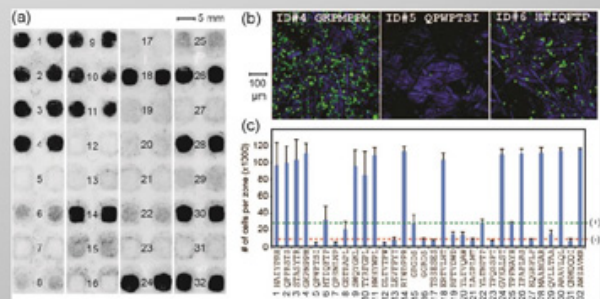
Nearly all the cancers we have focused on Breast, Ovarian, Bowel, Liver, Glioma have ***high rates of chemo and immunotherapy and radiation resistance***. TumorGenesis is offering an integrated Precision Oncology platform to deliver *tailored Therapeutic Solutions for next generation's precision oncology for each patient in a clinical trial or being evaluated for the best combination treatment.*

## Differentiators

- ✓ Genomically assessed patient cells expanded faithfully outside of the body and screened against a massive compound library, including new chemical entities for our pharma and biotech clients
- ✓ The result is patient tailored drug cocktails that deliver the right drugs, to the right patient, the first time, every time and help control clinical trials responsiveness of the patients to the new therapies

Next Generation (specific) Testing Tools for Clinical Trials Management and Compound Screening

Fooling Cancer Cells- Growing in the lab...

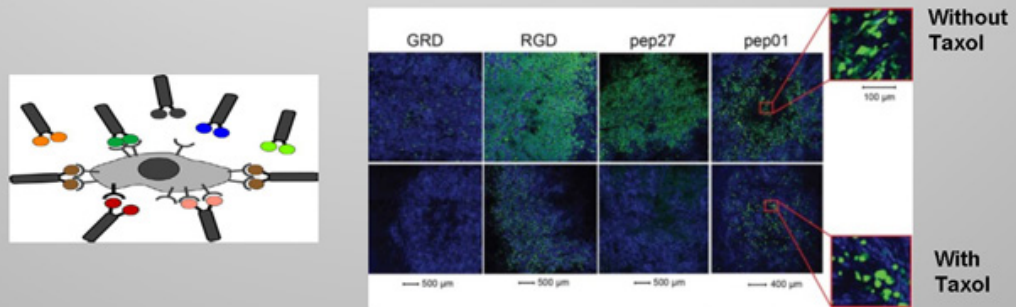


# TumorGenesis Overview

## About Us

1. **Rapidly Growing company in the emerging personalized / genomic / AI supported medicine space**, with patent protected technologies and trade secrets. Targeting the Clinical Trials market segment as well as the new compound discovery segment for Pharma and Biotech.
2. **Competent Management and Scientific Advisory Team**, having previously developed 15+ Approved Drugs, 100+ Approved Diagnostics and Trailblazing Population Genetics Technologies > \$3Bn sales. Adding to this our partners CLIA capabilities as well as our ability to roll out validated test kits for our clients use.
3. **Building a New Market Paradigm for Trials and Treatment**, current tools for patient tumor sample screening do not address the unmet medical need, by combining AI, fooling cancer cells into growing in the lab, genetics and combination plus dilution drug screening, TumorGenesis offers the best hope for patients that are in clinical trials or become resistant to treatment

**Revo/Evolutionary ex-vivo platform for matching patient disease cells with the right drugs.**



# TumorGenesis: Innovation in Personalized Precision Cancer

## Select the Specific Rx for Each Patient

### What do oncologist and cancer researchers need?

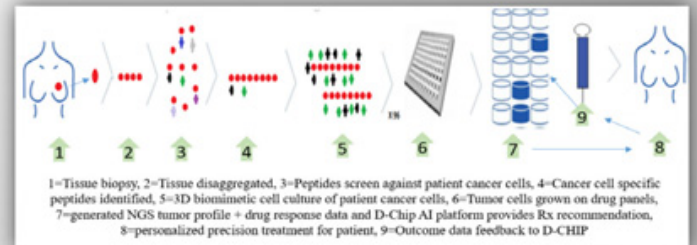
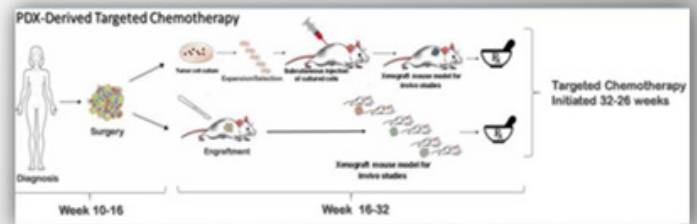
A single system that ...

- Accounts for the variability in every patient's tumour
- Is capable of testing multiple drugs, doses, and drug combinations in weeks
- Is a fraction of the cost of animal models
- Allows for that tailored patient therapy

...*TumorGenesis systems satisfies these needs*

### Today's environment and unmet medical needs

- Every patient's tumour is different and oncologists lack the tools to determine what the optimal treatment may be for each patient, especially in clinically relevant time periods
- Patient cancer cells injected in mice/rats as patient derived xenografts ('PDX') are used now to test drugs, but this process is slow, expensive, requires a lot of animals, and causes loss of gene expression that could modify tumour-drug response – cancer cells can behave differently in an animal compared to point of origin in the patient.



### TumorGenesis's Solution...

- Grows patient tumor cells in the lab, 'fooling' them to think they are still in the body
- This allows testing of various drugs on each patients cells to determine the best treatment, personalized per individual, helps minimize patient drug failures in clinical trials.

Potential market for academic and pharma research and clinical trial applications: US \$95-\$573 mm (0.5-3% est. market share)

## Cancer Type - Market Data

### Advantages over the traditional mouse model:

- PDx mouse takes 3-4 times longer for an answer
- Limited in the number of drugs, drug dilutions and combinations that can be tested
- Mouse, even if humanized, still affects cancer cells and cancer cell markers
- Mouse has its place in pre-Ind tox and dosing studies for the FDA but of little to no use for patient categorization and combination drug treatment

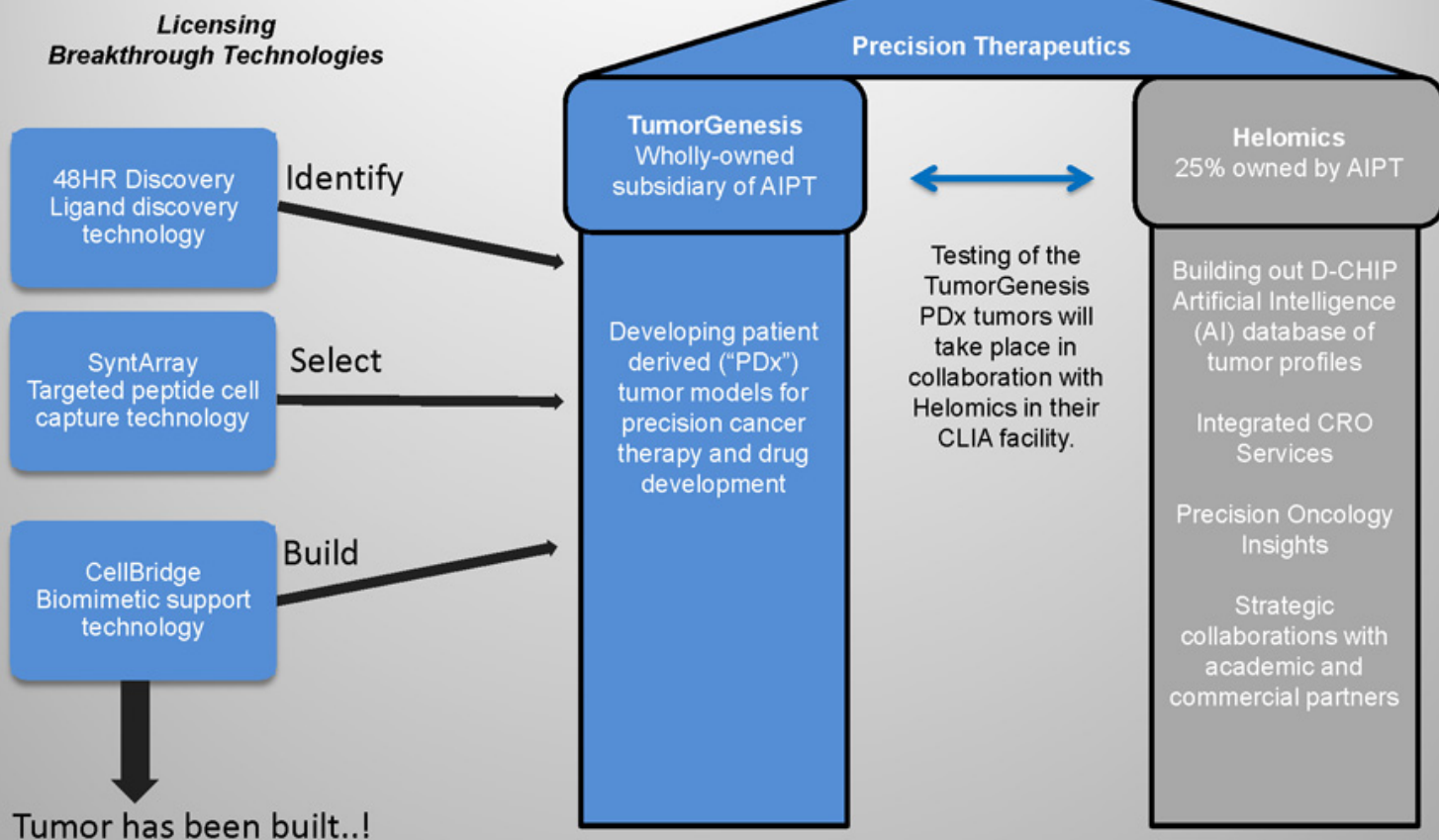
Cancer Type	New patients	TOTAL*
Leukemias & Lymphomas	203,970	\$2,550 million
Solid Tumors	1,322,830	\$16,535 million
All patients	1,526,800	\$19,085 million
Market share 0.5 %	7,634	\$ 95.4 million
Market share 1.5 %	22,602	\$ 286.3 million
Market share 3.0 %	45,804	\$ 573 million
<b>** National Cancer Institute Report-2018</b>		

\*Cost per patient \$12,500. Estimates are compared to PDx mouse at \$25,000 to \$45,000.

## New Patient - Market Data

Market size: 1,526,800 patients Leukemias, lymphomas and solid tumors			
Market share	0.5 %	1.5 %	3.0 %
Patients	7,634	22,602	45,804
Revenue	\$95.4 million	\$286.3 million	\$573 million
*Cost per patient \$12,500			

# Corporate Structure and Partnerships





# Helomics - Specialty Contract Research Organization (CRO) Services

- Three key differentiators
  1. TruTumor™: Proprietary *ex vivo* patient derived tumor platform
    - Generate a rich multi-omic profile of a patient
    - To be replaced by TumorGenesis
  2. D-CHIP knowledgebase
  3. CLIA Lab
  
- These boutique CRO services impact
  - Drug discovery: both large and small molecule
  - Biomarker discovery & validation
  - Pre-clinical: efficacy, off-target effects, toxicity
  - Clinical: Clinical trial assays / monitoring, patient stratification

## Investment Highlights

- ✓ **Bridging two emerging markets: precision medicine and actionable big data**
- ✓ **Proprietary data on +150,000 tumors through 25% equity stake in Helomics**
- ✓ **License agreements with ground-breaking technologies through TumorGenesis subsidiary**
- ✓ **Established revenue streams through Helomics investment, poised for commercial ramp**

# STREAMWAY System: Fluid Waste Management

# Our Patented Solution: The STREAMWAY System

## Surpassing the Competition

- Less hassle:
  - No transportation
  - No docking station
  - Frees up valuable floor-space
  - Direct-to-drain waste disposal
  - Fully automated, hands-free operation
- Safer – significantly reduced exposure risk
- Uninterrupted performance for greater efficiency and profit
- Removes need for costly canisters
- Better environmental stewardship
- Unlimited capacity
- Accurate fluid calculation



# A Better Way to Dispose of Fluid Waste

## Traditional canister systems are antiquated



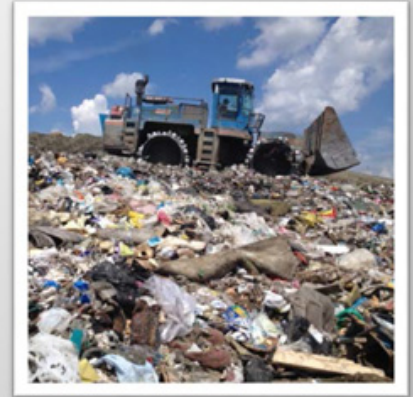
### Unsafe and Inefficient

- Exposure risk
- Labor intensive
- Require significant storage space



### Costly

- \$2 - \$3 cost to dispose of 1 liter canister
- Average biohazard disposal cost/pound = \$0.30
- Infectious fluid waste = 75% of disposal costs



### Environmental Hazards

- Canister disposal: 40% of waste from operating rooms
- 50 million canisters go to landfills annually

# The STREAMWAY System: Investment Highlights

- **Numerous benefits** for healthcare professionals and patients
- A **strong economic argument** for hospitals and outpatient facilities
- A **compelling market** directed toward the **40,000-60,000 U.S. healthcare facilities** looking to automate their fluid waste management system and lower costs
- A **recurring revenue stream** from filters and cleansers
- Regulatory clearances in the **U.S.** and **Canada**, CE mark in the **EU**
- A **focused marketing plan** gaining traction
  - Emphasis on infection control and prevention
  - Specifically targeting radiology suites (procedures typically generate large amounts of waste fluid)



# STREAMWAY Razor / Razorblade Solution

## Revolutionary Alternative in Medical Fluid Waste Management

- Meets an industry need
- Reduces healthcare operating costs
- Sizeable potential market:
  - **\$876 million**: estimated U.S. market for the STREAMWAY wall unit
  - **\$1.5 billion**: estimated U.S. market for the disposable cleaning fluid and filters

## STREAMWAY Pricing

- \$24,900 for our wall-mounted fluid disposal unit
- \$24,000 anticipated annual revenues from our cleaning fluid and filters, which are replaced after each operation (1,000 procedures per year, \$24 per kit)
  - Targeted *gross profit margins* are 80%

# Cart-based Systems

- Infection control risk
- Takes up valuable floor space
- Requires storage space – congested hallways
- Limited storage capacity
- Heavy carts to push









# Blood-borne Pathogen Exposure

- An estimated 400,000 U.S. healthcare workers are exposed to blood-borne pathogens every year<sup>1</sup>
- 50% of all surgical procedures observed resulted in at least one employee being exposed <sup>1</sup>
- 50-67% of exposures are estimated to go unreported by healthcare workers<sup>1</sup>
- Occupational infections acquired by healthcare workers are considered to be Hospital Acquired Infections (HAIs)<sup>2</sup>
- HAIs were responsible for 99,000 deaths in 2002 and cost the industry >\$6 billion in added costs<sup>2</sup>
- The STREAMWAY System reduces the risk of exposure to pathogens aerosolized when opening traditional suction canisters

1. EDWARD J. QUEBBEMAN, M.D., PH.D. Risk of Blood Contamination to Operating Personnel. Ann. Surg. Vol 215, No 5, 614-620.
2. World Health Organization – [http://www.who.int/gpsc/country\\_work/burden\\_hcai/en](http://www.who.int/gpsc/country_work/burden_hcai/en)

# STREAMWAY: safer, cheaper, more facility friendly

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

## Current STREAMWAY System Installations

**100+ installations**

**50 facilities**

**19 states**

**Duke**  
UNIVERSITY



Beth Israel Deaconess  
Medical Center

**MAYO**  
CLINIC



Dartmouth



Department of  
Veterans Affairs



**Centra Care**  
FLORIDA HOSPITAL URGENT CARE

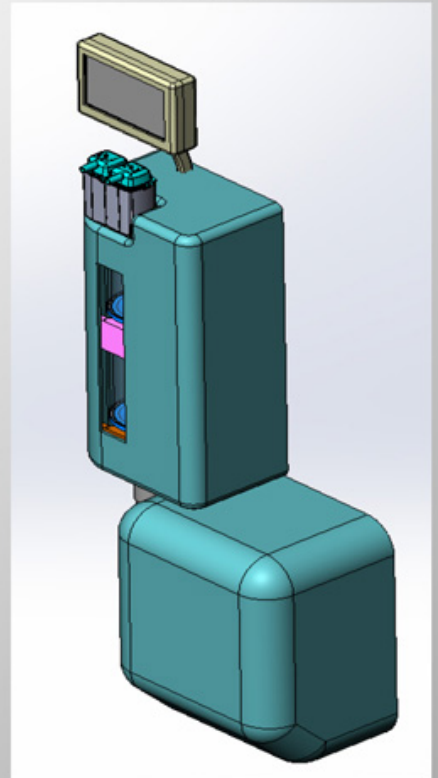
## Recent Achievements/Near-term Milestones

- ✓ Received Innovative Technology award from Vizient and placement on member formularies
- ✓ Received CE Mark to sell STREAMWAY in the EU
- ✓ Opened European office in early 2018; secured first sales in 2H 2018
- ✓ Appointed Jean-Paul Rasschaert as Vice President of International Sales
- ✓ Entered into innovative technology partnership with Intalere
- ✓ Added distribution for STREAMWAY in Europe, Canada, Australia, New Zealand, Fiji Island and Pacific
- ✓ Engaged distribution for U.S. government placements
- ✓ Appointed Kevin Hungerford as Global Vice President of Sales and Marketing

## STREAMWAY and STREAMWAY "Plus"

- Streamway and Streamway Plus developed to become the fluid management system of choice for all institutions
- Innovative, state of art technology developed to address needs of all facilities-especially those with poor vacuum
- Reduced footprint to free up space in OR's and procedure rooms-over 50% reduction from previous model
- Powerful, quiet, efficient on board vacuum pump to satisfy any fluid evacuation requirements on "Plus" System
- Video training available on menu-easy to answer any operator questions
- New Streamway (using hospital vacuum) available Q1 2019
- Regulatory approval for "Plus" system 2<sup>nd</sup>-3<sup>rd</sup> quarter 2019
- *Note: Streamway and Streamway "Plus" are identical except that the "Plus" will have a vacuum pump attached to unit, causing the "Plus" to require new 510(k) approval-(Have spoken to FDA and expect an expedited review)*

Streamway "Plus"



## UV Sterilization

- Developed system to kill pathogens before discharging into sewer system
- Of particular interest to DoD for mobile, emergency OR's in regards to inactivating pathogens in fluid waste
- In process of commercializing system for use